Office of the Vice President for Research

IRB Policies and Procedures
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Children

Economically or Educationally Disadvantaged

UConn Storrs Students

Psychology Department Participant Pool

UConn Storrs Employees

Decisionally Impaired

HIV-Infected Individuals

Members of the Armed Forces

Non-English Speaking Individuals

Types of Research Conducted at UConn Storrs

Review of Studies Conducted in Foreign Countries

Research Requiring Review More Frequent Than Annually

Verification from Sources Other Than Investigators:

Scientific Review

Categories of Study Status

Approved

Modifications Required in Order to Secure Approval

Deferred

Disapproved

Tabled

Closed

Terminated

Suspended

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Introduction
This document sets forth the standard operating policies and procedures for the Research Compliance Services's (RCS) Human Research Protection Program (HRPP) at the University of Connecticut, Storrs campus, the five regional campuses, the School of Social Work, and the School of Law. The RCS and the Institutional Review Board (IRB) are the institutional entities that implement the HRPP. This document also describes the relationships of the HRPP and IRB with other internal and external agencies. All members of the IRB, IRB staff, and research personnel are expected to be familiar with these policies.

Overview of the Human Research Protection Program
The UConn Storrs Institutional Review Board (IRB) is responsible for the review of all human participants research at the UConn Storrs campus, the five regional campuses, the School of Social Work, and the School of Law (hereafter named UConn Storrs). The primary purpose of the HRPP is to enforce the regulations which govern the protection of research participants enrolled in UConn Storrs studies through oversight by the IRB and IRB staff.

Reporting Structure
The IRB staff currently consists of the Director of Research Compliance (DRC), Regulatory Compliance Coordinator (RCC), IRB Administrator, and IRB Education and Compliance Monitor (IRB Monitor). The IRB Monitor, Regulatory Compliance Coordinator and the IRB Administrator report to the DRC. The DRC reports directly to the Vice President for Research (hereafter named VPR), the assurance signatory official (IO) for the institution.

Ethical Principles Governing Research
The HRPP supports the advancement of research by creating a collaborative relationship with the research community to ensure that research with human participants is conducted in accordance with the ethical principles of Respect for Persons, Beneficence, and Justice, as put forth in the Belmont Report. The principle of respect for persons is applied through the informed consent process. The principle of beneficence is applied through the risk/benefit analysis which includes a review of the design of the study and the procedures in place to minimize risks. The principle of justice is applied through recruitment strategies and selection of research participants.

These ethical principles are the basis of the regulations which govern the protection of human participants in research, and apply regardless of the regulatory category (i.e., exempt, expedited, or full board) under which a study is approved. Furthermore, UConn assures that equal protections will apply to all research involving human participants, regardless of funding source.
Authority from the Institution
As the IO, the VPR is charged with the responsibility of protecting human participants in research. The VPR empowers the IRB to suspend or terminate any study previously approved by the IRB or to require additional reviews. Suspension or termination may be due to serious and/or unexpected increased risks to participants, or continuing or serious noncompliance of the investigator(s) or other factors that the IRB deems warrant suspension or termination. The VPR cannot influence the decision of the IRB or approve a study that has not been approved by the IRB. The VPR also empowers the IRB to create and implement policy that will serve to protect human participants.

Policy Implementation
The authority to create, change and implement policy is shared by the IRB and RCS. New policies or changes to policies may be presented to the IRB to solicit input from the committee members. The VPR and DRC may also be asked to review and comment on new or changed policies and to advise the IRB/RCS regarding policy decisions. At the discretion of the VPR or DRC, input may also be sought from those parties that would be affected by the policy.

Policy Review
Every three years the VPR and DRC will review all RCS/IRB policies that are posted on its website, regardless of the date on which the policy was implemented. Such review will include an assessment of the accuracy and relevancy of the policies, a determination as to whether the policies are in-line with institutional policies and whether there is a need for new policies to be developed. Within this document and posted on the IRB website, if an individual policy has been revised, it will show a revision date.

Support from the Institution
The institution provides support to the RCS/IRB and the IRB members in terms of staffing, office space and an operating budget, including educational opportunities. The VPR reviews the ORB/IRB budget annually with the DRC to ensure adequate resources continue to be available.

Assessment of Resources
On an annual basis, corresponding with the budget cycles, the VPR will assess the operations of the RCS/IRB to determine if additional resources are required in terms of supplies, education, staff, and/or equipment. Expenditures from the previous year, response time from the IRB to investigators, number of protocols reviewed per meeting, the number of audits conducted and types of findings, will be among the items included in the assessment. Information may also be solicited from IRB members and staff. The VPR will also take into consideration whether there were any activities, supplies or equipment that were previously forgone due to lack of resources.
Assessment of RCS/IRB Performance

On an annual basis the VPR will review a number of criteria in order to assess the overall performance of the RCS/IRB and when necessary to take action to improve the performance. Criteria to be used in the evaluation include the following:

- The number of new full board studies reviewed by the IRB annually in order to assess whether additional boards are needed due to the volume of work or whether additional expertise is needed in a certain area.
- The findings of the audits conducted by the IRB Monitor to determine if there are common areas of noncompliance that could be improved upon with education, clarification of policy or development of new policies.
- The performance evaluations of IRB members which consider contribution to discussion, attendance, thoroughness of review, volume of work reviewed, and participation in educational activities.
- The performance evaluations of staff members which consider contribution to achieving the goals of the office, level of service provided to faculty, students and staff, and professional development activities.
- The nature, number and outcome of participant complaints to determine if proper action was taken or if improvements can be made.
- The educational opportunities with IRB members and staff attended throughout the year and whether opportunities were foregone due to lack of funding.
- The principal investigators' (PI) responses to the IRB Research Assessment Tool (RAT) Survey.

Applicable Regulations

It is the policy of UConn Storrs that all research involving human participants conducted by the faculty, students and staff of UConn, or research conducted using UConn facilities, is conducted in accordance with federal regulations, regardless of the funding source. Those regulations include, but are not limited to, the following:

- Code of Federal Regulations, Title 45 Public Welfare, Department of Health and Human Services, National Institutes of Health Office for Protection from Research Risks, Part 46, Protection of Human Participants;
- Code of Federal Regulations, 21 CFR 50, 56, 312, 812, as established by the Food and Drug Administration.

Per 45 CFR 46.103, because UConn Storrs is engaged in human subjects research (not otherwise exempt) that may be conducted or supported by an agency of the U.S. Department of Health and Human Services (HHS), UConn Storrs has an Office of Human Research Protections (OHRP)-approved Federalwide Assurance (FWA) whereby the University agrees to conduct all human subjects research in compliance
with the HHS regulations. The UConn Storrs FWA number is 00007125. UConn Storrs also has an FWA with the Department of Defense (DOD)/Navy. The DoD-Navy FWA Addendum number is DoD N-A3167.

Institutional Review Board (IRB)
The UConn Institutional Review Board is charged with reviewing all research involving human participants conducted by faculty, students or staff that is conducted at or makes use of the facilities of UConn.

Authority from the Institution

The RCS/IRB has the responsibility to review and the authority to approve, require amendments of or disapprove research involving human participants conducted by UConn faculty, students or staff, or such research involving the use of UConn facilities, in accordance with administrative policies and procedures established for this purpose. The IRB shall monitor and conduct continuing review of such research at intervals of at least once per year.

The IRB, or its staff acting on behalf of the IRB, has the authority to inspect research facilities and to obtain records and other relevant information relating to projects it has approved and to observe, or have a third party observe, the consent process and research. The IRB affords protections to participants, and may suspend or terminate approval of projects it has approved and take actions that it judges necessary to ensure compliance with regulations and internal policies. Review and approval must be obtained from the IRB prior to a research project being initiated.

Reliance on IRBs of Other Institutions
The IO at UConn may elect to rely on the IRB of other institutions for review and approval of a study. In order to do so, that IRB must be officially designated on UConn's Federalwide Assurance and a written agreement must be in place between the two institutions. This is generally used when a study involves UConn and a facility with which a close working relationship exists (e.g., Yale University, Hartford Hospital, or the UCHC). In such an event, the IRB of the other institution, referred to as the IRB of Record, holds the same rights, authority and responsibility as the IRB of UConn. The DRC is a designee of the IO to sign these documents.

Authority of Institutional Individuals
The IO of UConn may not approve a project that has not received the review and approval of the IRB or which has been disapproved by the IRB. In addition to the IRB, the IO may require additional review of research and has the authority to disapprove, suspend or terminate research previously approved by the IRB.
Purpose of the IRB
The primary purpose of the IRB at UConn is to ensure that proposed research studies involving human participants encompass the ethical principles of the Belmont Report and the protections provided by regulations and internal policies. The IRB application solicits relevant information pertaining to study design, recruitment procedures, inclusion and exclusion criteria, risks to participants and the procedures used to minimize those risks, possible benefits, procedures used to protect privacy and confidentiality and to obtain informed consent. Initial review and approval must occur prior to study initiation. Subsequent reviews, for expedited and full board studies, occur at least on an annual basis.

Membership of the IRB
The membership of the IRB is constituted in accordance with 45 CFR 46.107 and 21 CFR 56.107. The IRB has at least five members at all times. The membership will satisfy the requirements of having a non-scientist, a non-affiliated member, and a prisoner representative (whose presence is required when the IRB is reviewing a study involving prisoners). The membership will consist of individuals from various areas of expertise and various ethnic backgrounds and will also be composed of both genders. The membership of the IRB is registered with the Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA). The IRB Administrator will report changes in IRB membership to OHRP in a timely manner.

Appointment of IRB Members
On an as needed basis, the VPR or DRC will seek input from the IRB Chair, Vice-Chair, IRB members, and Department Heads regarding appointment of new members. Potential new members will be identified to fulfill the needs of the IRB. The Chair, in coordination with the DRC and RCC, will identify preferences from those recommended. The RCC will discuss the issue of being appointed to the IRB with the potential member. If interested in serving on the IRB, the RCC will verbally inform the VPR's office, and the VPR will issue the official appointment letter. Appointment periods are up to three years, but are determined in accordance with the availability of the new member.

The VPR appoints the IRB Chair and Vice-Chair. Appointment periods are for one year. The Chair will be employed by UConn, have at least 2 years of previous IRB experience, have a social sciences or biological sciences background, be familiar with clinical and social research and have demonstrated ability to work in committee. A member selected by the Chair and DRC will be invited to serve as Vice-Chair. The Vice-Chair must be a UConn employee, have at least one year of previous IRB experience, and have a social sciences or biological sciences background. Consideration will be given to length of time on the IRB, thoroughness of reviews and attendance at meetings when selecting a Chair and Vice-Chair. The VPR will issue an official appointment letter to the Chair and Vice-Chair.

Exceptions to the appointment process may occur. For example, if an individual expresses an interest in becoming an IRB member, the DRC in consultation with the Chair may choose to appoint the individual.
Community members and graduate student members are given gratis appointments so that each individual member is covered under the State Indemnity Insurance Sovereign Immunity Clause. This insurance provides protections afforded University employees.

**Responsibilities of IRB Members**

The responsibilities of IRB members include attending regularly scheduled meetings, generally once every three to four weeks. Members must thoroughly review all materials to which they are assigned as a primary reviewer, be prepared to present and discuss the material at the meeting, review and have a familiarity with all other material to be presented at the convened meeting such that they can participate in the discussion of all studies, reviewing all materials prior to the convened meeting, possessing an understanding of the principles of the Belmont Report and regulations pertaining to human participant protections, applying those principles and regulations to the review process, reviewing IRB minutes, and providing input/feedback on new policies that relate to the IRB. Members are responsible for excusing themselves from the deliberation and vote on any study for which they have a conflict of interest.

The amount of time required for review of each study will vary based on the complexity of the study. In general, a primary reviewer should expect to devote between 1 to 2 hours on each assigned review and 30 minutes for other reviews. A reviewer is typically assigned 1 to 2 studies per meeting. Therefore, members should expect to commit between five to fifteen hours per month to IRB-related duties.

The Chair is responsible for reviewing and approving exempt and expedited applications, or delegating this responsibility to appropriate IRB members, making the final determination as to the type of review required and appropriate approval categories, running the convened IRB meetings, giving final approval to studies that had been approved with modifications required, and serving as a resource to investigators and IRB members and staff. The Chair should expect to commit approximately 2 to 3 additional hours per week to IRB-related duties.

The IRB staff, in consultation with the Chair, assigns reviewers for full board reviews, ensuring that the primary reviewer will have the appropriate experience and scholarly or scientific expertise. An experienced member is considered to be one who has completed the required training and attended at least 6 IRB meetings. For initial review of studies subject to FDA oversight, the primary reviewer will be an M.D. or Pharm.D. If the Chair determines that the IRB does not have the appropriate expertise, the study will be referred to an outside expert. Newly appointed members will not be assigned as a primary reviewer prior to attending at least one meeting and completing training requirements.

Due to the absence or unavailability of the Chair, the Vice-Chair is authorized to perform all functions of the Chair. The Chair may also delegate some or all duties to another IRB member who is experienced and has the appropriate expertise. For example, if the Chair and Vice-Chair are unavailable on the date of a scheduled convened meeting, an experienced member may be asked to chair the meeting, conduct expedited reviews, sign documentation, etc. The IRB roster will be used to identify such members. If the
delegation of tasks is to someone other than the Vice-Chair, it will be noted via memo (e-mail) from the Chair to the IRB member with a copy given to the IRB Administrator to be kept on file with the IRB meeting minutes. Note: reference to the Chair throughout this document refers to the Chair, Vice-Chair or delegated IRB member unless otherwise noted.

The IRB must operate in an environment free from undue influence. Any member of the IRB or IRB staff who believes that undue pressure is being brought to bear on him/her or any other member of the IRB must report the concern to the DRC. Reporting may occur through the Chair to the DRC, or directly to the DRC. The IRB member reporting the concern should provide the name(s) of the individual(s) who may be creating the undue influence, the name(s) of who may be being influenced, and a summary of the situation, e.g., an associate professor being pressured to vote for approval of a full professor’s study. The IRB member may choose the method of communication. The DRC will follow through with the appropriate action based on the significance of the information presented. (Refer to the section on reporting undue influence).

A member not fulfilling his/her obligations may be asked to step down by the Chair, the VPR, or the DRC. Any member of the IRB may express a concern related to the performance of another member to the Chair, DRC, or RCC. Based upon findings, the Chair and/or DRC may take no action, hold a discussion with the member regarding expectations and performance, or require that the member step down.

Liability of IRB Members
Members of the IRB are either employees of or acting as agents of the UConn Storrs. When acting in the capacity of either employee or agent, and in accordance with IRB standard operating procedures, members are indemnified by the State of Connecticut. Employees are indemnified (for actions not willful, wanton or malicious) by virtue of their status as State employees. Community members are indemnified by receiving an appointment to the faculty of UConn. This appointment is an administrative acknowledgment only. The VPR will issue a letter of appointment for the community member.

Voting by IRB Members
All members present at a meeting are expected to vote on studies presented to the full board. If a member abstains from voting that abstention will be counted as a vote of no and the member's presence will count towards quorum.

A member cannot review or vote on a study, whether it is for initial review, continuing review, a request for modification, or other action such as a vote on actions to take regarding unanticipated problems or noncompliance, if: 1) the member is involved with the study as an investigator or participant, 2) the member has a conflict of interest with the study (refer to the Conflicts of Interest section on page 64 for definition.) and/or 3) the member arrived late to the meeting after discussion of the study was complete. Members who cannot vote on a specific study for reason number 1 or 2 may provide information to and/or answer questions from the committee but cannot be present for the deliberations and voting and cannot count towards quorum for that particular vote.
A majority vote of the members present will be required to carry a motion. In general, the vote will be
taken by a show of hands and the number for, against and abstaining will be reflected in the minutes.
The Chair reserves the right to use an alternate method of voting, such as by ballot, if it is deemed
necessary.

The Chair may not review or approve an expedited or exempt study for which s/he has any conflict as
noted above.

All studies approved through the exempt or expedited review process, and amendments to full board
studies approved through expedited review, are presented on the agenda of the next regularly
scheduled meeting. Any member may request that a study or amendment previously approved through
expedited review require full board review. A majority vote of the members present will decide the
issue. If the vote is in favor of full board review the Chair will contact the PI, or direct the IRB staff to do
so, to withdraw the approval until full board review is conducted. Notification will be done via memo (e-
mail). This is not considered a suspension or termination of approval that is reportable to the IO or
agency heads.

Decisions made at a full board meeting will supersede any decisions made through the expedited review
process. Should the full board vote to negate approval previously granted, the withdrawal of approval is
considered a termination of approval. The IRB will inform the VPR and DRC of this decision, via a copy of
the minutes, and the VPR will report to other institutional officials, as necessary, and agency heads, as
required. The investigators will be informed via letter from the IRB Chair and instructed to inform any
previously enrolled participants of the termination.

Alternate IRB Members
The VPR may appoint alternate IRB members using the official appointment process noted above. The
VPR may elect to appoint an alternate member if the volume of studies requiring a specific expertise
increases or for other reasons that the DRC deems appropriate. For example, an increase in the number
of studies involving prisoners may require the appointment of an alternate prisoner representative to
cover those meetings for which the regular member cannot attend. If implemented, the IRB
Administrator adds appointed alternate members to the official IRB roster, processes the registration
with the OHRP/FDA and indicates on the roster and the registration form the identity of the member or
class of members for whom the alternate may serve. An alternate member will have an area of expertise
similar to the member for whom s/he is designated to serve as the alternate. Alternate members will be
called upon on an as needed basis. Alternate members will have sufficient time for review of material
prior to meetings and will receive the same material for review that the regular IRB member would have
received.

Ad-hoc Reviewer/Consultant
At its discretion, the IRB may enlist the help of an internal or external reviewer who is not a member of
the IRB. Such reviewers will be called upon when, in the opinion of the IRB, someone with a specific
expertise is needed to conduct a thorough review of a study or to address specific questions related to a study. Such reviewers will have full access to that specific file. The reviewer, acting as a consultant to the IRB, may submit written comments to the IRB and/or participate in discussions and make recommendations to the IRB at a convened meeting but will be excused prior to deliberations and voting. Participation of an ad-hoc reviewer will be noted in the minutes of the IRB meeting. The Chair may determine that a consultant is required at the time of initially assigning reviewers, a reviewer may request that a consultant be called upon once assigned to a protocol, or the IRB may come to this conclusion at a meeting. Assigned reviewers may also contact colleagues directly for consultation. If a colleague is consulted, the reviewer must document 1) that s/he has affirmed that the consultant-colleague has no conflict of interest with the study or sponsor and 2) the name and comments of the consultant-colleague. This documentation will be included in the IRB study record. Conflict of interest for a consultant-colleague is defined in the same manner as a conflict of interest for an IRB member (refer to section title Conflicts of Interest).

Ad-hoc reviewers/consultants will first be sought by the Chair from within the institution and asked to provide the review as a courtesy to the IRB. No UConn employee will be paid for conducting a review. If an individual cannot be identified within the institution, an external consultant will be sought. The operating budget of the RCS will pay for such consultation if payment is required. No consultant may have a conflict of interest with the study for which s/he is being asked to review. Conflict of interest for an ad-hoc review-consultant is defined in the same manner as a conflict of interest for an IRB member (refer to Conflicts of Interest section). The Chair or Vice Chair will determine that no conflict exists in the course of communication with the consultant and document that such determination was made.

Compensation to IRB Members
Members receive no direct monetary compensation. The operating budget of the RCS/IRB covers expenses associated with continuing education of members. For members who are also UConn employees, service on the IRB is recognized by the faculty promotions committee.

IRB Member Evaluation
In July of each year the performance of IRB members will be evaluated. Elements taken into consideration will include attendance, number of studies reviewed (new and continuing), the ability to apply ethical principles to the review process, the thoroughness and clarity of presentations, contributions to discussions, and participation in educational activities. The Chair will evaluate committee members and the VPR will evaluate the Chair. The VPR will receive and review the forms.

Hiring and Evaluation of IRB Support Staff
The VPR and DRC are responsible for hiring IRB staff. The hiring of staff is done in compliance with Human Resources and Union policies. Applicants may also be asked to interview with other individuals such as the Chair, Vice Chair or RCC. Performance evaluations are done on an annual basis using the standard UConn employee evaluation form.
RCS/IRB Relationships
IRB/ Vice President for Research (VPR): The VPR is the highest ranking individual charged with the responsibility of research compliance oversight and is the IO. The VPR receives copies of the approved IRB minutes and of correspondence related to 1) audit results; 2) issues of noncompliance; 3) unanticipated problems involving risks to participants or others and 4) suspensions or terminations of IRB approval.

IRB/ Director of Research Compliance (DRC): The DRC reports to the VPR and is responsible for the daily operations of the RCS and is in direct communication with the VPR regarding developments, policies and procedures related to all elements of the HRPP. The DRC receives copies of the approved IRB minutes and of correspondence related to 1) audit results; 2) issues of noncompliance; 3) unanticipated problems involving risks to participants or others and 4) suspensions or terminations of IRB approval.

IRB/Office of the Attorney General: The IRB works with the Office of the Assistant Attorney General (AG) at the Storrs Campus on a range of significant legal issues, including litigation, contractual review, and responses to change in federal and state law. The IRB requests the AG’s office to participate in certain relevant meetings when deemed appropriate to the discussion. The AG’s office may provide the IRB with information that pertains to the protections of human participants in research such as information pertaining to Connecticut laws or revisions to or new federal regulations.

If the IRB or any component of the compliance staff learn of information that may pose risk to a participant’s safety or to the safety of others, and that risk does not pertain directly to the topic of the research study, the IRB consults with the AG’s office for legal advice on whether any action should be taken, and if so what action.

IRB/Office of Audit, Compliance and Ethics: The mission of the Office of Audit, Compliance and Ethics is to assist the University and the Health Center in achieving their financial, operational and strategic goals while maintaining compliance with all associated laws and/or regulations. The Office accomplishes this goal by identifying institutional risks, performing audits, reviews and investigations; augmenting institutional compliance through effective education and training programs; and fostering the values of knowledge, honesty, integrity, respect and professionalism outlined in the University's Code of Conduct.

IRB/Sponsored Program Services (SPS): The DRC works closely with the Executive Director and Assistant Vice Provost for Research Administration to ensure that grant applications are reviewed by the IRB as required and that the Executive Director is informed of reportable instances of noncompliance, unanticipated problems or suspensions or terminations of IRB approvals for sponsored research. The DRC and Executive Director meet at regular VPR staff meetings and raise any relevant issues.

IRB/Institutional Biosafety Committee (IBC): UConn Storrs established an IBC in accordance with the "NIH Guidelines for Research Involving Recombinant DNA Molecules". Additional guidelines are provided by the Center for Disease Control (CDC) in their "Biosafety in Microbiological and Biomedical
Laboratories" handbook. The University also complies with other applicable state and federal regulations. The IBC reviews research and teaching activities that involve recombinant DNA (rDNA), potentially hazardous biological materials and/or biological toxins. The purpose of this review process is to ensure that University activities comply with government regulations and provide appropriate safeguards for human health and the environment. The IBC meets at least four times per year and consists of University faculty and community representatives as proscribed by the NIH. As part of the initial review process, the IRB ensures that protocols that are reviewed by the IBC that also involve human participants have been reviewed and approved by the IBC prior to IRB approval.

IRB / Financial Conflict of Interest in Research Committee (FCOIC): The FCOIC serves as the resource with respect to matters involving individual conflicts of interest in research. Its responsibilities include the identification and management, or mitigation or elimination of specific conflicts of interest. The committee consists of not less than five faculty members with broad representation from the University, and one community member who is not a University employee. At the time of proposal submission to the Sponsored Program Services (SPS), all investigators and key personnel are required to submit a Significant Financial Interest Review Form to SPS. If any investigator listed on a protocol application was required to submit the follow-up form, "supplemental" Significant Financial Interest Review Form, a copy of the form must be submitted with the IRB application as part of the initial review process. (Refer to the Conflicts of Interest section for more information.)

IRB/Stem Cell Research Oversight Committee (SCRO): The SCRO provides oversight of all issues related to the derivation and research use of stem cell lines at all schools, colleges, campuses, and research arms of the University regardless of the source of funding. The SCRO ensures that sensitive research is well-justified and that inappropriate research is not conducted. Review by the SCRO supplements but does not replace the usual reviews for compliance with federal, state, and local regulations provided by the IACUC, the IBC and the IRB. As part of the initial review process, the IRB ensures that protocols that are reviewed by the SCRO that also involve human participants have been reviewed and approved by the SCRO prior to IRB approval.

IRB/Collaborating Institutions: The IRB application solicits information from the PI to determine where the research procedures are to take place and if a collaborating institution is involved in a research study. The IRB staff will assist the investigator in determining if an institution is merely a performance site or if it is "engaged in research covered by 45 CFR 46" and must therefore operate under a valid Federalwide Assurance. In making this determination, the IRB staff will follow the OHRP Guidance that institutions are so engaged when their employees or agents (1) intervene or interact with living individuals for federally supported research purposes or (2) obtain individually identifiable private information for federally supported research purposes. Institutions receiving federal awards are automatically considered to be engaged in covered research regardless of where the research activities are carried out.
If the information is not provided to the IRB, the PI will be asked to clarify the issue and provide supporting documentation to the IRB or to work with the IRB to ensure proper assurance is obtained through OHRP. In appropriate situations, the RCC will facilitate the signing of a Collaboration Agreement between the institutions.

IRB/IRB of UConn Health Center (UCHC): An agreement is in place between the IRBs of UConn Storrs and the UConn Health Center whereby one institution may rely upon the IRB of the other institution for review, approval and oversight of a study. The IRB of record is generally determined by where the majority of participant enrollment and study procedures will occur. Unless one will accept a copy of the other’s IRB application, each institution’s protocol application must still be submitted to each site. The IRB Chairs at each institution will make the final determination as to which site will serve as the IRB of record. Investigators will be informed in writing by the UConn RCS/IRB staff of the decision to serve as the IRB of record or to accept a UCHC panel as the IRB of record.

IRB/IRB of Hartford Hospital: An agreement is in place between the IRBs of UConn Storrs and Hartford Hospital whereby one institution may rely upon the IRB of the other institution for review, approval and oversight of a study. The IRB of record is generally determined by where the majority of participant enrollment and study procedures will occur. Both IRBs’ protocol applications or, if the IRBs agree, a copy of one IRB’s application must be submitted to each site. The IRB Chairs at each institution will make the final determination as to which site will serve as the IRB of record. Investigators will be informed in writing by the UConn IRB staff of the decision to serve as the IRB of record or to accept Hartford Hospital as the IRB of record.

IRB/IRB of Yale University: An agreement is in place between the IRBs of UConn Storrs and Yale University whereby one institution may rely upon the IRB of the other institution for review, approval and oversight of a study. The IRB of record is generally determined by where the majority of participant enrollment and study procedures will occur. Both IRBs’ protocol applications or, if the IRBs agree, a copy of one IRB’s application must be submitted to each site. The IRB Chairs or their designee(s) at each institution will make the final determination as to which site will serve as the IRB of record. Investigators will be informed in writing by the UConn IRB staff of the decision to serve as the IRB of record or to accept Yale University as the IRB of record.

IRB/Sponsor: In most cases, contact with sponsors is either through the Sponsored Program Services, while negotiating a contract, or through the PI. However the IRB reserves the right to contact the sponsor directly to clarify issues pertaining to the grant application. The IRB expects all sponsors to conduct research in accordance with federal regulations and the principles of the Belmont Report.

IRB/Principal Investigator and Key Personnel: The members and staff of the IRB work with investigators throughout the conduct of a study. The IRB staff is available to answer questions and assist in the preparation of materials for submission. Assigned reviewers may contact investigators directly to have questions addressed by the PI. The IRB reserves the right to invite principal investigators to attend
meetings to explain a proposed study. The Chair will determine when it is appropriate for an investigator to attend. The investigator may be present to answer questions or provide explanations but must not be present during deliberations and voting. The IRB expectations of investigator responsibilities are described later in this document.

IRB/Independent Investigator: Any investigator not affiliated with UConn Storrs, with a collaborating institution with an approved FWA, or otherwise covered by a contract between UConn and a sponsor, will be required to submit an Independent Investigator Agreement form which will be modeled on the template provided by the OHRP. The form will commit the investigator to comply with all relevant IRB determinations, federal and state regulations, and local policies pertaining to the prospective review of studies and protection of human participants in conducting a study. Independent investigators will also be asked to complete the same disclosure of conflict of interest form that employees of the institution are required to complete. The conflict of interest committee will be asked to review such disclosures and determine if a conflict exists, if it is manageable and if so what actions must be implemented for that management.

IRB/Research Participants: Most contact with research participants will be through the PI or other study personnel. Direct contact between the IRB and a participant may occur if the participant calls to express a complaint or concern, if the IRB or its designee observes the consent process, or if the IRB solicits information regarding an individual's experience as a research participant for purposes of quality improvement.

IRB/IRB Support Staff: The support staff of the IRB is responsible for managing the review and approval process of studies. Responsibilities for administrative staff include, but are not limited to, the following:

- Screening protocol submissions for completeness prior to review by Chair or the full board
- Preparing the meeting agenda
- Preparing and mailing packets for committee members prior to meetings
- Maintaining meeting files
- Entering new studies into the data base
- Tracking studies in the data base
- Sending reminder notices for continuations and notices of protocol expiration
- Reviewing submitted revisions to determine amendments were made, as requested, prior to IRB approval
- Maintaining files for approved studies

Responsibilities for professional staff include, but are not limited to, the following:
• Acting as a resource for investigators and other study personnel by answering questions related to preparing applications, completing forms, complying with regulations and internal policies
• Acting as a resource for the IRB Chair and members by providing regulatory guidance, acting as liaison between investigators and the board, and assisting with the development of policies and procedures
• Taking minutes at convened meetings
• Preparing correspondence to PIs
• Conducting preliminary reviews of expedited and exempt applications in preparation for the primary reviewer

IRB/IRB Education and Compliance Monitor (IRB Monitor): The IRB Monitor reports directly to the DRC and works closely with the IRB Chair and staff. The IRB Monitor conducts audits of approved studies, including audits of the IRB review process. The Chair and Vice Chair receive copies of the audit correspondence that is prepared by the IRB Monitor and signed by the DRC. The correspondence may include oversights of the IRB during the review process, recommendations for corrective action, or requirements for suspension or termination of a study.

General Meeting Information
IRB meetings are not public meetings. Guests, including PIs, may attend only at the invitation of the Chair. The IRB reserves the right to invite investigators to attend meetings to explain a proposed study. Guests and PIs may partake in discussion, but will be excused at the time of deliberations and voting. All people present are reminded that any information provided in writing or discussed at the meeting may be sensitive or proprietary and must be considered confidential.

The meeting will be called to order when a quorum is reached. At least 50% plus 1 of members must be present, including a non-scientific member and a non-affiliated member. One member may fulfill both requirements. A non-scientific member's primary activity does not relate to the field of social sciences, medicine, dentistry, nursing, pharmacy, other biomedical health professions, or medical or dental research. A non-affiliated member is not employed by or retired from, or otherwise compensated by the institution, and is not involved on any other governing board of the institution. The IRB staff will ensure that a quorum is maintained throughout the convened meeting. If quorum is lost, the IRB may take no further action or vote until quorum is restored. However, members remaining in attendance may provide guidance about the protocol to the PI. Members may be considered present via video or teleconferencing that allows for two way communication. The IRB roster will be used for attendance at the meeting to ensure that a quorum has been met. IRB files will be available and accessible during convened meetings.

IRB Meeting Agendas
The IRB staff prepares the meeting agenda. The agenda includes:

• conflict of interest statement
• a list of studies approved during the previous month by the expedited review process
• a list of studies approved during the previous month and determined to be exempt from continuing IRB review
• a list of amendments to full board protocols that were approved during the previous month by expedited review process
• a follow-up report on the status of protocols that were previously reviewed by the full board
• minutes for review and approval
• new studies submitted for full IRB review
• studies to be reviewed for continuation
• requests for approval of an amendment
• adverse event report submissions
• protocol deviation report submissions
• miscellaneous discussion items

IRB Meeting Minutes
Minutes will be taken at all convened meetings. Minutes will reflect:

• members, staff and guests present
• date and start and stop time
• minutes of the previous month's meeting for review and approval
• new studies approved via exempt and expedited review during the previous month
• amendments to full board protocols approved via expedited review during the previous month
• protocol number, title, PI, primary reviewer, grant reviewer, and vulnerable population, if applicable
• summary and findings of each project discussed,(new studies, continuing review, requests for amendments, amendments, or other)
• vote to approve, request amendments, not approve, or abstain
• interval of IRB approval, if less than one year
• maintenance of quorum, and a notation of when a member leaves or joins a meeting
• identity of any IRB member recused from deliberations and voting because of a conflict of interest

When applicable, minutes will also reflect:

• attendance of any member who is serving as an alternate, and the identity of the member for whom they are the alternate
• applicable regulations, e.g., under what category prisoner research funded by DHHS is allowable
• protocol specific information for how criteria for vulnerable populations are satisfied
• information justifying an alteration to or waiver of informed consent
• the requirements that were met to grant a waiver of the requirement to document consent
• the rationale for a determination of significant risk or non-significant risk for device studies
• review of the grant application in addition to IRB application
• review and approval of data safety monitoring plans/boards
• discussion and determination regarding unanticipated problems involving risk to participant or others
• discussion and determination regarding serious or continuing noncompliance
• discussion and determination of any suspension or termination of IRB approval
• other controverted issues and the outcome of those issues
• other discussion items and the motion and vote of those discussions
• a justification of any deletion or substantive modification of information concerning risks or alternative procedures contained in the DHHS-approved sample informed consent document
• review and approval of economic considerations/participant payment.

The approved minutes are sent to the IO, DRC, and IRB members by the IRB Administrator.

**IRB Files**

IRB files and documentation are considered privileged information. Every effort will be made to maintain confidentiality and non-disclosure of this information. The IRB staff will maintain a file (electronic and hard copy) containing the minutes and the agenda for each convened meeting, plus a report of expedited and exempt approvals and a protocol status report.

That IRB staff will also maintain study specific files. These files will contain all documentation submitted by the investigator for IRB review, (initial review, continuing review, amendments), correspondence from the IRB to the investigator, correspondence from the investigator to the IRB, adverse event reports, reports of injuries to participants, statements of significant new findings provided to participants, and when applicable investigator brochures, grant applications, results of scientific reviews and audit reports. The IRB staff will maintain study files by assigned protocol number, with the most recent activity being in the front of each folder within the file. Files will have a designated section for adverse event and protocol deviation reports.

**Submission to the IRB**

IRB approval must be obtained prior to initiating any research activity that meets either the DHHS definition of research involving human participants or the FDA definition of clinical investigation involving human participants and prior to implementing amendments to previously approved research (except when necessary to eliminate apparent immediate hazards to participants). The IRB will publish submission deadlines for studies requiring review by the convened board at the start of each semester.
New submissions requesting expedited review or exempt status can be submitted at any time and are reviewed on an on-going basis.

All forms required for an IRB submission are available on the IRB website. The PI is responsible for submitting complete forms and required supporting documentation. The PI must sign all submissions. Students are required to sign the submission when the research is student initiated (research is related to the doctoral dissertation or master's degree). The signature of the Department Head or Dean is required for all submissions unless the research is funded by an external grant or contract. The signature of the medical monitor is required for interventional studies that are monitored by a physician. The IRB staff and reviewer reserve the right to return any submission that is incomplete or on out-dated forms.

**Determination of Level of Review**

Investigators make an initial determination for which type of review is appropriate for their study (full board, expedited, or exempt) and submit the required number of copies of the protocol and supporting documentation. Upon receipt, the IRB staff, in consultation with the Chair or an IRB member, screens the protocol to verify the PI's initial determination. The protocol is then placed into the appropriate queue for review. The Chair, or his/her designee, makes the final determination of the type of review required and the appropriate expedited or exempt category.

**When Submission to the IRB is Required**

A protocol application must be submitted to the IRB for any study for which research is the intent and the researcher proposes to use or involve any of the following:

- identifiable data collected for non-research purposes (e.g., academic or medical records);
- interaction (communication or interpersonal contact between investigator and participant) through interviews, surveys, and other forms of communication;
- intervention (physical procedures by which data are gathered and manipulations of the participant or the participant's environment that are performed for research purposes);
- student research projects conducted as part of Research Methods Courses;
- access to medical records and data through the medical information systems;
- pathological specimens (directly identifiable or identifiable via codes);
- diagnostic specimens (directly identifiable or identifiable via codes).

The IRB reviews projects when the research:

- is sponsored by the institution;
- is conducted by or under the direction of an employee or agent of the institution in relation to his/her institutional responsibilities;
- is conducted by or under the direction of an employee or agent of the institution using resources of the institution; or
• involves the use of the institution's non-public information (i.e. alumni, students, staff, etc.) to identify or contact human research participants or prospective participants.

Pilot Research and Protocol Development
Per 45 CFR 46.102, Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

In some cases, the UConn IRB must review pilot research and protocol development, including but not limited to the following activities:

• Development and testing of instruments or measures on human subjects* (even if it is just one subject);
• Testing of research procedures on human subjects*;
• Procedures done on human subjects* for the purpose of refining research design.
• Data collected that will be used solely or in combination with other data for purposes of publication, reports or presentation;
• Development and testing procedures on human subjects* involving needles, catheters, radiation, drugs or devices that are swallowed or inserted in an orifice require IRB approval.

*Please note that the Office for Human Research Protections (OHRP) considers the Principal Investigator as well as all research personnel to be human subjects if testing procedures are to be conducted on them. Therefore, even when pilot tests are conducted on study personnel, the protocol must be reviewed and approved by the IRB prior to initiation. Please refer to the policy on the Involvement of UConn Students and Employees in Research. Pilot studies should be identified as such in applications to the IRB. The informed consent process must explain to subjects that the research is a pilot study.

Procedures that are not considered to be pilot research and do not need to be reviewed by the IRB include, but may not be limited to, the following:

• Training programs designed to teach proven methods that will be used during the conduct of research (i.e., blood drawing training, interview techniques training);
• Refining data collection procedures or preparation of an instrument, such as a survey. For instance, "How could this survey question be misunderstood?", or "In what order should survey instruments be distributed?" This type of study development does not contribute to generalizable knowledge, and therefore is not considered research and does not require IRB review. Such data cannot be used in publications or reports.
Meeting Schedule and Submission Deadlines
The meeting schedule and submission deadlines are posted on the web. Adjustments to the meeting schedule may be made due to holidays or other issues. Adjustments will either be noted in the published meeting schedule (when known in advance) or announced via e-mail. The submission deadline for full board reviews is 10 working days prior to the meeting date.

Material requiring full-board review must be submitted by the published submission deadlines to provide sufficient time for screening and review prior to the meeting date. The IRB staff will send the agenda and material to IRB members via hand delivery or express mail within 2 – 3 working days after the submission deadline to allow members to have at least 7 working days for review of the material prior to the meeting date.

Under unusual circumstances, the Chair may call an emergency meeting of the board. However, such a meeting will not be called due to the negligence of the investigator to submit material on time. An emergency meeting may be called, for example, when a quorum for the originally scheduled meeting was not met and review is required to prevent lapse of a study, or if an investigator is faced with a situation beyond his/her control. If not already distributed, material must be distributed to members as soon as possible to allow for sufficient review. The investigator may be asked to attend the meeting to address questions, or provide additional information or clarification.

Under unusual circumstances, the IRB staff, in consultation with the Chair, may also add an item to the agenda after the submission deadline. Such circumstances generally involve situations in which an investigator is faced with a situation beyond his/her control and an amendment must be made to the protocol. The material must be distributed (via hand delivery, e-mail or express mail) to members as soon as possible to allow for sufficient review.

Submission of New Applications
The PI is responsible for submitting a complete protocol and relevant supporting documentation. The required number of copies for each category of review and the types of supporting documentation required are listed in the instructions for the protocol application. Investigators have the option of submitting applications in hard copy or via the on-line InfoEd submission process.

For studies using devices or substances not yet approved by the FDA, the IRB may require copies of IND submission and FDA opinions depending on the anticipated risks to participants. All substances used in clinical trials are to be human grade materials, and the PI must provide evidence of compliance with Good Manufacturing Practice. For some studies, especially those involving substances not yet approved by the FDA, substances not requiring FDA approval or substances being used for a purpose other than the approved indication, the IRB may require investigators to strengthen the literature review regarding previous studies and potential side effects.
Eligibility for Principal Investigator (PI) Status
In most cases, only faculty of UConn Storrs (including those at the regional campuses, the School of Law, and School of Social Work) and the UConn Storrs Health Center qualify to serve as PIs on IRB protocols. Only one person may be designated as the PI. Students may be designated as co-investigators but not PIs. On occasion, staff members of UConn Storrs may also qualify to serve as PIs on IRB protocols. In rare circumstances, requests by someone not affiliated or employed by the University (a collaborating independent investigator) to serve as PI will be reviewed on a case-by-case basis by the RCC in consultation with the IRB Chair. The intended PI must submit written requests for an exception to the RCC. Such requests will involve two parts. The first part is a request to the RCC from the individual seeking appointment as the PI. The request must include 1) a description of the level and nature of involvement s/he has with the University, 2) how that involvement relates to the mission of the University, 3) appointment of a UConn Storrs faculty member to serve as a co-investigator and 4) if applicable, to what data s/he is requesting access. The RCC will inform the PI via copy of the memo noting the approval, if such a request is approved. In addition, the IRB will enter into an Individual Investigator agreement with the PI, who is acting as a collaborating independent investigator, to extend the applicability of its FWA in accordance with OHRP’s January 31, 2005 guidance. The DRC is a designee of the IO to sign these documents.

Submission of Request for Amendments/Amendments
A PI may amend his/her approved protocol by submitting an IRB-3 Amendment Review form. Requests for amendment must be submitted for IRB review and approval prior to being implemented. The PI is responsible for providing the necessary number of copies and all material requested on the instructions. An exception may be made when the changes are necessary to eliminate apparent immediate hazards to the participants. Such changes must be reported to the IRB using the IRB-6 Protocol Deviation Report form and, when applicable, to the FDA within 5 business days. The Protocol Deviation Report form is to be accompanied by the consent form and any other document affected by or related to the change that was instituted. IRB staff, in consultation with the IRB Chair, will determine whether the change was consistent with ensuring the participant’s continued welfare and will also determine whether the change should be reviewed by the full IRB. The convened IRB will determine whether the event requires reporting as an unanticipated problem or serious or continuing noncompliance if the change is found to be inconsistent with ensuring the welfare of the participant.

Submission of Requests for Continuation (Re-approval)
Continuing review and approval must be obtained prior to the end of the day on which approval expires. Continuing review is required through all follow-up and data analysis activity (data is being maintained, and/or analyzed, and the identity of participants has not been separated from the research data), even if the study is closed to enrollment and research related interventions are complete. Continuing review is also required for studies that have been suspended, in whole or in part. Requests for continuation are submitted using the IRB-2 Re-Approval/Completion form. A request for approval of an amendment may be incorporated into a request for continuation. The PI must indicate that an amendment is being made
at time of continuing review and submit the IRB-3 Amendment Review form along with supporting documentation. As a courtesy, the IRB staff will send one reminder notice by e-mail to the PI to request continuation approximately 6 weeks before the study approval expires. The PI retains the responsibility for submitting requests for continuation. A request for continuation requiring full board review that is submitted early will be placed on the agenda of the next regularly scheduled IRB meeting. The approval period by which subsequent continuing review must occur will be adjusted accordingly. Requests for expedited continuation will be forwarded by the IRB staff to the Chair or IRB member for review and approval as they are received.

Submission of Requests for Closure/Completion
A PI may close his/her approved protocol by submitting an IRB-2 Re-Approval/Completion form to the IRB. A summary of the findings must be provided on the form or on an attached document. Requests for completion should be submitted at the time the next continuation application is due or within 30 days after data analysis is complete, the identity of participants has been separated from the research data, and there is no additional research beyond the original intent planned for this data. Requests for completion are typically reviewed by IRB staff.

Categories of Review/Process of Review and IRB Decision

Initial Review of All Submissions
IRB staff screen all submissions for completeness. PIs will be notified by phone or e-mail if a submission is missing documentation or necessary signatures. The IRB staff, in consultation with the Chair or an IRB member, screens the protocol to verify the PI’s initial determination for exempt, expedited or full board review. Any questions concerning the appropriate review level, applicability of the definition of human participants and/or the definition of research, jurisdiction of IRB, or otherwise relating to necessity of review are directed to the IRB Chair.

Exempt Procedures (New Protocol Submissions)
The PI must complete and submit the IRB-5 Request for Exemption from Continuing Review protocol form to the RCS. Exempt research must be minimal risk. Only the IRB Chair, IRB member, or IRB staff (acting as a designee of the Chair), may determine if a protocol is granted exempt status under the six categories described in 45 CFR 46.101(b). In most cases, an IRB staff member reviews the protocol application and all of the material required for submission for exempt studies. The IRB staff member may contact the PI directly to resolve any questions or concerns, or to require amendments prior to approving the exempt status. Contact will generally be made via e-mail to provide documentation of the correspondence. The IRB staff, after consultation with the IRB Chair or an IRB member, may determine that the research qualifies for expedited or full-board review, but may not deny the project. The PI will be notified via e-mail or by letter if expedited or full board review is required, be given the reasons why it is required, and be asked to resubmit the study on the IRB-1 Protocol Application form. Requests for Exemption from Continuing Review are generally reviewed within two weeks of receipt.
Although the regulations do not require informed consent for exempt research, the IRB has determined that informed consent is ethically appropriate to ensure that prospective participants are informed of the research and have an opportunity to decide for themselves whether or not to participate. In most cases, the IRB will waive written consent and ask that the PI prepare an information sheet according to the requirements set forth under 45 CFR 46.116.

If the study qualifies for exempt status, the IRB staff will notify the PI via the standard exempt approval letter. As a designee of the Chair, the IRB staff will issue the approval letter on behalf of the Chair and sign or initial the Chair's name. The approval letter describes the exempt category under which the study was approved. The letter will also inform the PI that the study is subject to audit by the IRB Monitor. A list of exempt approvals is provided to the IRB for review and approval by the IRB at each meeting. Any member can request to review the entire IRB file for an exempt study.

For administrative purposes of maintaining the InfoEd database and files, the IRB staff may periodically contact the PIs of exempt studies during the three year approval period to determine if the study is still active.

**Categories of Research that May be Reviewed by the IRB Through an Exempt Review Procedure**

Federal regulations allow six specific categories of human participant research to be exempt from continuing IRB review. Although these six categories do involve research with human participants, the research does not expose participating participants to psychological, social or physical risks. Per 45 CFR 46.101(b), the exempt research categories are:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
   - information obtained is recorded in such a manner that human participants can be identified, directly or through identifiers linked to the participants; and
   - any disclosure of the human participants' responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation.

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:
   - the human participants are elected or appointed public officials or candidates for public office; or
   - Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.

5. Research and demonstration projects which are conducted by or participant to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:
   - Public benefit or service programs;
   - procedures for obtaining benefits or services under those programs;
   - possible changes in or alternatives to those programs or procedures;
   - or possible changes in methods or levels of payment for benefits or services under those programs

6. Taste and food quality evaluation and consumer acceptance studies,
   - if wholesome foods without additives are consumed or
   - if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Category 4 applies to retrospective studies of specimens and/or data that have already been collected. The materials must be "on the shelf" (or in the freezer) at the time the protocol is submitted to the IRB. Research that involves the ongoing collection of the specimens and/or data does not meet the criteria for category 4. Category 5 pertains only to studies sponsored or funded by DHHS. Research participant to FDA regulations does not qualify for exemption categories 1 – 5.

Per 45 CFR 46.101(i), the exemptions at 45 CFR 46.101(b) do not apply to research involving prisoners, subpart C. Also, the exemption at 45 CFR 46.101(b)(2), for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, subpart D, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

In addition, although not required by regulations, IRB policies and procedures do not allow exemption of most research involving deception, audio or video taping, or HIV+ individuals.

**Initial Review by Expedited Procedures**

The PI must complete and submit the IRB-1, IRB-7 or IRB-9 Protocol Application for the Involvement in Human Participants in Research protocol form to the RCS. Expedited research must be no more than minimal risk. As defined in the federal regulations, "minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (45 CFR 46.102(i)). Only the IRB Chair or an IRB member may determine if a
protocol is granted expedited status under seven of the nine categories as published in the federal register as 45 CFR 46.110 and 21 CFR 56.110. Categories 8 and 9 do not pertain to initial review.

Only the Chair or an IRB member can make one of the following three determinations in regard to the protocol and consent forms:

- **APPROVED:** IRB approval indicates that the IRB reviewer(s) has concluded that the research and consent forms meet the federal criteria for approval.
- **MODIFICATIONS REQUIRED IN ORDER TO SECURE APPROVAL:** The IRB reviewer(s) withhold approval pending submission of revisions/additional information.
- **FULL REVIEW REQUIRED:** The IRB reviewer(s) may determine that the protocol requires full review by the IRB at a convened meeting.

The Chair or IRB member may not disapprove any research reviewed using the expedited procedure. An IRB staff member screens the protocol and material required for submission for completeness and corresponds with the PI by e-mail and/or phone until the submission is complete. Once the submission is complete, an IRB staff member conducts a preliminary review of the protocol application and material required for submission of expedited studies. The staff member may also complete the Primary Reviewer Checklist. The preliminary review consists of the following: (1) a review of the protocol to determine if there is missing information or information that requires further clarification, (2) a review of the consent form to see if it contains the required elements set forth in 45 CFR 46.116 and 117 and University policy, (3) a review of the recruitment procedures, (4) approval category, (5) if applicable, permissible categories and required findings for vulnerable populations and/or waivers or alterations of the consent process, and (6) a recommendation regarding one of the three determinations described above. The IRB staff does not review scientific issues such as the study design, feasibility of specific aims or data analysis plans. IRB staff prepares a draft review letter to the PI. The IRB staff, in consultation with the IRB Chair, selects an experienced IRB member (the "Reviewer") with appropriate scientific experience to review the protocol and material required for submission as well as the draft review letter. The Reviewer may contact the PI directly to discuss questions or concerns. The Reviewer may complete the Primary Reviewer Checklist. The purpose of the checklist is to assist the reviewer. It is an unofficial document that does not become part of the study file.

The preliminary review and the review conducted by the IRB Chair or IRB member Reviewer is conducted in accord with the criteria set forth in 45 CFR 46.111 and 21 CFR 56.111. In addition, the Reviewer must also determine 1) that the research is minimal risk, 2) that if identification of the participants and/or their responses reasonably place them at risk of criminal or civil liability or could be damaging to the participants’ financial standing, employability, insurability, or reputation, or be stigmatizing there are reasonable and appropriate protections that will be implemented so that risk related to invasion of privacy and breach of confidentiality are no greater than minimal, and 3) that the research is not classified or does not involve prisoners, with the exception that the expedited review of minor amendments for approved studies involving prisoners may be used.
If the Reviewer determines the protocol is approved, the IRB staff will notify the PI or correspondent via the standard expedited approval letter. The IRB staff will issue the approval letter on behalf of the Reviewer and sign or initial his/her name. The approval letter describes the expedited category under which the study was approved. The letter will also inform the PI that the study is subject to audit by the IRB Monitor. The approval period for studies approved through expedited review will be for one year from the date the initial approval or approval for continuation is granted. Approval is valid through the expiration date (also known as 'valid through' date) noted in the approval letter. For example, an expedited study given approval (either initially or for continuing review) on October 8, 2007 would be approved as valid through October 8, 2008, meaning that research is approved to be conducted on October 8, 2007, but will no longer be approved on October 9, 2008, and may not be conducted on or after that date without continuing approval by the IRB. A list of studies approved via the expedited mechanism during the interim between agenda dates is provided to the IRB for review and approval IRB at each meeting. Any member can request to review the entire IRB file for an expedited study.

If the Reviewer determined the protocol requires modifications to secure approval, he/she reviews and may revise the draft preliminary review letter prepared by IRB staff. The Reviewer may add comments to the letter directly or provide comments about the protocol and letter to IRB staff by e-mail. The IRB staff incorporates the revisions and sends the letter by e-mail to the PI or correspondent listed on the protocol. If the research is student directed, the student will also receive a copy of the letter by e-mail. If the requested revisions or clarifications are minor, the PI may be notified by e-mail to provide documentation of the correspondence. The PI responds to revisions requested by the IRB in writing and sends the response to the RCS. PIs are encouraged to submit a point by point response to the IRB’s initial determination letter to facilitate review. The PI must submit one copy of the protocol and/or consent form with the revisions highlighted and one copy of the protocol "clean," without revisions highlighted, to expedite review of the revisions. The IRB staff member who conducted the preliminary review will review the revisions to determine if the Reviewer’s concerns were properly addressed. Any requested revisions involving the addition or deletion of specific elements is eligible to be reviewed by IRB staff. Any revisions that involve controverted issues or pertain to the scientific review will be reviewed by the Reviewer rather than IRB staff. In addition, any new procedures added to the protocol that result from the IRB's review will be reviewed by the Reviewer. In most cases, the IRB staff member will forward the revisions to the Reviewer by e-mail. If the IRB staff and/or the Reviewer determines that all concerns have been addressed, the IRB staff will issue the approval letter on behalf of the Reviewer and sign or initial his/her name. The approval letter describes the expedited category under which the study was approved. The letter will also inform the PI that the study is subject to audit by the IRB Monitor. The approval period for studies approved through expedited review will be for one year from the date the initial approval or approval for continuation is granted. If the Reviewer and the investigator cannot agree on the amendments required for approval, the research will be sent to the convened IRB for review. The PI will be notified by the IRB staff via e-mail or by phone if full board review is required, given the reasons as to why it is required, and may be asked to submit additional copies.
Continuing Review (Re-Approval) by Expedited Procedures

To request re-approval, the PI must complete and submit the IRB-2 Re-Approval/Completion form along with any required material as described in the instructions. An IRB staff member screens the IRB-2 form and, if applicable, the protocol, consent form or material required for completeness and corresponds with the PI by e-mail and/or phone until the submission is complete. To be eligible for expedited review, the research protocol must satisfy the criteria set forth in 45 CFR 46.111 and 21 CFR 56.111 for the IRB to approve the protocol for continuation. The IRB may only use expedited review procedures for continuation review under the following circumstances:

1. The study was initially eligible and continues to be eligible for expedited review procedures; OR
2. The research is permanently closed to the enrollment of new participants; all participants have completed all research-related interventions; and the research remains active only for long-term follow-up of participants; OR
3. Where no participants have been enrolled and no additional risks have been identified either at the University or at any site if the research involves a multi-site study; OR
4. The research involves the study of drugs and/or medical devices AND either does not require an Investigational New Drug (IND) (21 CFR Part 312) and/or an Investigational Drug Exemption (IDE) (21 CFR Part 812) and/or the device is approved for marketing and being used in accordance with the approved labeling. The IRB must also have determined and documented at a convened meeting that the research is no greater than minimal risk and no additional risks have been identified.

Categories 1 through 9, excluding 8b, apply to continuing review. In accord with federal requirements, the IRB approval period can extend no longer than one year after the start of the approval period. The PI may not continue research after expiration of IRB approval; continuation is a violation of federal requirements specified in 45 CFR 46.103(a) and 21 CFR 56.103(a). If the IRB approval has expired, the PI must cease all research activities and may not enroll new participants in the study after the expiration of the IRB approval. However, if the IRB determines that an overriding safety concern and/or ethical issue is involved or that it is in the best interests of the individual participants to continue participating in the research activities, the IRB may permit the participants to continue in the study for the time required to complete the re-approval process.

If the request for re-approval meets the circumstances defined above, the continuing review is conducted in the same manner as a new expedited protocol submission whereby IRB staff conduct a preliminary review and forwards the review to the IRB Chair or an IRB member.

Continuing review and approval for expedited studies must be obtained prior to the end of the day on which IRB approval expires. Any amendments that are made at the time of re-approval will be reviewed in accord with the procedures for Review of Amendments to Previously Approved Research by Expedited Procedures.
For expedited review, the outcomes of continuing review are the same as the options outlined under Initial Review by Expedited Procedures.

**Review of Amendments to Previously Approved Research by Expedited Procedures**

A PI may amend his/her approved protocol by submitting an IRB-3 Amendment Review form. An IRB staff member screens the IRB-3 form and, if applicable, the protocol, consent form or material required for submission for completeness and corresponds with the PI by e-mail and/or phone until the submission is complete. The IRB staff, in consultation with the IRB Chair or an IRB member, conducts a preliminary review of the IRB-3 to determine if the requested amendment is eligible for review under expedited procedures. To be eligible for review under the expedited procedures the amendment must be minor. A minor change is one which makes no substantial alteration in:

- The level of risk to participants;
- The research design or methodology;
- The participant population;
- Qualifications of the research team;
- The facilities available to support the safe conduct of the research; or
- Any other factor which would warrant review of the proposed changes by the convened IRB.

If the IRB Chair or an IRB member determines that the research qualifies for expedited review, the amendment is reviewed in the same manner as a new expedited protocol submission whereby IRB staff conducts a preliminary review and forwards the review to the IRB Chair or an IRB member. Amendments of research involving vulnerable populations may be approved via the expedited process. However, for research involving prisoners, the prisoner advocate will also be asked to review the requested change or addendum to determine that it meets the definition of minor change to previously approved research.

For expedited review, the outcomes of review of amendments are the same as the options outlined under Initial Review by Expedited Procedures.

**Categories of Research that May be Reviewed by the IRB through an Expedited Review Procedure**

Federal regulations allow nine specific categories of human participant research to be reviewed through an Expedited Review Procedure. Per 45 CFR 46.110 and 21 CFR 56.110, the research should present no more than minimal risk to human participants and involve only procedures listed in one or more of the following categories:

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
   a. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
b. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
   a. From healthy, nonpregnant adults who weigh at least 110 pounds. For these participants, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
   b. From other adults and children considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) Hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: (a) Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the participant or an invasion of the participant's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
5. Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (Note: Some research in this category may be exempt from the HHS regulations for the protection of human participants. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

6. Collection of data from voice, video, digital, or image recordings made for research purposes.

7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (Note: Some research in this category may be exempt from the HHS regulations for the protection of human participants 45 CFR 46.101 (b)(2) and (b)(3). This listing refers only to research that is not exempt.)

8. Continuing review of research previously approved by the convened IRB as follows:
   a. Where (i) the research is permanently closed to the enrollment of new participants; (ii) all participants have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of participants; or
   b. Where no participants have been enrolled and no additional risks have been identified; or
   c. Where the remaining research activities are limited to data analysis.

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

**Initial Review by the Full Board**

Proposed research that does not qualify for either exempt status or expedited review will be sent to the convened board for review. The PI must complete and submit the IRB-1 Protocol Application for the Involvement in Human Participants in Research form to the RCS. The application form used for expedited and full board review is the same. If the PI indicates that he/she believes the research is more than minimal risk and requires review by the convened board, the original and 15 copies of the protocol and material are submitted. This packet is set aside for the next IRB meeting. Prior to the meeting, the IRB staff, in consultation with the IRB Chair or an IRB member, reviews the protocol to determine if the PI's assessment is correct. If the submission is determined to be of no greater than minimal risk and satisfies the criteria for expedited review, the protocol is added to the queue for review by expedited procedure.

Protocols that do not qualify for either exempt or expedited review are assigned a primary reviewer for initial review at the convened meeting. Each member of the IRB receives a complete copy of the protocol submission. The Chair and primary reviewer also receive a copy of the grant application, when...
applicable. In cases where the standardized assessment measures are substantial, only the Chair and primary review will receive copies. IRB members are informed that the packet they receive is not complete and may request a copy of the material by contacting the RCS. The full file is also available to all IRB members at the meeting. The primary reviewer is responsible for the following: (1) comparing the detailed grant application or industry protocol with the IRB application; (2) informing the full IRB of any discrepancies between the detailed protocol and the summary application materials; and (3) conducting an in-depth review. Any member of the IRB may request to see additional information, including all of the information presented to the primary reviewer, the IRB file and previous minutes related to the study. Each reviewer is provided with the Primary Reviewer Checklist and other review sheets as an aid to making determinations. These work sheets are unofficial documents that do not become part of the study file. The determinations of the convened board are noted in the minutes.

At the convened meeting, the primary reviewers will present a summary of the study, any concerns with specific items on the reviewer sheet and any additional concerns or comments. Discussion and voting will follow. IRB members are expected to be familiar with all items on the agenda and contribute toward the discussion or each item. If the primary reviewer is absent, the review will be presented by the Chair or Vice-Chair.

Full Board reviews are conducted in accord with the criteria set forth in 45 CFR 46.111 and 21 CFR 56.111. The Board can make one of the following four determinations in regard to the protocol and consent forms:

- **APPROVED**: IRB approval indicates that the Board has concluded that the research and consent forms meet the federal criteria for approval.
- **MODIFICATIONS REQUIRED IN ORDER TO SECURE APPROVAL**: A vote for amendments required indicates the IRB has given the meeting Chair the authority to approve the minor revisions. The IRB withholds approval pending submission of minor revisions/additional information.
- **DEFERRED**: The IRB withholds approval pending submission of major revisions / additional information. For some studies, the IRB may appoint one or more members of the IRB to discuss the reasons with the investigator. Once the revisions have been made by the PI and submitted to the RCS, the revised protocol is added to the next IRB meeting agenda for review.
- **DISAPPROVED**: Disapproval of a protocol usually occurs when the IRB determines that the risk of the procedures outweighs any benefit to be gained or if the proposed research does not meet the federal criteria for IRB approval.

If the full board determines the protocol is approved, the IRB staff will notify the PI or correspondent via the standard full board approval letter. The IRB staff will issue the approval letter on behalf of the individual chairing the meeting and sign or initial his/her name. The letter will also inform the PI that the study is participant to audit by the IRB Monitor. During the convened meeting, the IRB determines the approval period, as appropriate to the degree of risk but not less frequently than once per year. The IRB will generally set a shorter approval period for high risk protocols or protocols with high risk/low
potential benefit ratios. When a protocol receives final approval, the IRB staff assigns the start of the approval period as the date of the convened IRB meeting. If a protocol was determined to require amendments to secure approval and the PI completes the revisions, the approval period starts from the meeting date of the convened IRB at which the protocol was initially reviewed.

If the full board determined the protocol requires modifications to secure approval, the IRB staff prepares a draft determination letter based upon the IRB's discussion at the meeting. The letter describes the revisions requested by the IRB. If the revisions requested are particularly controverted or complex, the staff may first e-mail the draft letter to the primary reviewer for review and comment. The draft letter is then e-mailed to the meeting Chair for final review and approval. The primary reviewer and Chair may add comments to the letter directly or provide comments about the protocol and letter to IRB staff by e-mail. The IRB staff incorporates the revisions and sends the letter by e-mail to the PI or correspondent listed on the protocol. If the research is student-directed, the student will also receive a copy of the letter by e-mail. A hard copy of the letter is sent as a follow-up. The PI responds to revisions requested by the IRB in writing and sends the response to the RCS. PIs are encouraged to submit a point by point response to the IRB's initial determination letter to facilitate review. The PI must submit one copy of the protocol and/or consent form with the revisions highlighted and one copy of the protocol "clean," without revisions highlighted to expedite review of the revisions. If the revisions are straightforward and minor, the IRB staff may review the revisions to determine if they were addressed. Any revisions that involve controverted issues or pertain to the scientific review will be reviewed by the primary reviewer or meeting Chair rather than IRB staff. In addition, any new procedures added to the protocol that result from the IRB's review will be reviewed by the primary reviewer or meeting Chair. The Chair or primary reviewer may request that the new procedures be reviewed by the full board. In most cases, the IRB staff member will forward the revisions by e-mail. If the IRB staff, primary reviewer and/or the meeting chair determines that all concerns have been addressed, the IRB staff will issue the approval letter on behalf of the meeting Chair and sign or initial his/her name. The letter will also inform the PI that the study is subject to audit by the IRB Monitor. During the convened meeting, the IRB determines the approval period, as appropriate to the degree of risk but not less frequently than once per year. The IRB may set a shorter approval period for high risk protocols or protocols with high risk/low potential benefit ratios. When the protocol was determined to require modifications to secure approval and the PI completes the revisions, the approval period starts from the meeting date of the convened IRB at which the protocol was initially reviewed. If the IRB and the investigator cannot agree on the modifications required for approval, the research will be sent to the convened IRB for further review. The PI will be notified by the IRB staff via e-mail or by phone if full board review is required, given the reasons as to why it is required, and may be asked to submit additional copies.

If the full board determines that a protocol must be deferred, the IRB staff will prepare a draft determination letter based upon the IRB's discussion at the meeting. The letter lists the reasons for the deferral and includes a description of the revisions or clarifications requested. The draft letter is reviewed according to the same procedures described above. The approved letter is sent by e-mail to
the PI or correspondent listed on the protocol. If the research is student directed, the student will also receive a copy of the letter by e-mail. A hard copy of the letter is sent as a follow-up. The PI responds to revisions requested by the IRB in writing and sends the response to the RCS. PIs are encouraged to submit a point by point response to the IRB’s initial determination letter to facilitate review and to meet with IRB staff to discuss revisions. The PI must submit one clean copy of the protocol and/or consent form and 15 copies of the protocol and/or consent form with the revisions highlighted. The protocol is then added to the agenda for the next scheduled IRB meeting. When a protocol that was initially deferred receives final approval, the IRB staff assigns the start of the approval period as the date of the meeting the protocol was approved or required modifications to secure approval.

If the full board determined the protocol must be disapproved, the IRB prepares a draft determination letter based upon the IRB’s discussion at the meeting. The draft letter is reviewed and approved in the same manner as described above. The approved letter is sent to the PI by hard copy. If the research is student-directed, the student will also receive a copy of the determination letter. A copy of the disapproval determination letter is also sent to the IO, AVPR, the PI’s Department Head, Sponsored Programs Services (if applicable), and other University offices, as necessary.

Continuing Review (Re-approval) by the Full Board
To request re-approval, the PI must complete and submit the IRB-2 Re-Approval/Completion form along with any required material as described in the instructions. The application form used for continuing review for expedited and full board review is the same. A primary reviewer system is used for continuing review. Reviewers are selected in the same manner as described for Initial Review by the full board. Each member of the IRB receives a complete copy of the protocol submission. The Chair and primary reviewer each receive a copy of the grant application. In cases where the standardized assessment measures are substantial, only the Chair and primary reviewer will receive a copy. IRB members are informed that the packet they receive is not complete and may request a copy of the material by contacting the RCS. The full protocol file is available at the meeting. The research protocol must satisfy the criteria set forth in 45 CFR 46.111 and 21 CFR 56.111 for the IRB to approve the protocol for continuation.

If a request for continuation is received early, the study will be reviewed at the next convened meeting and the review cycle will be adjusted accordingly based on that meeting date. The instructions for the request for continuation form describe in detail the requirements for submission.

For full review, the outcomes of continuing review by the convened board are the same as the options outlined under Initial Review by the Full Board.

Review of Amendments to Previously Approved Research by the Full Board
A PI may amend his/her approved protocol by submitting an IRB-3 Amendment Review form. The application form used for amendments for expedited and full board review is the same. Minor changes can be approved by expedited review. All other changes will be reviewed by the full board. A primary
reviewer system will be used to review requests for amendments to determine whether the modified research continues to fulfill the criteria for approval. Reviewers are selected in the same manner as described for Initial Review by the full board. Each member of the IRB receives a complete copy of the protocol submission. The Chair and primary reviewer each receive a copy of the grant application. In cases where the standardized assessment measures when are substantial, only the Chair and primary review will receive a copy. IRB members are informed that the packet they receive is not complete and may request a copy of the material by contacting the RCS. The full protocol file is available at the meeting. The instructions for the request for amendment form describe in detail the requirements for submission.

For full review, the outcomes of review of amendments by the convened board are the same as the options outlined under Initial Review by the Full Board.

**Human Participant Research Determination**

The IRB Chair, IRB member, or IRB staff (acting as a designee of the Chair), may determine if a proposed project using human materials/data constitutes human participant research. Investigators are encouraged to submit their proposed project to the IRB using the IRB-5 Request for Exemption from Continuing Review protocol form. The form will be reviewed and a final determination will be made as to whether a study meets the definitions of human participant research set forth in 45 CFR 46.102(d)(f). If the determination is that the project does not constitute human participant research, a letter of determination will be sent to the investigator and the RCS/IRB will have no further involvement. If the determination is that the research does involve human participants, the IRB-5 will be reviewed and approved in accordance with the exemption process described above. An IRB-1 application may be required if the research project does not qualify for exempt status. The IRB staff will send a written determination regarding the proposed project to the PI.

**Lapse In Approval**

If continuing approval is not obtained, or will not be obtained due to failure to meet submission deadlines, by the end of day on the expiration date, the IRB staff will send the investigator the standard notification letter or e-mail that a lapse in approval has occurred. The letter informs the investigator that all research-related activity must stop until IRB re-approval is obtained. For studies requiring full board review, if review does not occur by the next convened meeting, the study is administratively closed by the IRB. For studies requiring expedited review, if review has not been obtained within 30 days after the expiration date the study is administratively closed by the IRB staff. The IRB staff sends written notification to the PI of administrative closures. This type of study closure is not considered a suspension or termination that is reportable to the IO or agency heads.

The PI may appeal the requirement to stop all research related activity or the administrative closure if continuation of an activity is required due to it being in the best interest of the participant. The appeal must be submitted in writing to the IRB Chair, must request permission for continuation of specific
activity(ies), and explain why the continuation of the activity is in the best interest of the participant. The PI must also confirm that continuation is actively being sought. The IRB Chair reserves the right to deny the appeal and require that a new application be submitted for review and approval.

Investigators must respond to the IRB's letter which outlines the modifications required in order to secure approval within six months, or the initial application is withdrawn. An investigator may request additional time. In the case of modifications related to continuing approval, the study is administratively closed by the IRB staff if a response is not received within 1 month. The IRB staff will notify the investigator in writing of such closures.

Criteria for Approval
In order to grant approval to a research study, the IRB must find and document that the following criteria are met, per 45 CFR 46.116(a)(b), at the time of initial approval and sustained through continuing review and requests for an amendment:

- risks to participants are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk, and (ii) whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes;
- risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies participants would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility;
- selection of participants is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disable persons, or economically or educationally disadvantaged persons. For example vulnerable populations in proposed studies selected as populations of convenience is not acceptable;
- informed consent will be sought from each prospective participant or the participant's legally authorized representative, in accordance with, and to the extent required by regulations (or a request to waive or alter the elements of consent must be approved);
- informed consent will be appropriately documented, in accordance with, and to the extent required by regulations (refer to informed consent section);
- when appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of participants (refer to data safety monitoring section); and
• when appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data (this criterion applies to all studies).
• when some or all of the participants are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these participants.
• when biomedical research procedures are included in a research study, the IRB requires that information be provided by the PI that documents the specific training/credentials for each individual identified as key personnel that qualifies them to perform each procedure.

Review of Studies Involving Vulnerable Populations
Studies proposing the involvement of vulnerable populations are reviewed to ensure that inclusion of these participants is justified and, if so, that adequate procedures are in place to minimize the risks related to physical harm, psychological harm and breach of privacy and confidentiality. The research must be relevant to the vulnerable population and not otherwise capable of being carried out with a non-vulnerable population. The IRB will fulfill the additional duties required by Federal Regulations outlined in Subparts B, C and D of 45 CFR 46 regardless of the source of funding for initial and continuing review by expedited or full board proceedings. For studies requiring full board review, a member or consultant who is knowledgeable about or experienced in working with vulnerable populations must review all material and be present (in person or via teleconference) at the meeting. The IRB Chair may use the IRB roster to identify such members and/or consultants to assign as reviewers. Consultants may participate in the discussion but may not vote. For studies requiring full board review, any decision made by a convened board will supersede the opinion of an individual reviewer. The minutes will reflect the determinations of the convened board regarding the required findings.

Vulnerable populations include those defined 45 CFR 46 Subparts B (Pregnant Women, Human Fetuses and Neonates), Subpart C (Prisoners), and Subpart D (Children), and those mentioned in 45 CFR 46.111(b): mentally disabled persons, or economically or educationally disadvantaged persons. The IRB also considers UConn students, employees, and HIV+ individuals to be vulnerable populations. The IRB may also require additional protections for any other group not specified in this policy but determined to be vulnerable by the IRB. Such additional protections may include, but are not limited to, the witnessing of the consent process, more frequent continuing review, or additional review by someone with a specific expertise.

Pregnant Women, Fetuses or Neonates
Proposed studies involving pregnant women, fetuses or neonates may qualify for exempt or expedited review when no more than minimal risk is involved. The Chair or an IRB member will make the final determination. Studies requiring full board review will be reviewed and approved in accordance with the criteria of 45 CFR 46 Subparts A and B. The primary reviewers will be provided with the standard reviewer sheet that addresses Subpart A and information provided by the investigator that outlines the
additional duties/findings required of the IRB under Subpart B. Unavailability of the father as related to consent issues is interpreted to mean that he is either deceased or that his whereabouts are not known and cannot be determined with a reasonable amount of effort.

Note: The regulations specified in Subpart B apply when investigators engage in human participants research conducted or supported by any federal department or agency that has adopted the Federal Policy for the Protection of Human Subjects unless the research is otherwise exempt from the requirements of the Common Rule or a department covered by a separate assurance. In cases where clinical research is not supported by the federal government, as described above, the University will apply equivalent standards when 45 CFR 46.204 applies. However, this may not always be possible in social/behavioral research because such research (while the risk is not greater than minimal risk) may not directly benefit the pregnant woman and/or the fetus. In order to engage in social/behavioral research involving pregnant women, the IRB determined that it will allow pregnant women to be enrolled in research involving interview, focus group, survey or similar procedures. These studies will be reviewed by the IRB following equivalent standards as set forth in the Common Rule.

Pregnant women or fetuses may be involved in research only if the IRB finds that:

a. where scientifically appropriate, preclinical studies, including studies in pregnant animals, and clinical studies, including studies on pregnant women, have been conducted and provide data for assessing potential risks to pregnant woman and fetuses;

b. the risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means;

c. any risk is the least possible for achieving the objective of the research;

d. the woman's consent is obtained in accordance with the provisions of Subpart A if the research holds out 1) the prospect of direct benefit to the pregnant woman, 2) the prospect of a direct benefit to both the pregnant woman and the fetus, or 3) no prospect of direct benefit for the woman or the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means;

e. if the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accord with the informed consent provision of Subpart A. The father’s consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest;

f. each individual providing consent under paragraph d or e of this section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;
g. for children who are pregnant, assent and permission are obtained in accord with the provisions of Subpart D – children involved as participants in research; (Subpart D is described under the section for children)

h. no inducement, monetary or otherwise, will be offered to terminate a pregnancy;

i. individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and

j. individuals engaged in the research will have no part in determining the viability of neonates.

Neonates of uncertain viability and nonviable neonates may be involved in research if all of the following conditions are met:

a. Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.

b. Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate.
   - For neonates of uncertain viability, the legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence or temporary incapacity, the legally effective informed consent of the either parent’s legally authorized representative is obtained in accordance with Subpart A, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.
   - For nonviable neonates, the legally effective informed consent of both parents of the neonate is obtained in accord with Subpart A. The provisions to request a waiver or alteration of consent described in Subpart A do not apply. If either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable neonate will suffice. The consent of the father need not be obtained if the pregnancy resulted from rape or incest. The consent of a legally authorized representative of either or both of the parents of a nonviable neonate will not suffice.

c. Individuals engaged in the research will have no part in determining the viability of a neonate.

d. The following requirements have been met as applicable to neonates of uncertain viability.
   - until it has been ascertained whether or not a neonate is viable, a neonate may not be involved in research unless the IRB determines that 1) the research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and 2) any risk is the least possible for achieving that objective; or 1) the purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and 2) there will be no added risk to the neonate resulting from the research;
   - the legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence or temporary incapacity, the legally effective informed consent of the either parent’s legally authorized representative is
obtained in accordance with Subpart A, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.

Nonviable neonates: After delivery a nonviable neonate may not be included in research unless all of the following additional conditions are met:

a. vital functions of the neonate will not be artificially maintained;
b. the research will not terminate the heartbeat or respiration of the neonate;
c. there will be no added risk to the neonate resulting from the research;
d. the purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and

e. the legally effective informed consent of both parents of the neonate is obtained in accord with subpart A of this part. The provisions for a waiver or alteration of consent (46.116 c and d) do not apply. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable neonate will suffice. The consent of the father need not be obtained if the pregnancy resulted from rape or incest. The consent of a legally authorized representative of either or both of the parents of the nonviable neonate will not suffice.

Viable neonates: A neonate, after delivery, that has been determined to be viable may be included in research only to the extent permitted by and in accord with the requirements of subparts A and D, Additional Protections for Children Involved as Participants in Research, describe in subsequent sections.

Research involving, after delivery, the placenta, the dead fetus, or fetal material may be conducted only if the IRB finds that:

a. research involving, after delivery, the placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus, shall be conducted only in accord with any applicable Federal, State or local laws and regulations regarding such activities.

b. if information associated with material described in paragraph a of this section is recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, those individuals are research participants and must be afforded the applicable protections of 45 CFR 46 its subparts as applicable.

Research involving pregnant women, fetuses or neonates that does not fit into one of the above categories may only be conducted if the IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problems affecting the health or welfare of pregnant women, fetuses or neonates and after the Secretary has consulted with an expert panel and there has been opportunity for public review and comment. The required findings for such
research are that the research does present the aforementioned opportunity, the research will be conducted in accord with sound ethical principles and informed consent will be obtained.

**Prisoners**
The full board must initially review all studies involving prisoners. The membership of the board will be such that the majority of members have no association with the prisons involved and at least one member will be a prisoner, or a prisoner representative. Such membership constitutes compliance with 45 CFR Subpart C 46.304, Composition of Institutional Review Boards where prisoners are involved. A prisoner representative will be assigned as the primary reviewer. The primary reviewer will be provided with the standard reviewer sheets that address Subpart A and information provided by the investigator that outlines the additional duties/findings required of the IRB under Subpart C.

Minimal risk as related to studies proposing to involve prisoners is defined as the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental or psychological examination of healthy persons. In assessing the level of risk involved in a study, the IRB will not use risks that face prisoners in the prison setting as the standard for acceptable risk, and will only allow risks that are commensurate with those that would be accepted by non-prisoner volunteers. The IRB must find that the involvement of prisoners as participants is justified.

Requests for amendments to approved studies that are administrative in nature and/or that pose no change to the involvement of the prisoner or to the level of risk, for example corrections of typographical errors in consent documents or additional data elements in a file review study, may be approved through the expedited review process by the Chair or the prisoner representative. However, the Chair or the prisoner representative reserves the right to require full board review of any request for modification.

Continuing review of studies involving prisoners will require full board review unless no participants have been enrolled and no additional risks have been identified or the remaining activity is limited to data analysis in which case the PI may request expedited review under category 8(b) or (c).

Per 46.305(a)(1), when reviewing proposals involving prisoners the IRB will ensure that the research is permissible under one of the categories of 46.306(a)(2) which are:

- study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the participants;
- study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the participants;
- research on conditions particularly affecting prisoners as a class (e.g., vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on
social and psychological problems such as alcoholism, drug addiction and sexual assaults) provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology medicine and ethics, and published notice in the Federal Register of his intent to approve such research; or

- research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the participant. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology medicine and ethics, and published notice in the Federal Register of his intent to approve such research.

Per 46.305(a)(2-7), the IRB will also determine that the following additional criteria for approval have been satisfied:

- any possible advantages accruing to the prisoner through his or her participate in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;
- the risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers;
- procedures for the selection of participants within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the PI provides to the Board justification in writing for following some other procedures, control participants must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;
- the information is presented in a language which is understandable to the participant population; (note: use a 5th grade reading level as a benchmark)
- adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and
- where the Board finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoner's sentences, and for informing participants of this fact.
When funding is from DHHS, the institution shall certify to the Secretary, in such form and manner as the Secretary may require, that the duties of the Board under Subpart C have been fulfilled. The certification letter will be sent from the RCC or DRC on behalf of the IRB.

**Epidemiologic Research Involving Prisoners**

Effective June 20, 2003, the Secretary of the DHHS may also approve epidemiologic research involving prisoners as participants under a provision allowing for a waiver of the applicability of provisions 46.305(a)(1) and 46.306(a)(2) as set forth above. While prisoners may be included in such studies, they cannot be the only population included within the study. The epidemiologic research can present no more than minimal risk and no more than inconvenience to the prisoner-participants. To qualify for such a waiver the epidemiologic study must meet the following criteria:

- the sole purposes are to describe the prevalence or incidence of a disease by identifying all cases, or to study potential risk factor associations for a disease, and
- for DHHS supported research, the IRB, via the RCC or DRC, must include in the certification letter to OHRP that the additional criteria of 46.305(a)(207), as described above, have been satisfied.
- that the research presents no more than minimal risk and no more than inconvenience to the prisoner-participants, and
- prisoners are not a particular focus of the research

Studies for which the waiver may apply include epidemiological research related to chronic disease, injuries, and environmental health.

**Children**

Research that involves children is subject to the additional requirements of Subpart D. Under DHHS and FDA regulations "children" are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

When research is conducted in Connecticut, persons who meet the above definition are all individuals under 18 years of age with the following exceptions:

1. Individuals between 16 and 18 years of age adjudicated as emancipated by a probate court
2. All individuals under 18 years of age, if the research procedures are limited to:
   - HIV testing, counseling, and treatment
   - Outpatient mental health services
   - Testing or treatment for sexually transmitted diseases
   - Treatment or rehabilitation for alcohol or drug dependence
   - Abortion counseling and treatment
3. All individuals between 16 and 18 years of age, if the research procedures are limited to:
   - Inpatient mental health services
4. All individuals between 17 and 18 years of age, if the research procedures are limited to donation of blood or any component thereof and to the withdrawal of blood in conjunction with any voluntary blood donation program.

Proposed studies involving children may qualify for exempt or expedited review if the study falls into one of the federally-approved categories defined in 45 CFR 46.101 or in the guidance published in the Federal Register for categories for which expedited review is acceptable. Exemption categories 1-5 do not apply to FDA regulated studies. Also the exemption noted at 45 CFR 46.101(b)(2) for research involving survey or interview procedures or observations of public behavior does not apply to research involving children unless the research involves the observation of public behavior and the investigator(s) do not participate in the activities being observed. The Chair will make the final determination regarding approval status and categories. Studies requiring full board or expedited review will be reviewed and approved in accordance with the regulatory criteria as summarized below. The primary reviewers will be provided with the standard reviewer worksheets that address Subpart A and information provided by the investigator within the protocol that outlines the additional duties/findings required of the IRB under Subpart D.

For research not involving greater than minimal risk, the IRB must find and document that adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians.

For research involving greater than minimal risk but presenting the prospect of direct benefit to the individual participants the IRB must find and document:

- the risk is justified by the anticipated benefit to the participants;
- the relation of the anticipated benefit to the risk is at least as favorable to the participant as that presented by available alternative approaches; and
- that adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians.

For research involving greater than minimal risk and no prospect of direct benefit to individual participants, but likely to yield generalizable knowledge about the participant's disorder or condition the IRB must find and document:

- the risk represents a minor increase over minimal risk;
- the intervention or procedure presents experiences to participants that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;
- the intervention or procedure is likely to yield generalizable knowledge about the participant's disorder or condition which is of vital importance for the understanding or amelioration of the participant's disorder or condition; and
that adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians.

For research not otherwise approvable that presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children the IRB must find and document:

- the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children, and
- for studies funded by DHHS, the Secretary, after consultations with a panel of experts in pertinent disciplines and following opportunity for public review and comment, has determined either that the research in fact satisfies one of the set of conditions described above, or the following:
  - the research presents a reasonable opportunity to further the understanding, prevention or alleviation of a serious problem affecting the health or welfare of children;
  - the research will be conducted in accordance with sound ethical principles; and
  - adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians.
- for studies regulated by the FDA, the Commissioner of Food and Drugs, after consultations with a panel of experts in pertinent disciplines and following opportunity for public review and comment, has determined either that the research in fact satisfies one of the set of conditions described above, or the following:
  - the research presents a reasonable opportunity to further the understanding, prevention or alleviation of a serious problem affecting the health or welfare of children;
  - the research will be conducted in accordance with sound ethical principles; and
  - adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians.

The IRB must determine that adequate provisions are made for soliciting the assent of the children when in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. The judgment may be made for all children to be involved in research under a particular protocol, or for each child. When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

Assent is not a necessary condition for proceeding with the research if the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research. The IRB may also waive the assent requirement under provisions noted in 45 CFR 46.116 and/or 21 CFR
50.55(d)(1-4). Examples when assent might be waived include certain school-based behavioral studies or studies that meet the criteria under 45 CFR 46.101(b)(1).

In accordance with and to the extent that consent is required under regulation, the IRB shall determine that adequate provisions are in place for soliciting the permission of each child's parents or guardian. Under DHHS regulations, "guardian" means an individual who is authorized under applicable State or local law, to consent on behalf of a child to general medical care. Under FDA regulations "guardian" means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care when general medical care includes participation in research, or an individual who is authorized to consent on behalf of a child to participate in research. When research is conducted in Connecticut, the persons who meet the definition of guardian are court-appointed guardians with the authority to consent to major medical, psychiatric or surgical treatment with specific authorization to consent to research.

Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research not involving greater than minimal risk or research involving greater than minimal risk but presenting the prospect of direct benefit to the individual participants. If the research is greater than minimal risk and offers no prospect of direct benefit to individual participants, but is likely to yield to generalizable knowledge about the participant's disorder or condition or is not otherwise approvable but presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children and permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

In addition to the provisions for waiver of consent contained in DHHS regulations, if the IRB determines that a research protocol is designed for conditions or for a participant population for which parental or guardian permission is not a reasonable requirement to protect the participant (e.g., neglected or abused children) it may waive the consent requirements in 45 CFR 46 provided an appropriate mechanism for protecting the children who will participate as participants in the research is substituted, and provided further that the waiver is not inconsistent with Federal, state or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research participants, and their age, maturity status and condition. This is not applicable to FDA regulated studies.

Permission by parents or guardians shall be documented in accordance with and to the extent required by regulations. FDA regulated studies do not qualify for the exception to the requirement to document consent noted at 46.117(c)(1).

Per regulations, children who are wards of the state or other agency, institution, or entity can be included in research involving greater than minimal risk and no prospect of direct benefit to the individual participants, but likely to yield generalizable knowledge about the participant's disorder or
condition, or research that is not approvable under a defined regulatory category but that presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children only if the research is 1) related to their status as wards, 2) conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as participants are not wards. If the research is approved, the IRB will require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One individual may be the advocate for more than one child. The individual acting as the advocate shall have the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except as the advocate or IRB member) with the research, the investigators, or the guardian organization.

**Economically or Educationally Disadvantaged**

Economically or educationally disadvantaged individuals may be particularly vulnerable to the risks of research. The IRB may require additional protections. For example, the IRB may require the use of a witness to the consent process or videotaping the consent process.

Educationally disadvantaged participants may not be able to fully understand the concepts presented by the research and the investigator must take extra precautions to ensure that the participants fully understand what is being asked of them.

Similarly, economically disadvantaged participants may be easily persuaded to participate in research if the economic compensation is so great that it would result in the participant ignoring or disregarding the research risks because of the income offered by the study. In such cases investigators must be careful to set economic compensation at a meaningful level that compensates the participant for her/his time, but it not so great that it unduly influences a participant's decision to enroll. It is also important in such cases that the risks to the participants be made clear to the participants.

**UConn Storrs Students**

Studies that focus on UConn students as participants may raise concerns with issues of coercion, undue influence and privacy. While these studies may qualify for exempt or expedited review, the Chair, Vice Chair or authorized designee reserves the right to require full board review. The IRB may consult with students when considering approval of a study that involves them as participants.

Each application that involves students as participants must outline procedures to ensure that the students will not be subject to undue influence or coercion and to ensure that the student's privacy will be respected. While a PI may use his/her own students as participants, it is preferable for the PI to recruit students with whom he/she does not have a direct relationship. If it is not possible or practical to recruit from the general population of students due to the nature of the research (e.g., research on teaching methods or curriculum development) the study must be designed in such a way that any element of undue influence or coercion is minimized.
Suggestions to minimize elements of undue influence and coercion include anonymous data collection methods and the use of an independent third party to collect data or consent participants (a graduate teaching assistant in the class in which the student/participant is enrolled does not qualify as a third party for collecting the data on behalf of the instructor). In this way, the instructor does not know who did or did not participate. Another is to hold off seeking consent until after course grades have been determined. For example, if the research project involves evaluating the effectiveness of a new teaching method, once final grades are determined, consent from the student should be sought as to whether his/her individual information can be used in the research study. In this way, the element of coercion is minimized since grades would already have been determined. Students should also be recruited by a general announcement, central posting or announcement mechanism and should include a clearly written description of the project and a statement of the proposed student participation. In addition to being provided with the traditional information and consent forms, the student should also be provided with the name and contact information of a neutral third party to contact should they feel coerced at any time during the process. Note: The PI is required to submit the proposed study to the IRB prior to implementing the new teaching method that is the subject of the research and at that time may request the IRB’s approval to delay the consent process. Also, the IRB suggests that when students are the targeted population, any payment for participation should be proportionate to the expense incurred with participation, for example parking expenses. Because students are often under financial constraints, larger payments may influence decisions to enroll.

As with all participants, participation must be voluntary and based on disclosure of complete and accurate information. Students should not be asked to participate in any study that will interfere with their curricular activities and obligations. A student's decision to participate or not participate can not have any bearing on grades awarded by the instructor.

If extra credit is awarded for participation in a study, other comparable means of earning the same amount of extra credit must be available to those students who choose not to participate. Examples of other comparable means include: short papers, special projects, book reports, and brief quizzes on additional readings, research seminars, or completing a similar project. These projects should be comparable in terms of time, effort and educational benefit to participation as a research participant to ensure that students are not being pressured or coerced into becoming participants.

Whenever possible, researchers should avoid data collection during regular class meetings. When study participation consumes a significant portion of a class section, loss of instructional time for both participants and non-participants may be considered a loss of benefits. Also, when research participation is expected during the same session at which participation is invited, students may be unduly influenced to take part due to peer pressure, perceived stigmatization from non-participation, or a sense of having otherwise wasted time by attending that day’s class.

Since there are special risks of confidentiality in the close environment of the university, special attention should be given to full disclosure of these risks in the consenting of a student to participate.
The plan for handling research data should also be designed to minimize the risk that confidentiality will be breached. When instruments call for the disclosure of information which participants may view as personal or sensitive, data should be collected in a manner that minimizes the chance of one participant learning the response of another.

Students must be allowed to withdraw from the study at any time. The informed consent statement should make clear the consequences of withdrawing from a project prior to completion. In general, it is favorable to give credit if the participant withdraws, unless the student withdraws immediately or there is evidence of bad faith on the part of the student.

If the research is such that data are collected from a group project or perhaps a videotape of the group interaction, each student's consent is necessary for the use of that data in the instructor's research. If one student does not consent, the data may be used only if the non-consenting student’s data can be effectively excluded.

Students have the right to full disclosure as soon as possible. Whenever possible a teaching opportunity in the form of an "educational debriefing" should be employed. Students should know something about the rationale for the study, the process of data collection, and intent of the researcher. In exceptional circumstances, the full or true purpose of the research may not be revealed to the participants until the completion of data collection. In such cases, students must not be subjected to undue stress or embarrassment and must have the right to full disclosure of the purpose of the study as soon as possible after the data have been collected. During the debrief students should be told why the use of deception was necessary to carry out the research and be given an opportunity to decide whether the researcher(s) can use the data collected (refer to Informed Consent Requirements with Use of Deception in Research).

Research conducted by graduate students in a class in which the researcher teaches, assists in the class, or does any grading will be subject to the same restraints described above.

**Psychology Department Participant Pool**

Undergraduate students enrolled in Psychology 1110, 1101 or 1103 are required to participate in research studies as a learning experience. The IRB provides guidance and oversight of the participant pool and reviews all research requesting participant pool participation. The IRB reviews bi-annually the pre-screening measures to be used. All student participation in participant pool research must be completely voluntary. The department provides participants with research participation credits as an incentive. For example, Psychology 1110 students must earn 5 credits of research participation (each credit = ½ hour of participation). Students have the option of earning 7 additional credits as extra credit for the course. Alternatives to research participation must meet the guidelines established for UConn Students. The IRB notes that access to participant pool students is limited to Psychology department faculty members and graduate student researchers and that the department has established an internal review panel that reviews research studies, after receiving IRB approval, before opening the studies for
participation. For more information about the Psychology Department Participant Pool, refer to the Psychology Department website.

**UConn Storrs Employees**

Studies that focus on UConn employees as participants may raise concerns of coercion, undue influence and privacy. While these studies may qualify for exempt or expedited review, the Chair, Vice Chair or authorized designee reserves the right to require full board review. The IRB may consult with employees when considering approval of a study that involves them as participants.

Within each application that involves employees as participants, the PI must outline procedures to ensure that the employees will not be subject to undue influence or coercion and to ensure that the employee's privacy will be respected. While a PI/supervisor may use his/her own direct report employees as participants, the preference of the IRB is that the PI recruit employees with whom the PI does not have a direct relationship. For example, if the research study is an analysis of the performance evaluation process, the PI may recruit employees from the general population of the institution as opposed to employees from the PI's department. If colleagues or subordinates will be recruited the PI must provide a rationale for their recruitment other than for convenience sake.

Additional suggestions to minimize concerns of coercion, undue influence and privacy include the general recruitment of participants through IRB approved advertisements, collection of data in an anonymous method, the use of an independent third party to recruit, consent and/or collect data. The IRB will also closely review how study data is reported back to management.

The employee's participation must be voluntary and based on disclosure of complete and accurate information. Employees should not be asked to participate in any study that will interfere with their job obligations. An employee's decision to participate or not participate can not have any bearing on the employee's performance evaluation.

The IRB will follow these same policies and procedures when it reviews research studies that seek to enroll non-UConn employees in research.

**Decisionally Impaired**

Individuals considered to be decisionally impaired may include those with psychiatric, cognitive or developmental disorders, substance abuse problems or individuals in chronic pain. Studies involving decisionally impaired participants may qualify for exempt or expedited review. However, the Chair, Vice Chair or designee reserves the right to require full board review. Individuals who are decisionally impaired may still be capable of providing consent. If evidence is present that they are incapable of providing informed consent, for example, due to the incapacity to understand, an individual who is legally authorized to consent for them must sign and date the consent document. The IRB will make a determination as to whether the target participant population is capable of providing consent or whether a legally authorized representative must provide consent. The IRB may also require additional
protections such as a witness to the consent process or requiring the PI to determine on an individual basis whether an individual is capable of providing consent, e.g., the IRB may require that the PI ask the participant to articulate in his/her own words the purpose of the study, the risks involved with the study, the benefits of the study and may request that those responses be documented. If the participant cannot answer such questions, consent from a legally authorized representative must be obtained.

When reviewing protocols that focus on decisionally impaired participants as the target population, the IRB must find that they are an appropriate participant population for the study, that the research question focuses on an issue unique to this population, that the level of risk is appropriate to the study and that, unless a waiver or alteration of consent has been approved, the provisions for obtaining informed consent from a legally authorized representative and the assent of the participant are adequate.

The IRB will use the additional protections set forth in Subpart D 46.404 (Research not involving greater than minimal risk), 46.405 (Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual participants), 46.406 (Research involving greater than minimal risk and no prospect of direct benefit to individual participants, but likely to yield generalizable knowledge about the participant’s disorder or condition) or 46.407 (Research not otherwise approvable via 404, 405 or 406 which presents an opportunity to understand, prevent or alleviate a serious problem affecting the health or welfare of the individuals) as guiding standards for the review process. Legally authorized representative will be substituted for reference to parent or guardian made in subpart D. Research involving decisionally impaired adults that would fall under category 407 will not require a Secretarial consult but the IRB may call upon consultants with additional expertise.

The provisions for obtaining the assent of an individual with impaired decision making ability are based on those set forth in subpart D. The IRB shall determine that adequate provisions are made for soliciting the assent of the decisionally impaired individual, when in the judgment of the IRB the individuals are capable of providing assent. In determining whether the individuals are capable of assenting, the IRB shall take into account the maturity and psychological state of the individual involved. This judgment may be made for all individuals to be involved in research under a particular protocol, or for each individual, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the individuals is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the individual and is available only in the context of the research, the assent of the individual is not a necessary condition for proceeding with the research. Even where the IRB determines that the participants are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accord with 46.116(d)(1-4). For FDA regulated studies, assent may be waived in accordance with 50.55(d)(1-4).
The IRB may impose additional protections. For example, the IRB may require the use of a witness to the consent process or videotaping the consent process. The IRB may also require that the investigator consider the following issues and address each issue as appropriate:

The investigator should explain how he/she plans to determine competency to consent. Observed deficits in cognitive or mental status testing may indicate need to evaluate participant’s decision making in more detail. Cognitive functions related to competency are attention, abstraction, judgment, reasoning, memory, learning, comprehension, language expression, mood and affect. In addition, severe decisional impairment to the extent that institutionalization (nursing home, hospitalization) is probable or actual for the potential participant should be considered a criterion in the determination of competency to consent. Components of the research consent capacity should be evaluated and documented during the consent process.

The investigator should address how he/she will separate the roles of clinician and clinical investigator, if applicable.

It should be recognized that decision-making capacity may fluctuate, requiring ongoing assessment during the course of the research. The consent process should be ongoing and periodic reconsent may be needed. The investigator should describe his/her process for reconsent or reassent or reassessment of willingness to continue participation.

As impairment increases, along with risks and discomforts, safeguards should increase according to a sliding scale, i.e., protections should be proportional to the severity of capacity impairment, or to the magnitude of experimental risk, or both.

**HIV-Infected Individuals**

HIV-infected individuals will be considered a vulnerable population because of the risks of social stigma, employability and insurability facing them if their HIV status were revealed. The University will comply with federal and state guidelines, including those concerning notification of seropositivity, counseling, and safeguarding confidentiality where research activities directly or indirectly involve the study of human immunodeficiency virus (HIV).

All research with HIV-infected individuals is reviewed by the full IRB to ensure that the participants’ rights and privacy are thoroughly safeguarded. At such a review the IRB may determine that a particular research study is sufficiently low in risk so as to allow continuing review to be conducted on an expedited basis. Research about HIV/AIDS that does not include HIV-infected individuals may be considered exempt or expeditable.

In addition, the IRB will consider the guidelines set forth from OHRP with regards to AIDS/HIV Related Research (OHRP: Institutional Review Board Guidelines, Chapter 5, Section F). When necessary the IRB may call upon consultants with additional expertise in this area.
Members of the Armed Forces

Studies that focus on military personnel may also raise concerns of coercion, privacy and, in particular, undue influence. While these studies may qualify for exempt or expedited review, the Chair, Vice Chair or authorized designee reserves the right to require full board review. The IRB may consult with military personnel when considering approval of a study that involves them as subjects.

Within each application that involves military personnel as participants, the PI must outline procedures to ensure that personnel will not be subject to undue influence or coercion and to ensure that the employee's privacy will be respected. The IRB suggests that PIs review the Department of Defense (DoD) directive 3216.2 (Reissued March 25, 2002). While this directive concerns clinical research studies, it describes additional protections for certain categories of research that go beyond those outlined in 32 CFR 219 (the DoD implementation of the "Common Rule" Federal Policy) and are relevant for social and behavioral research. The directive includes the following requirements (see section 4.3) to minimize concerns of coercion, undue influence and privacy as they apply to more than minimal risk studies. The requirements include ensuring that unit officers and noncommissioned officers (NCOs) shall not influence the decisions of their subordinates to participate or not to participate as research participants. Unit officers and senior NCOs in the chain of command shall not be present at the time of research subject solicitation and consent during any research recruitment sessions in which members of units under their command are afforded the opportunity to participate as research subjects. When applicable, officers and NCOs so excluded shall be afforded the opportunity to participate as research subjects in a separate recruitment session. During recruitment briefings to a unit where a percentage of the unit is being recruited to participate as a group, an ombudsman not connected in any way with the proposed research or the unit shall be present to monitor that the voluntary nature of individual participants is adequately stressed and that the information provided about the research is adequate and accurate. These requirements should also be taken into consideration for studies not supported by the DoD. The IRB will also closely review how study data is reported back to officers.

The service member's participation must be voluntary and based on disclosure of complete and accurate information. Military personnel should not be asked to participate in any study that will interfere with their responsibilities. A service member's decision to participate or not participate can not have any bearing on the service member's performance evaluation.

Non-English Speaking Individuals

The involvement of non-English speaking individuals in research studies raise concerns with issues of informed consent as well as their inclusion and exclusion in research. While these studies may qualify for exempt or expedited review, the Chair, Vice Chair or authorized designee reserves the right to require full board review.

Investigators must be aware that individual participants, and sometimes significant portions of the potential participant population, may not speak English. Investigators must plan for populations that are likely to be recruited into the research and incorporate translations into the study design to allow for
appropriate recruitment and enrollment. When applicable, the PI must outline in the protocol application procedures to recruit non-English speaking participants as well as procedures to translate study material and consent documents. The protocol must also describe procedures for ensuring that informed consent is presented to participants in a language understandable to them. Procedural requirements for the informed consent process for these participants can be found in the informed consent section of the policies (see Consent for Participants Not Fluent in English).

Non-English speaking participants, who meet enrollment criteria, may not be excluded because they cannot understand or read English. Non-English speaking participants may not be excluded from research that may have direct potential benefits. If non-English speaking participants will be specifically excluded from research, the PI must provide an ethical and scientific explanation for doing so.

**Types of Research Conducted at UConn Storrs**

While FDA-regulated and other biomedical studies are conducted on campus, the research conducted at UConn Storrs is primarily social/behavioral in nature. Although Federal regulations for the protection of human participants cover both biomedical and social/behavioral research, they are not specific regarding the various types of social/behavioral research. Therefore, the IRB developed the guidance to assist in the development and review of Qualitative/Ethnographic, Focus Groups, Oral History and other types of social/behavioral research. The guidance is available on the IRB website.

**Review of Studies Conducted in Foreign Countries**

Research conducted by UConn investigators in foreign countries remains under UConn purview and guidelines. While adjustments may be made to some requirements to respect cultural differences, our standards for ethical conduct are not relaxed.

The IRB may require that research projects be approved by the local equivalent of an IRB before the IRB will grant final approval. Where there is no equivalent board or group, investigators must rely on local experts or community leaders to provide approval. The PI must provide the IRB with documentation of this "local approval" and documentation of the authority and expertise of the individual or group who granted approval. There must also be detailed plans in place for local monitoring of studies that pose more than minimal risk to participants. Researchers must describe what, if any, knowledge or experience they possess regarding the language and culture of the country in question. If the IRB is not satisfied with the review of local experts and/or the plans for continued monitoring there is the possibility that the study will not be approved.

The IRB may seek guidance first from OHRP’s International Compilation of Human Subject Research Protections or it may contact OHRP to determine whether procedures described by a foreign institution afford protections that are at least equivalent to U.S. regulations 45 CFR 46.101(h) and may be substituted for the U.S. regulations. Under this provision, OHRP investigates the foreign country’s guidelines for human participants research, and if the foreign guidelines are found to be equivalent to U.S. regulations, the investigator is permitted to substitute those foreign procedures.
Research Requiring Review More Frequent Than Annually
The IRB will require that continuing review occur more often than annually in the following circumstances:

- The research involves the use of procedures that have not been studied in humans.
- The research is expected to result in a high frequency of morbidity or mortality.
- The investigator has a history of serious or continuing noncompliance that the IRB believes necessitates closer monitoring.
- Any other situation in which the IRB believes that more frequent continuing review is warranted.

Verification from Sources Other Than Investigators:
The IRB will require independent verification from sources other than the investigator that no material changes (i.e. changes that are both relevant and consequential) have occurred since previous IRB review in the following situations:

- When there is inconsistency in the information presented by the investigator to the IRB and those inconsistencies cannot be easily resolved.
- When the IRB questions the ability or the willingness of the investigator to provide accurate information.
- When concerns have been raised, via continuing review or from other sources, that material changes have been implemented without IRB approval.
- Other circumstances for which the IRB deems independent verification is needed.

In most cases the Research Compliance Monitor will conduct the verification. The monitor has access to all research data and may observe the research and consent process. The IRB may require that an ad-hoc consultant with particular expertise review the research activity. Such consultants will not have a professional or financial interest in the research. The IRB Chair may determine who will act as the consultant and will also confirm that no conflicts exist. The individual performing the verification will provide the IRB staff with a written statement of the verification. The IRB staff will make this information available to the IRB members and also place a copy in the IRB study file.

Scientific Review
The Common Rule and corresponding FDA regulations require the IRB to determine that the study is designed so that risks to participants are minimized and justified by potential benefits (refer to 45 CFR 46.111(a)). Therefore, the IRB will carefully consider the study design and overall scientific quality of each study, particularly those studies that are investigator-initiated and/or unfunded. In evaluating the scientific design, the primary reviewer (exempt and expedited studies) or the primary reviewer and convened IRB (full board studies), will consider the following:
• clarity of the research question
• appropriateness and efficiency of design
• rigor and feasibility of methods
• qualifications and expertise of the research team
• scholarship and pertinence of background material and rationale
• adequacy of sample size and relevance of controls and
• the validity of the statistical analysis plan.

When necessary the IRB may ask consultants with additional expertise to review the research study.

Categories of Study Status
Submissions to the IRB will fall into one of the status categories noted below:

Approved
This decision is used when a study is given final approval either through the exempt, expedited, or full board review process. Final approval of a full board study means that all modifications initially required have been addressed. If the study is approved through the expedited or exempt review process, the specific category by which expedited or exempt review is permissible is noted. A study can begin only after final approval is granted. This category is also used to reflect approval of requests for continuations and amendments.

Modifications Required in Order to Secure Approval
This decision is used when the full board has reviewed a study at a convened meeting and requires minor modifications before final approval will be given. This category may also be used for expedited review, requests for continuation (re-approval), and amendments. Upon satisfactory response to the request for modifications, the Chair or his/her designee is authorized to grant final approval without re-review by the full board.

The IRB may also request that the PI make modifications to an application for initial or continuing expedited or exempt review. This is communicated to investigators through letters from the IRB. Final approval of an expedited or exempt study means that the requested modifications initially identified have been satisfactorily addressed.

Deferred
This decision is used when the full board has reviewed a study at a convened meeting and has significant concerns with the protocol, consent document or other relevant material, or requires substantive clarifications on issues that relate to the required criteria for approval. For example, if the protocol contains insufficient information to assess the nature and purpose of the study, or if the IRB requires clarification as to why a procedure is being followed in the study, the study will be deferred until the
convened IRB can determine that risks to participants are minimized. The PI is encouraged to make a point-by-point response in writing, and must resubmit the application for full board review. This category may also be used for requests for continuation and amendments.

**Disapproved**
This decision is used when the full board reviews a study and determines that one or more of the elements required for approval (refer to Criteria for Approval section) has not been met, and in the Board's opinion, cannot be satisfied through revisions to the application (for example, if the Board determines that balance of risks to benefits is unacceptable). This category may be used for requests for continuation and amendments. The decision is made by the convened IRB. Protocols may not be disapproved by the expedited or exempt review mechanism.

**Tabled**
This category is used only when a study is not reviewed at the meeting for which it was originally scheduled, for example, due to loss of quorum. This category may also be used for requests for continuation and amendments.

**Closed**
This decision is used to reflect that a study is closed/completed. An investigator may request closure of a study when the research project will no longer be pursued, or when data analysis is finished, and the essential work of the study is completed.

**Terminated**
This decision is used to reflect that a study has been closed by the IRB. A study may be terminated due to failure to request continuing review beyond a 30-day grace period after the study expiration date. The IRB may terminate a study for noncompliance or due to the occurrence of serious or unexpected risks to participants. Termination of previously approved research is defined as a permanent withdrawal of study approval that requires all study related activity to cease. The investigator will be notified of studies terminated by the IRB. Terminations are not reportable events.

**Suspended**
This decision is used to reflect the imposition of a temporary hold on any or all research activity associated with a study, or a permanent stop to some portion of a previously approved research activity.

**IRB Decision Appeals Process**
In the event that an application is disapproved, suspended, or terminated by the IRB, the PI may appeal the decision in writing to the IRB. The appeal must include information that supports the PI’s position. The appeal may be referred to the full board for consideration.

At the discretion of the Chair, the PI may be invited to attend the next regularly scheduled IRB meeting or one convened specifically for the appeal purpose. The PI will explain to the IRB why the appeal is being made, provide justification for the appeal, and approval/reinstatement of approval for the study,
and may engage in discussion with the IRB to provide additional information. The PI will be excused prior to deliberations and voting. The PI will be informed in writing of the final decision of the IRB. The letter will be prepared by the IRB staff for signature by the Chair.

When the IRB has determined that serious or continuing noncompliance or issues that expose participants to unnecessary risks are present, the decision of the IRB to terminate or suspend approval of such a study is effective immediately upon such determination. An investigator must comply with the decision, but may make an appeal to the convened IRB to lift the suspension or termination.

The investigator may also appeal modifications required by the IRB for approval. The initial appeal will be through a written response to the requested modifications, explaining why the modifications identified by the IRB are not appropriate. The Chair may elect to agree with the investigator, disagree with the investigator and still require that modifications be addressed, or refer the matter back to a full board meeting for review, e.g., if the Chair and investigator cannot come to an agreement. This procedure also applies to expedited reviews.

**Request for Permission to Recruit on Campus**
Researchers who are unaffiliated with the University but wish to recruit participants on the UConn Storrs campus, the five regional campuses, the School of Social Work, or the School of Law, must request permission from the IRB before recruiting students or employees on UConn campuses (via poster, flyer, email announcement or newspaper ad).

Unaffiliated researchers must submit one copy of the full packet of materials submitted to the IRB of their own institution, including the letter of IRB approval for the project. The packet should include, but may not be limited to, the IRB protocol application, consent form or information sheet, recruitment flyer or ad, instruments or measures to be used, and any supporting documentation.

The IRB Chair or his/her designee will review the request and issue a letter of permission to recruit on campus. The IRB reserves the right to have requests for permission to recruit on campus go to the full board for review and approval, should the Chair or Vice Chair decide that the nature of the study requires the independent scrutiny of the IRB to protect its students and employees.

**Conflicts of Interest**
In conducting human participant research, a conflict of interest is defined as a situation in which an investigator or key personnel (or someone in his/her immediate family - spouse, children, and any other person living in the same household) has a significant financial, professional or personal, interest in the approval or outcome of a study and the interest could affect decisions related to either the design, conduct or reporting of the research, or adversely affect the rights and welfare of research subjects. This applies to all research protocols regardless of funding source, including those that are unfunded. Such conflicts must be identified and managed appropriately.
The Conflict of Interest (COI) Committee serves as the resource with respect to matters involving individual conflicts of interest in research. Its responsibilities include the identification and management, mitigation or elimination of specific conflicts of interest. The Institutional Policy on Individual Conflicts of Interest in Research can be viewed in its entirety at http://www.compliance.uconn.edu/conflict.html. The Policy provides guidelines for relationships between the University and its investigators with private industry, federal and state government, and the nonprofit sector that will help to assure the primacy of academic integrity. This Policy applies to all investigators, key personnel, and IRB members.

What Must Be Disclosed by Investigators, Coordinators, Persons Obtaining Consent and Persons Involved in the Design, Conduct or Reporting of the Research

Individuals must disclose interests in public and non-public companies, including interest in the specific article or service being researched. The following interests must be disclosed to the IRB if the individual or an immediate family member holds the interest:

- Any ownership interest, stock options, or other financial interest related to the research unless it meets the following four criteria:
  - <$10,000 when aggregated for immediate family
  - publicly traded on a stock exchange
  - value will not be affected by the outcome of the research
  - <5% interest in any one single entity
- Any compensation related to the research unless it meets two tests:
  - <$10,000 in the past year when aggregated for immediate family
  - the amount will not be affected by the outcome of the research
- Any proprietary interest related to the research including, but not limited to, a patent, trademark, copyright or licensing agreement.
- Any board or executive relationship related to the research, regardless of compensation

Disclosure and Management Procedures for Investigators, Key Personnel, and Persons Involved in the Design, Conduct or Reporting of the Research

All faculty members must complete the Significant Financial Interest Review Form and submit it to the COI. The IRB-1 protocol application asks investigators to disclose whether a significant financial interest has been reported to the COI. If "yes", then a copy of the Significant Financial Interest Review Form(s) must be attached to the IRB-1. The IRB staff will bring it to the attention of the IRB Chair and the primary reviewer. The COI will determine whether the conflict represents a significant financial interest and if so, a management plan will be developed. The IRB staff will also provide the COI management plan to the Chair and reviewers. Approval for a study cannot be given until a response, and if applicable, a plan has been received from the COI and reviewed by the convened IRB. The convened IRB reserves the right impose management strategies in addition to those outlined by the COI. The convened IRB also makes the final determination as to whether the conflict can be managed sufficiently to allow for approval of the research.
At the convened meeting the IRB will discuss disclosures of conflicts and the measures in place to manage, reduce or eliminate the conflict. The convened IRB is responsible for taking the appropriate action(s), i.e.:

1. Reviewing the nature of the conflict and the management plan developed by the COI.
2. Determining whether the COI plan is sufficient to properly oversee and manage the conflict(s), or whether additional management strategies are required, taking into consideration the possible remedies as outlined below.
3. Determining whether the conflict can be sufficiently managed to ensure protection of participants is not affected and to allow for approval of the research.
4. Informing the investigator and the COI of the actions and decisions of the IRB, including restrictions.

Restrictions that might be imposed to manage a conflict of interest to prevent it from adversely affecting the rights and welfare of participants, include, but are not limited to:

1. Monitoring of the research by independent reviewers;
2. Modification of the research plan;
3. Disqualification from participation in all or a portion of the activities affected by the conflict;
4. Divestiture of significant financial interests, or;
5. Severance of relationships that create the conflict.

Any financial benefit to the investigator must be disclosed in the consent form and during the consent process. However, disclosure alone is not sufficient to manage a conflict that might affect the rights and welfare of participants.

**Sanctions**

Failure of an investigator to comply with the requirements of disclosure or a management plan may lead to disciplinary action. Such actions may include, but are not limited to:

1. Letter or reprimand;
2. Notification to funding agencies and/or professional journals or societies;
3. Reassignment of duties;
4. Suspension or termination of a research project;
5. Recommendations for suspension or termination of employment.

In determining the appropriate course of action, consideration will be given to whether the Noncompliance has biased the design, conduct or reporting of the research or compromised the safety or welfare of participants. The IRB may make recommendations for suspension or termination of employment but cannot impose that action.
What Must Be Disclosed by IRB Members

- all items listed above for investigators and key personnel;
- any involvement of the IRB member or the member’s family member in the design, conduct or reporting of the research;
- Other reasons for which an IRB member believes he or she cannot objectively review the research, e.g. a sponsor is a client of a community member’s law firm.
  - The subordinate / supervisor relationship, or someone’s departmental or center affiliation with a project, does not necessarily create a conflict of interest. The IRB member is expected to exercise his/her judgment and is encouraged to solicit advice from the IRB to determine whether or not to review/vote on a study.

Procedure for Disclosing and Managing IRB Member Conflict of Interest

An IRB member or consultant may not participate in the IRB’s initial or continuing review of any project in which the member or consultant has a conflict of interest, except to provide information requested by the IRB.

A conflict of interest of an IRB member (or consultant) generally includes the following. The aggregate interest of the member (or consultant) and his/her immediate family (investigator’s spouse, minor children, and any other persons living in the same household) is considered.

1. Participation in a project (IRB member is listed as an investigator on the project or is a member of the research team);
2. Supervision of a project (IRB member is a faculty sponsor of the Protocol Director, or a situation in which any investigator must report to or is under the professional supervision of the IRB member);
3. Significant financial interest as described in the University of Connecticut Financial Disclosure Policy;
4. Personal relationship with investigator (IRB member has an immediate family relationship or other close personal relationship with the investigator);
5. Fiduciary relationship to sponsor (IRB member serves as a consultant to a company sponsoring the research, or serves on the company’s board of directors);
6. Other non-financial interests that may be conflicting interests, such as (a) the IRB member has an interest that he/she believes conflicts with the member’s ability to review a project objectively; or (b) the IRB member is in direct competition with the investigator for limited resources, funding, sponsorship, or research participants, or the IRB member is considered a personal or professional adversary of the investigators (for (b), the IRB member must disclose the circumstances to the IRB Chair or DRC for a determination of whether a conflict of interest exists);
7. Any other reason for which the IRB member believes he or she has a conflict of interest with the research.
IRB members will determine if a conflict exists by reviewing the agenda that lists the names of all investigators and sponsors. The following statement is read at the start of each convened meeting by the IRB Chair or Vice-Chair, and it is also printed on the meeting agenda:

"Any member who has a conflict with any of the protocols discussed at this meeting should either recuse her/himself from the discussion and vote for that protocol or else abstain from the vote. If you are unsure whether you have an actual conflict, or are unsure as to what constitutes a conflict, you are welcome to discuss it with me (IRB Chair) in private and our conversation will be considered confidential."

Members will make disclosures orally and the IRB staff will note them in the minutes. If a conflict is disclosed, when the study is reviewed, the member with the conflict is required to leave the meeting for the deliberation and voting. If assigned as a reviewer for a study in which the member has a conflict, the member is responsible for contacting the IRB Office so that another reviewer may be assigned. This policy also pertains to reviews conducted through the expedited process.

IRB members receive initial and on-going education to ensure their awareness of institutional policies regarding non-financial conflicts of interest.

**Informed Consent**

The informed consent process is an interaction between the prospective participant and the PI, co-investigator and/or designated qualified personnel, during which a research study is explained to the participant. The purpose is to ensure that the participant understands the study (purpose, risks, benefits) in which s/he may enroll. The process must allow the participant sufficient time to ask questions and to consider whether to participate. The process must also be conducted in a setting that affords sufficient privacy to the potential participant. The informed consent process is most often documented by use of an IRB approved and validated informed consent form.

At the outset of the consent process, the PI or designated individual authorized to obtain consent should ask the participant if any special provisions are required by them for the consent process. For example, hearing impaired individuals may want a sign language interpreter present or individuals with dyslexia may prefer to have the document read to them.

Consent must be obtained prior to any involvement of the participant in a study. All consent forms must include instructions for the participants as to whom to contact regarding research related questions, research related injuries (if applicable) and how to contact the IRB regarding their rights as a research participant.

In general, participants must consent to any screening procedures as well as to participation in the study. The PI may choose to use two different forms or to use one form encompassing both elements. Participants are considered enrolled at the time of signing the consent form. Participants must be
informed that they may be withdrawn if it is determined that they do not meet inclusion criteria. Participants who did not meet the screening criteria are to be reported as withdrawals from the study at the time of continuation.

Exceptions to obtaining consent prior to screening may be made, e.g., if the screening is done through a phone call that the participant initiates and that does not involve extensive or intrusive questions. During the screening process identifiable information should not be recorded 1) until after a participant signs an informed consent form, and HIPAA Authorization, if applicable, or 2) without an IRB-approved partial waiver of the requirement to obtain consent, and a waiver of HIPAA Authorization, if applicable.

In addition to the required elements of consent, the top of the first page of the consent document must indicate the name of the PI, the name(s) of student investigators, the title of the research study (abbreviated title is permissible if approved by the IRB). The form must leave a one inch margin at the bottom for IRB approval stamps. Researchers are encouraged to use the IRB’s consent form template, however, deviations from this format are allowed on a case by case basis in order to best suit the individual research study (i.e., use of a consent form in the format of a letter to an individual). The PI must explain why the standard template is not suited to the study in the protocol application.

Informed consent is an on-going process and the investigator and/or study personnel must keep participants apprised of any developments that may affect their willingness to continue to participate.

The informed consent form is submitted as part of the IRB application. The consent form must contain a signature and date line for the participant (or the legally authorized representative) and for the person obtaining consent. Unless specifically required by the IRB, witnessing of consent is optional. The IRB may also determine whether assent is required and if so how it shall be obtained and/or documented.

Upon approval, an informed consent form will be stamped with the date of IRB approval and the date through which the approval is valid. The PI and study personnel are required to use copies of the most recently approved and stamped IRB forms when obtaining consent. The participant must be provided with a copy of the IRB approved document that has been signed and dated by the participant (or legally authorized representative) and the person obtaining consent. The PI should also keep one copy of the consent form. Investigators are required to keep consent forms on file for 3 years following the completion of the research (refer to Record Retention section).

**Requirements of Informed Consent**

Except as subsequently noted, informed consent will be sought and documented for each participant choosing to participate in an approved project. Consent will be in lay terms and in a language understandable to the participant. (Preferably native language if the participant is not fluent in English.) Potential participants must be given sufficient time to have questions answered and to decide whether to participate. It must be explained that participation is voluntary and that choosing not to participate has no impact on benefits to which the participant is otherwise entitled. The consent process and
document will contain the elements required in 45 CFR 46.116(a)(1-8) and 46.117 and 21 CFR 50.20, 50.25 and 50.27 as noted below and may contain additional elements in 45 CFR 46.116(b)(1-6), 21 CFR 50.25(b)(1-6) and institutional requirements, as applicable. Exculpatory language which releases or appears to release the institution, sponsor or investigator from liability or which makes or appears to make participants waive any legal rights cannot under any circumstance be included in the informed consent document or process.

Required basic elements of a consent document include:

- a statement that the study involves research,
- an explanation of the purposes of the research,
- an explaining of why the participant is being invited to participate,
- the expected duration of the participant's participation,
- a description of the procedures to be followed,
- identification of any procedures which are experimental,
- a description of any reasonably foreseeable risks or discomforts to the participant,
- a description of the safeguards to be used to protect participants from incurring the risk,
- a description of any benefits to the participant or to others which may reasonably be expected from the research,
- if applicable, a statement that participants will not benefit directly,
- a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant,
- a statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained (for studies involving the use of drugs, devices or biologics, indicate that the FDA and sponsor may inspect records),
- a statement that the IRB and the RCS may inspect study records,
- an explanation as to whether participants will be compensated for participation and if so the terms of the compensation,
- an explanation as to whether any compensation is available if injury occurs, and, if so, what it consists of, or where further information may be obtained,
- an explanation as to whether any medical treatment is available if injury occurs and, if so, what it consists of, or where further information may be obtained,
- an explanation of who to contact for answers to pertinent questions about the research and research participants' rights, and who to contact in the event of a research-related injury to the participants, and
- a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.
Additional Elements of Consent That May be Required

Additional elements that the IRB may require within a consent document include:

- a statement that the particular treatment or procedure may involve risk to the participant which are currently unforeseeable (required when the study involves the use of investigational, drugs, devices or biologics, or drugs for which post marketing safety/efficacy data are being collected);
- a statement indicating the approximate number of participants involved in the study;
- a statement that the particular treatment or procedure may involve risks to the embryo or fetus, if the participant is or becomes pregnant which are currently unforeseeable (required when the study involves the use of investigational drugs, devices or biologics and participants are or may become pregnant or when there is insufficient data on how a marketed drug impacts embryos or fetuses and participants are or may become pregnant);
- anticipated circumstances under which the participant’s participation may be terminated by the investigator without regard to the participant’s consent (required when the investigator may remove a participant from a trial due to medical /safety issues, participants inability to continue to provide informed consent, participant’s noncompliance with the direction of the investigator, or other scenarios when the investigator may determine it is in the best interest of the participant to withdraw them from the trial);
- any additional costs to the participant that may result from participation in the research (required if the participant will incur any permanent or temporary out-of-pocket expense related to participation in the trial, e.g., for procedures, drugs, research related injury, etc.);
- the consequences of a participant’s decision to withdraw from the research and procedures for orderly termination of participation by the participant (required if the participant’s decision to withdraw will raise safety concerns, e.g., withdrawal from medications that should be tapered rather than abrupt);
- a statement that significant new findings developed during the course of the research which may relate to the participant’s willingness to continue participation will be provided to the participant (required for treatment trials or trials of moderate or more risk);
- disclosure of when a blind will be broken if the participant has an adverse event;
- disclosure of whether participants are / are not intended to share in financial gains resulting from the study (required when the study results may lead to the development of a product or technique that will provide financial benefit to UConn, the sponsor, and/or the PI);
- a statement describing alternatives to course-required participation;
- an explanation that the study involves use of video or audiotaping, including a statement about how the recordings will be used and how long they will be kept. This statement should include who will see/hear the recording and where it will be used (e.g., in a classroom, professional meeting). If the investigator wants permission for the recording to be viewed/heard by anyone other than the research staff, or if it involves sensitive material, participants should also be given an opportunity to view (or listen to) the recording after it is completed. Permission for the tape
to be used should then be obtained. The consent form must also clearly state who will transcribe the tapes and, if third-party transcriptionists will be used, what steps will be taken to protect participant confidentiality.

Additional Requirements of Consent for Genetic Research Studies
The IRB may require the following elements for studies involving genetic research:

- if family members may become aware of the information related to the study and to participant, or the participants may become aware of information about themselves or family members that they would preferred not to have known, that possibility must be disclosed by the PI in the consent form. Consent from the participant for disclosure of relevant information to relatives when the release of that information may improve the prognosis of the relatives will be sought. However, the participant must be made aware of the possibility of such a disclosure without consent. Disclosure that breaks confidentiality may occur if there is a treatment that will help the prognosis of the family member(s). To break confidentiality the following conditions outlined by the President's Commission (1983) must be satisfied:
  - reasonable efforts to obtain voluntary consent for disclosure have failed;
  - there is a high probability that harm will occur from withholding the information and that the disclosure will avert that harm; and
  - the harm that would likely occur would be serious.
  - only the information needed for diagnosis and treatment is disclosed;
- a statement that the action of the participants may place them risk (e.g., if they self disclose to their employer);
- a detailed description of what information will be presented to participants including:
  - what type of information will be provided to them or others,
  - who will provide the information,
  - how the information will be communicated,
  - at what point in the study it will be provided,
  - whether interim findings will be disclosed or not,
  - the reliability of the information being provided, and
  - what information will not be provided to them;
- if study information is intended to be shared with participants, the consent form must include an option whereby participants retain the choice of being told or not being told that information. An exception to the right not to know may occur when treatment could improve the prognosis. The PI must explain to the participant within the consent form whether the right not to know will be honored in such a circumstance;
• if the study is likely to yield unexpected or unrelated findings the consent must:
  o state that findings that do not affect the health of the participant or health of family members. For example, issues of maternity or paternity, will not to be disclosed,
  o either provide participants with an option of receiving or declining to receive information on unexpected and/or unrelated findings that are health-related, or
  o inform the participant that such information will be disclosed;
• information regarding genetic counseling by qualified genetic counselors if a study may reveal important genetic information, e.g., being a carrier for an illness that has not yet manifested. At whose expense the counseling is provided must also be disclosed.

Who May Obtain Consent
The PI or a qualified individual authorized by the PI on the IRB application may obtain informed consent. The individual who obtains consent must possess an in-depth knowledge of the protocol and be able to answer all questions posed by the participant. The individual obtaining consent must disclose their role in the study to the participant (e.g., PI, co-investigator, study coordinator, research assistant, etc.). The individual obtaining consent is required to have completed training in the protection of human participants in research. Completion of training will be verified through the screening of IRB applications and the auditing of approved studies.

Standard Consent and Documentation
With the few exceptions noted below, consent must be obtained from individuals of at least 18 years of age who are competent to give informed consent. Such individuals are considered to have decision-making capacity if (1) they have not been declared incompetent by a court and (2) they are generally capable of understanding the consequences of alternatives, weighing the alternatives by the degree to which they promote their desire, and choosing and acting accordingly. The investigator is to make a practical assessment of the participant's capacity.

Consent will most often be documented using a long form consent document that satisfies the required elements of consent. The participant (or the participant's legally authorized representative) and the person obtaining consent must sign and date the form prior to study participation. The person obtaining consent must provide the participant (or the participant's legally authorized representative) with a copy of the signed and dated document. When it is feasible, the person obtaining consent must sign and date the form in the presence of the participant.

Waiver of Consent or Alterations to Elements of Consent
There are some scenarios by which it is possible for the IRB to waive or alter the elements of informed consent.

Scenario 1: The first method relates to studies that are conducted by or subject to the approval of state or local government officials (45 CFR 46.101(b)(5)). The study must also be designed to study, evaluate, or otherwise examine one or more of the following items:
i. public benefit of service programs;
ii. procedures for obtaining benefits or services under those programs;
iii. possible changes in or alternatives to those programs or procedures; or
iv. possible changes in methods or levels of payment for benefits or services under those programs.

The IRB must also find that the research could not practicably be carried out without the waiver or alteration. To request this method of waiver or alteration the investigator must complete the Waiver or Alteration of Consent section of the IRB-5 Exemption protocol application. The Chair will make the final determination as to whether or not to approve the request for an expedited study and IRB will make the determination for full board studies.

Scenario 2: PIs may request that the requirement of informed consent be waived or altered. In order to do so the investigator must complete the Waiver or Alteration of Consent section of the IRB-1 protocol application. The Chair will make the final determination as to whether or not to approve the request for an expedited study and the IRB will make the determination for full board studies. In order to do so the IRB must find that:

- the research involves no more than minimal risk to participants;
- the waiver or alteration will not adversely affect the rights and welfare of the participants;
- the research could not practicably be carried out without the alteration or waiver; and
- when appropriate participants will be provided with additional pertinent information regarding participation.

Alterations to the requirements of consent process allow for deviations from the regulatory requirements of consent but consent is still obtained. Examples of potentially approvable alterations to consent include:

- the use of implied/passive consent (e.g., via the return of completed surveys); or
- deception in research (see Informed Consent Requirements with Use of Deception in Research later in this document).

The IRB must find and document justification for any alteration to the requirements of consent.

The request to waive or alter consent described in method 1 and 2 are not applicable to FDA regulated studies.

Occasionally investigators will seek information about individuals who are not principals to the research ("secondary participants"). These individuals could be members of the principal participant's family, sexual partners, friends, co-workers, etc. Such individuals may be participants in their own right, even if the investigator never has any contact with the individual. The federal regulations define a human participant not only as someone with whom the investigator interacts, but also as someone about
whom the investigator seeks information. Therefore, the IRB must evaluate the consent process for each class of participant and will expect the protocol to describe an appropriate consent process for each such class. It may be possible for the investigator to ask the IRB to waive the requirement for consent, but only if the criteria described in scenario 2 are met.

**Waivers of Documentation of Consent**

In certain scenarios the IRB may still require that consent be obtained but waive the requirement to obtain documentation of consent. In order to do so the IRB must find that:

- the only record linking the participant to the study is the signed consent document and the principal risk would be harm resulting from a breach of confidentiality (participants must still be given the option of signing a consent document and the participant’s wishes will prevail), or that
- the research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context.

For studies subject to FDA regulations, only the latter provision is applicable.

If the requirement of documentation is waived, the IRB usually requires the investigator to provide the participant with a written summary of the research (i.e., "information sheet"). The IRB must review and approve that summary. The PI may request and the IRB may approve that a consent form also serve as the written summary.

**Assessment of Participant’s Understanding of the Research and Consent Process**

The IRB may require the PI or individual obtaining consent to confirm the potential participant's level of understanding, e.g., the IRB may require that the potential participant be able to describe in his/her own words the purpose of the study, the risks involved in the study, the possible benefits of the study either in writing or verbally with or without a witness present. The PI can facilitate this process by asking the participant open-ended questions such as:

- Just so that I'm sure you understand what is expected of you, would you please explain to me what you think we’re going to ask you to do?
- Describe in your own words the purpose of the study.
- What more would you like to know?
- What is the possible benefit to you of being in the study? What are the risks?

**Consent from Emancipated Individuals**

Emancipated individuals between the ages of 16 - 18 may provide consent to participate in research activities. The emancipated participant must provide proof of emancipated status. The person obtaining consent must attach this proof to the informed consent form. An emancipated individual does not meet the federal definition of child and therefore subpart D is not applicable.
Consent from Individuals Under 18 years of Age for Certain Research Procedures

In specific circumstances, individuals under the age of 18 may provide consent to participate in research without demonstrating emancipated status when the research is limited to the categories noted below. In such circumstances the individuals are not considered children and therefore subpart D is not applicable.

1. All individuals under 18 years of age, if the research procedures are limited to:
   - HIV testing, counseling, and treatment
   - Outpatient mental health services
   - Testing or treatment for sexually transmitted diseases
   - Treatment or rehabilitation for alcohol or drug dependence
   - Abortion counseling and treatment

2. All individuals between 16 and 18 years of age, if the research procedures are limited to:
   - Inpatient mental health services

3. All individuals between 17 and 18 years of age, if the research procedures are limited to donation of blood or any component thereof and to the withdrawal of blood in conjunction with any voluntary blood donation program.

Informed Consent Requirements with Use of Deception in Research

The use of deception in research (e.g., participants are initially misinformed deliberately for purposes of the study) raises special issues that the IRB will review closely. One consideration is whether the deception is necessary. An investigator proposing to use deception should justify its use. Federal regulations prohibit the use of deceptive techniques that place participants at greater than minimal risk.

The IRB may modify the informed consent process for research involving deception when participants are not placed at risk. However, potential participants should be advised in the consent form that the information they are given is not complete and that they will be debriefed after the research procedures are completed.

The debriefing should include a detailed description of the ways in which deception was used. The investigator is responsible for ensuring that the participant leaves the research setting with an accurate understanding of the purpose of the research and why deception was used. The debriefing process, including any written materials, should be provided to the IRB as a part of submitted protocols. The following statement, or some similar statement, must appear in every consent form/information sheet for studies involving deception:

"Research designs often require that the full intent of the study not be explained prior to participation. Although we have described the general nature of the tasks that you will be asked to perform, the full intent of the study will not be explained to you until after the completion of the study. At that time, we will provide you with a full debriefing which will include an explanation of the hypothesis that was tested and other relevant background information pertaining to the study. You will also be given an
opportunity to ask any questions you might have about the hypothesis and the procedures used in the study."

Consent by Phone/Fax
Consenting a participant, including consent from legally authorized representatives, is a process that should occur in person. Only for extenuating circumstances or minimal risk studies will the IRB consider the possibility of obtaining consent by phone or fax. The IRB may implement either of the following procedures:

Procedure 1:

- the potential participant must be given a copy of the approved, IRB-stamped consent document (either by mail, fax or e-mail of scanned document) prior to the phone conversation and with enough time allowed to read the document prior to the conversation;
- the individual obtaining consent must have a witness present for the entire conversation;
- participant must be informed that the witness is present and consent to the witness listening to the entire conversation (via speaker or extension phone);
- participant must be instructed that if s/he agrees to participate s/he must return the signed, dated and time stamped consent document (either by mail, fax or e-mail of scanned signed document); and
- the individual obtaining consent and the witness must sign, date and time stamp the IRB approved consent document upon completion of the phone conversation;

Procedure 2:

- the investigator requests a waiver of the requirement to document consent at the time of initial application or via a request for modification using the IRB-3 Amendment Review Form;
- a script of the phone conversation incorporating the elements of consent must be submitted to the IRB for approval;
- the IRB may require that the investigator provide participants with an IRB approved written statement (via mail, e-mail or fax) regarding the research.

In Procedure 1, the participant's signed and dated consent form must be received before any research intervention occurs.

Witnessing of Consent
The consent process generally does not have to be witnessed but the IRB may require this. For example, the IRB may require this when vulnerable or special classes of participants are involved in the study, the study is very complex in nature, or when the consent process occurs via phone. When an individual is signing the form as a witness, exactly what is being witnessed must be explained. For example, is the individual a witness to the signature only or a witness to the entire consent process? The IRB may
determine what is required to be witnessed and who may serve as the witness. For example, the IRB may require that the entire consent process be witnessed by a research participant advocate, a representative of the IRB, research study personnel, a primary caregiver or other appropriate individual.

Per Federal regulation 45 CFR 46.117(b)(2), a witness will be required if a short form written consent has been approved for oral presentation to the participant.

**Requirement for Witness Signature on the Consent Form**

It is possible to conduct an oral presentation of informed consent information in conjunction with providing 1) a short form written consent document stating that the elements of informed consent have been presented orally and 2) a written summary of what is presented orally. Per 45 CFR 46.117(b)(2), a witness must be present throughout the process. The IRB must approve the short form consent and a written summary of what is to be said to the participant or the representative (an approved informed consent form may serve as the written summary). At the time of consent the participant or the participant's representative signs and dates the short form. The witness shall sign and date both the short form and a copy of the summary, and the person actually obtaining consent shall sign and date a copy of the summary. A copy of the summary and the short form shall be given to the participant or the legally authorized representative. This process also applies to FDA regulated studies.

**Consent for Participants Not Fluent in English**

For participants not fluent in English, the consent process and document must be presented in a language (preferably native) understandable to them. Refer to the section on translation policy later in this document for more detailed information on the acceptable methods of translating documents. If it is expected that participants who do not speak English will be enrolled in a study, translated documents should be made available.

At times investigators may unexpectedly encounter a potential participant who does not speak/understand English. In such an event it may be acceptable to use the oral consent process. If using the alternative approach of an oral presentation of informed consent, as described above, a witness who is fluent in both languages must be present throughout the process. The English version of the informed consent form may serve as the summary form. The participant receives copies of the short form document and the summary. The oral presentation and short form document must be in a language (preferably native) understandable to the participant. At the time of consent the short form is signed and dated by the participant, the summary is signed and dated by the person obtaining consent, and both forms should be signed and dated by the witness.

The IRB must receive all foreign language versions of the short form document as a condition of approval under the provision of 45 CFR 46.117(b)(2). For studies initially reviewed via the full board, expedited review of the translated document is acceptable only if the English language version of the informed consent document and short form document have already been approved.
The IRB makes the final determination as to whether to require a complete written informed consent form or to accept an oral presentation of consent with the summary documents.

**Consent Forms in Research Records**
The PI will maintain the original informed consent document in a participant's research record or file. The participant must be informed of where the consent form (as well as other research related information) will be filed.

**Re-Consenting Participants**
The IRB requires that participants be re-consented if there have been developments that may affect a participant's willingness to continue to participate. The investigator must submit a request to amend the informed consent form to the IRB and then, after obtaining approval, re-consent the participants at the next regularly scheduled visit. Re-consenting a participant will serve to demonstrate that s/he has been informed of the additional information and that s/he willingly consents to continued participation. If the consent document has not yet been approved by the IRB at the time of the visit, a qualified member of the research team must provide a verbal explanation of the information to the participant and document the explanation in the research or medical record as appropriate to the study. In this circumstance, the participant is to sign the revised consent document at the next available opportunity.

The investigator or IRB may also determine that participants need to be contacted immediately depending on the nature of the information and the level of risk it presents to participants. This may occur prior to the consent document being approved. For example, if the PI learns that a drug is causing life threatening adverse events, the PI will determine the best way to communicate the information to the participants in the study. Consideration must be given to the participant's underlying condition, available support systems, and the nature of the information being conveyed. The PI must document the contact with the participants and inform the IRB of the contact.

Minor participants who are actively participating in a study when they reach the age of majority should be re-consented as adults at the next regularly scheduled visit.

If procedural changes are made to the informed consent form and those changes are not pertinent to an individual participant there is no need to re-consent. For example, if a procedure is added to the first visit and some participants have already progressed beyond that phase of the study they do not have to be re-consented. A member of the research team should however note in the record why the participant was not required to be re-consented.

If there are administrative changes to a consent document, e.g., in terms of contact names or numbers, participants still actively enrolled may be re-consented but it is not a requirement. However, the PI must ensure that the participants are provided with the revised information via letter, e-mail or some other means approved by the IRB.
Long-Term Follow-up
Participants in long-term follow-up must be informed of outcome data and safety related information. They need not be informed of changes to the protocol if they are no longer in the active phase of the study. The PI will determine the mechanism of communication, giving consideration to the participant's underlying conditions, available support systems and the nature of the information being conveyed.

Observation of Consent Process
The consent process may be observed by the IRB Monitor or other representative of the RCS or IRB. The observation will be done to ensure compliance with regulations and policy, for quality improvement and for educational purposes. Verbal consent of the participant may be sought prior to the observation.

Assent from Children or Decisionally Impaired Individuals
The IRB expects that children and those individuals who are not competent to provide consent should be given the opportunity to assent to participate in the research project. Assent is a knowledgeable agreement to participate in the project. Adequate provisions should be made for soliciting the independent, non-coerced assent from children or cognitively impaired persons who are capable of a knowledgeable agreement. In cases where assent is obtained from a child or cognitively impaired participant, permission must also be obtained from parents or legally authorized representatives. In accordance with the ethical principal of respect for persons, if the person from whom assent is sought refuses, the person should not be enrolled, even if the parents or legally authorized representatives give permission. Alternatively, if the person from whom assent is sought agrees to participate, the person may not be enrolled if the parents or legally authorized representatives do not give permission. In rare circumstances, depending on the nature of the study and the age and circumstances of the child or decisionally impaired person, the IRB may waive the requirement for permission from parents or legally authorized representatives.

The scenarios outlined below are general and may be altered by the IRB depending on the nature of a specific study and the mental and physical status of the individual involved. The assent of the child may not be required in all situations. The IRB will determine, whether one or both parents must sign a parental permission form. The IRB may find that permission from one parent (or legally authorized representative) is sufficient for research involving no greater than minimal risk or for research involving greater than minimal risk but holding out the prospect of direct benefit to the participant. If the IRB finds that permission from one parent is sufficient the justification for this finding will be documented in the 'requires modification' and/or approval letters and, for full board reviews, in the minutes of a convened meeting.

If the participant is 12 years of age or older, the child signs and dates an assent signature line on the parental permission form and a parent or guardian also signs the parental permission form. In certain circumstances, the PI may propose or the IRB may require that a separate assent statement is necessary. For example, the PI may wish to reinforce the voluntary nature of participation and the nature of the
study with minor participants in studies taking place at a school where the parents have already given permission of the minor participant to participate in the study.

- If a separate assent form is required, both the form and the assent discussion with the participant should be in language especially tailored for the participant class and should describe the following:
  - Explain why the study is being conducted;
  - Describe what will happen and for how long or how often;
  - State it is up to the child/individual to participate and that it is okay to say no;
  - Explain if it will hurt and for how long and how often;
  - Say what the child's/individual's other choices are;
  - Describe any good things that might happen;
  - Say whether there is any compensation for participating; and,
  - Ask for questions.

The assent form should be limited to one page. Illustrations might be helpful and larger type makes it easier for some individuals to read. In studies involving older children or adolescents it may be possible for the child to read and indicate assent on the assent form.

If the child is between 7-12 years of age, and the study is a therapeutic trial, the parent signs the parental permission form and the child participant does not have to sign. If the study is not a therapeutic trial, the parents or guardians sign the parental permission form and the participant signs an assent statement that is either included at the end of the parental permission form after the signature lines or as a separate document.

If the child is less than 7 years of age, the parent or guardian signs the parental permission form, the participant signs nothing. No assent statement is required. However, the PI or person obtaining consent must document in the study record that the child was willing to participate.

**Consent from Illiterate Participants**

At the onset of the consent process, the PI or designated individual authorized to obtain consent must ask the participant if any special provisions are required by them for the consent process, including having the consent document read to them. A witness to the process is required when obtaining consent from illiterate participants. An illiterate participant may make their mark on the consent form to indicate a willingness to participate. A video or audio tape of the process is recommended but the participant must consent to the taping and that consent must be on the tape. If taped, a copy of the tape must be provided to the participant and a copy must be retained with the study records.

**Consent from Legally Authorized Representatives**

When a potential participant is unable to provide consent due to impaired competency, it must be obtained from a legally authorized representative of the participant. Under DHHS and FDA regulations
"legally authorized representative" means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective participant to the procedure(s) involved in the research. When research is conducted in Connecticut, the persons who meet the above definition are a child's parent(s), court-appointed conservators with specific authorization to consent to research, or court appointed guardians with specific authorization to consent to research, and individual who holds a research power of attorney.

Mentally retarded adults who have been declared incompetent must have an appointed legal guardian provide consent to participate in research. The natural parents of the adult are not authorized to give permission unless they have been appointed legal guardian(s). If a developmentally disabled adult has not been declared incompetent, the PI must decide if the participant is capable of understanding the elements of informed consent. A family member or other representative may be asked to co-sign. If the investigator determines the participant is not capable of providing consent, a legal guardian must be appointed and must provide consent before the participant can be enrolled.

**Waiting Period Requirement**
The IRB reserves the right to require a waiting period between the time a study is explained to a potential participant and/or the potential participant's representative, and the time consent is sought from the potential participant or representative. Scenarios when this option may be exercised include, but are not limited to, studies that involve vulnerable populations or studies that are of high risk.

**Staged Consent Process**
The IRB reserves the right to require a staged consent process whereby consent is obtained at various stages in the study to ensure the participant is still willing and/or still able to provide consent. Scenarios when this option may be exercised include, but are not limited to, studies that involve vulnerable populations, for example populations with diminishing capacity, longitudinal studies, or studies that are of high risk.

**Considerations for Informed Consent for International Research**
Field research done outside of the United States, especially in non-western societies or places where the participants do not speak English, poses some problems in obtaining written documentation of informed consent. In these situations, it is sometimes impossible, for a variety of reasons, to obtain written consent. If that is the case, the investigator must provide the IRB with a statement of the reasons why it should waive written consent, and also provide an acceptable alternative method of obtaining oral consent, which is appropriate to both the participants and their culture (refer to Ethnographic Research section).

If the participants may be economically or educationally disadvantaged, the investigator should pay particular attention to these issues and ensure that appropriate safeguards have been implemented.
Informed Consent Requirements for Research with a Certificate of Confidentiality

A certificate of confidentiality protects the participant's confidentiality by protecting research records from subpoena. The certificate goes beyond the consent form in ensuring confidentiality and anonymity. Without the certificate, researchers can be required by a court-ordered subpoena to disclose research results (usually as part of a criminal investigation of the participants). Certificates of Confidentiality are provided by the federal Department of Health and Human Services, however, the study's funding source is not relevant to the granting of a certificate.

While a Certificate of Confidentiality offers retroactive protection, it is advisable to apply for the certificate at least three months prior to the expected initiation of research procedures. It is helpful to the IRB for researchers to submit the certificate with their IRB application.

The following language is typical of Certificate of Confidentiality requirements. Either this or other similar language must be present in the consent form.

"To help protect your privacy, the researchers have obtained a Certificate of Confidentiality from the National Institutes of Health. With this certificate, the researchers cannot be forced to disclose the information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below. The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the Federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself and your involvement in the research. If an insurer, employer or other person obtains your written consent to receive research information, then the researcher may not use the Certificate to withhold that information.

The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant of the research project in instances such as evidence of child abuse or a participant's threatened violence to self or others."

Recommendations for Translation of Documents and the Consent Process

Study related documents (e.g., the informed consent document, the HIPAA authorization, or survey instrument) must be presented in a language understandable to the participant. The IRB recommends the use of one of two methods for translation. One method is that the document be translated by a professional translation service that will attest to the accuracy of the translation. The second is the use of back-translation into English. In this scenario:
• the English version of the document is translated into the foreign language;
• the name and credentials of the individual who did the translation are provided to the IRB by the investigator;
• another individual who has not seen the English version of the document translates the foreign language document back into English;
• this individual provides his/her name, credentials and a statement that s/he has not seen the original English version to the IRB via the investigator;
• both English versions of the form and the foreign language version are submitted to the IRB for review; and
• the IRB will compare both English versions of the documents.

If the IRB determines that the translation is accurate, the foreign language document will be approved for use.

The informed consent process must also be conducted in a language understandable to the participant and may therefore require the use of a translator or sign language interpreter. In most cases, the translator may be a family member or friend of the participant, an employee of the institution or may be hired by the PI. The IRB will determine whether a professional translator is required on a case-by-case basis.

The PI is responsible for covering the cost of the translation. The cost of the translation will not be incurred by the participants.

If one of the two recommended methods is not feasible, the IRB will accept certification from the PI that he/she or a member of the research staff translated the document and that the translation is accurate. This verification must accompany submission of the translated documents.

**Health Insurance Portability and Accountability Act (HIPAA) and Research**

The Health Insurance Portability and Accountability Act (HIPAA), also called the Federal Privacy Rule, went into effect on April 14, 2003. HIPAA requires that "covered entities" engaged in research maintain the privacy of the Protected Health Information (PHI) that is created, accessed or shared in the course of Research activity. A covered entity is a health care provider, payor, or clearinghouse that conducts certain types of electronic billing. PHI is individually identifiable information transmitted or maintained in any form (electronic means, on paper, or through oral communication) that relates to the past, present or future physical or mental health or conditions that can reasonably be used to identify an individual.

A request for the use and disclosure of PHI requires permission from each subject, called an Authorization to Use and Disclose Protected Health Information. "Use" of PHI is the sharing of PHI within the institution (i.e., from clinician to investigator). "Disclosure" of PHI is the sharing of PHI outside of the institution (i.e., from investigator to a participant's physician).
The University of Connecticut, Storrs, is not a HIPAA covered entity. However, there are four locations on campus that are HIPAA covered entities:

1. Nayden Rehabilitation Clinic (outpatient physical therapy)
2. Speech and Hearing Clinic
3. Student Health Services (including Sports Medicine)
4. Emergency Medical Services (EMS, Ambulance)

Each of these locations has a HIPAA policy, and an individual responsible for ensuring HIPAA compliance. The University of Connecticut Privacy Officer is responsible for overall HIPAA compliance on this campus.

While the IRB is not responsible for HIPAA compliance at the covered entities on campus, the IRB will review each protocol on a case-by-case basis to ensure that when the HIPAA regulations apply, they are complied with. Each investigator is responsible for complying with the HIPAA regulations from the institution(s) from which they wish to obtain PHI or where they will be conducting their research.

**General Recruitment Practices and Advertisements**

**General Recruitment**

Recruitment of participants into a study may not begin prior to final IRB approval. The IRB must approve all recruitment methods and material (flyers, letters, brochures, e-mail advertisements, radio announcements, etc.) prior to use. Materials must also be submitted for review and re-approval at the time of continuation. The content of recruitment materials and the method for communicating it cannot contain misleading or exculpatory language or tactics that create undue influence.

Examples of acceptable methods of recruitment include general advertisements in print, radio or televised format, mailings using purchased lists available to the public, class announcements, e-mail listserve, or participation in health fairs. Investigators may re-contact participants from a previous study if the request for permission to re-contact for future studies was part of the consent process in the original study.

For studies that involve recruitment of patients from a medical practice or other treatment facility, it is not acceptable for investigators not affiliated with that practice or facility to directly recruit patients. The initial contact must be initiated by the physician or an employee of the practice or facility. Recruitment can take the form of a flyer posted in the waiting area or handed to potential participants by a physician or employee of the practice or facility. Due to HIPAA regulations, medical practices or treatment facilities may not give out telephone numbers or addresses of their patients to individuals not employed by them.
If applicable to the study design, or required by a funding agency, the PI is responsible for tracking the ethnicity or race of participants who are recruited into studies. In such cases, investigators should ask participants to self-identify at the time of consent.

Advertisements
Advertisements should contain limited information that provides enough detail to allow the prospective participant to determine his/her eligibility and interest. Visual effects that may create undue influence cannot be used, for example, placing the phrase "GET PAID $100" in all capital letters while the rest of the ad is in lower case is not acceptable.

Generally, the elements of any advertisement to recruit participants should be limited to the following:

- the name of the PI and UConn Storrs department affiliation;
- an accurate description of the condition under study and/or the research purpose, e.g., 'low fat vs. low carb diets for weight loss', or 'acclimation of Cuban immigrants';
- in summary form, the key eligibility criteria that will be used to admit (or exclude) participants into the study, e.g., acceptable age range or unacceptable physical limitations;
- a straightforward and truthful description of the benefits, if any, to the participant from participating in the study, e.g., "free health screening";
- if applicable, a statement that compensation is available or a statement of how much compensation is available, e.g., "Participants may receive up to $100";
- the amount / length of time or other commitment required of the participants;
- the location of the research and contact information for obtaining additional information;

Advertisements must display the IRB validation stamp, unless an exception has been granted by the IRB. If it is not feasible to make copies of the validated version, it is acceptable to use the exact wording of the validation stamp: "UConn IRB, Approval On (date), Approved until (date), Approved by (initials)".

Advertisements cannot incorporate elements that:

- state or imply a certainty of favorable outcome or other benefit beyond what is in the informed consent form;
- For studies on nutritional supplements:
  - make claims that the supplement is safe or effective for the purpose under investigation or that it is known to be equivalent or superior to any other supplement;
  - use terms such as new treatment or new supplement without identifying it as investigational.
- For FDA-regulated research studies:
  - make claims that the drug, device or biologic is safe or effective for the purpose under investigation or that the drug, device or biologic is known to be equivalent or superior to any other drug, device or biologic;
use terms such as new treatment, new medication or new drug without identifying it as investigational.

If the study involves the use of FDA regulated products (drugs or devices) no claims should be made, either explicitly or implicitly, that the drug or device is safe or effective for the purposes under investigation, or that the drug or device is in any way equivalent or superior to any other drug or device. Such representation would not only be misleading to participants but would also be a violation of the FDA’s regulations concerning the promotion of investigational drugs (21 CFR 312.7(a)) and of investigational devices (21 CFR 812(7)).

Advertisements may be reviewed through the expedited review process. The IRB reserves the right to require full board review of any recruitment material.

The IRB must review and approve the final taped version of any radio or TV advertisement. The ad may be granted approval pending amendments based on the script, but the final product must be submitted for additional review and approval to ensure consistency with the language / tone presented in the script. The final approval of taped ads may be granted through the expedited review process by the Chair, Vice Chair or designated experienced IRB member.

Financial Payment and Other Incentives for Enrollment

Payment or Incentives Related to Participants
It is acceptable to offer financial payments or other types of incentives (e.g., small toys or gift certificates) to research participants for participation in a study. However, the value of the payment or incentive(s) cannot create undue inducement for participants to enroll. Furthermore, the payment structure should not be such that a participant cannot withdraw from a study without forfeiting the entire payment. There are no federal regulations that determine what is an acceptable payment or payment structure and it is therefore judged on a case-by-case basis taking into consideration:

- the types and numbers of procedures to be involved
- the time commitment involved
- the expenses incurred by the participant
- the anticipated discomfort or inconvenience
- the level of risk of the study
- the type of populations likely to be enrolled
- the option of using a tiered approach in which participants receive payment at various stages of the study.

Payment to participants who withdraw from a study may be held until such time as the payment would have been paid had the participant not withdrawn, unless holding the payment will create a coercive
practice or an undue inconvenience to the participant. For example, it may be acceptable to hold payment until the end of the study if the study is only a couple of weeks long, or to hold payment until the first disbursement would have been made if there is only a couple of weeks difference between the date the participant withdrew and the date the payment was scheduled to be made. The wishes of the participant should be honored when possible. Compensation offered to potential participants may not include a coupon for discounts on the purchase price of the product being tested.

Grant Review to Ensure Adequate Funds for Financial Payments
The PI is responsible for ensuring that funds are available to make financial payments to participants as described within the informed consent document. However, if the research is supported either in whole or in part by external funds (federal, state or private), the IRB will review the grant application to determine if adequate funds have been budgeted for this purpose. If the IRB is not able to make this determination, it will ask the PI to provide an explanation. Review of the grant application is conducted by the Primary Reviewer and an IRB staff member at initial submission, if applicable, or when the PI informs the IRB of a new funding source at reapproval or via an amendment.

Financial Reporting Obligations
The confidentiality of a participant must be respected throughout his/her participation in a study. However, in order to make a payment by check payable to the participant certain information may be required to be recorded on financial records and forwarded to accounts payable for compliance with state and federal requirements for income reporting. The participant must be informed of this by the person obtaining consent and the information must be contained in the consent document. The participant may choose to decline receiving payment if s/he does not want the information reported outside of the study. Information may include name, social security or taxpayer identification number, mailing address, and amount paid to the participant.

The participant must also be informed that if cumulative payments to a participant within a year add up to $600 or more, a Form 1099 will be issued by UConn Storrs and the income will be reported to the IRS.

Payment Methods to Maintain Participant Confidentiality
In order to maintain confidentiality or to provide many participants a small cash payment, it is possible for the PI to request a cash advance from Accounts Payable. A check would be made out to the PI who then cashes it and gives cash payments to individual participants. The PI is responsible for maintaining a receipt system in order to reconcile the cash advance with payments made to participants. Copies of receipts must be forwarded to Accounts Payable. In order to maintain confidentiality, the PI may either provide receipts with the participant identified by a number or with the participant’s name redacted.

Psychology Participant Pool Participation Credits
Psychology 1100/1101/1103 students are offered the opportunity to participate in psychological experiments for credit. Students are required to earn 5 credits of research participation. Students earn credits at a rate of one credit for each ½ hour of participation. In addition, students may earn up to 7
additional participation credits (up to 12 credits total) as extra credit for the course. Students are not obliged to participate in any experiment that they do not wish to or that makes them uncomfortable. At any point during the experiment, they may stop participating. Students will receive credit even if they choose to withdraw. All students must be offered an alternative option(s) to participation in research studies. The IRB expects that alternative options presented to students are equivalent to the amount of time and work involved in participating in psychological experiments. Examples of alternatives include: attendance at a research seminar; writing a brief research abstract or journal article report; or other assignments with educational value and comparable to research participation in terms of time, effort and convenience. If evaluated, these projects should be graded on a "credit/no credit" scale.

Payment of Extra Credit to Students
Students may receive extra class credit as "payment" for their participation in research studies. The extra credit is meant to add to the student’s grade for the course. Investigators must demonstrate to the IRB that the amount of extra credit is not coercive (i.e., the amount of extra credit is a small percentage of the overall grade for the course). If students in more than one class are enrolled in the same study, the amount of extra credit offered should be equivalent across classes. All students must be offered an alternative option(s) to participating in research studies. The IRB expects that alternative options presented to students are equivalent to the amount of time and work involved in participating in research studies. Examples of alternatives include: attendance at a research seminar; writing a brief research abstract or journal article report; or other assignments with educational value and comparable to research participation in terms of time, effort and convenience. If evaluated, these projects should be graded on a "credit/no credit" scale.

Payment to Student Athletes and Compliance with NCAA Rules
According to the NCAA Compliance Office and the Big East Compliance Office, student athletes may be paid for their participation in research studies provided that the student athletes are being recruited from the general student body because they are students at UConn and not because they are student-athletes. If a research study targets individuals who are athletic and, as an example, a soccer or field hockey player wants to participate in the study, they may be able to participate and get paid. However, student athletes may not be recruited for a study and be provided with payment for participation because of their student-athlete status.

Payment or Incentives Related to Investigators and Staff
Within the IRB application the PI must disclose whether any financial or other benefit is to be received by the research personnel from the sponsor for participant recruitment. If a benefit (financial or otherwise) is to be received, the PI must disclose the value of the benefit and explain how it is justified, e.g., that the payment covers the administrative cost of participant enrollment and management. The IRB will determine on a case-by-case basis whether such payment places undue influence on the investigator(s) or research staff to recruit participants.
Payments to investigators and research staff that are tied to the rate or timing of enrollment (i.e. bonus payments) are designed to accelerate recruitment and are prohibited.

**Payment or Receipt of Finders Fees**
Investigators on an IRB approved study may not offer or receive payments for the referral and ultimate enrollment of participants into a study. For example, investigators may not award a treating physician with a financial payment or other incentive for referring a participant to a study. Likewise, investigators may not accept payment or other incentives for referring a participant to another study.

**Participant Privacy and Confidentiality**
The PI must address within the IRB application the plans for protecting participant privacy and data confidentiality. This information must also be disclosed within the informed consent document. When appropriate, the IRB Monitor verifies that the plans to protect privacy and confidentiality as submitted to the IRB are being followed, as determined during the course of an audit.

Privacy refers to the individual. Therefore the PI must ensure that the consent process and study activities are conducted in a setting that affords sufficient privacy to the participant. Confidentiality refers to the data related to the participant. Confidentiality encompasses the storage of electronic and paper files and samples. The PI must address in the IRB application plans for maintaining confidentiality of participants’ data during and after participation in a study.

**Sponsored Research**
Written agreements with sponsors may be negotiated by the Office for Sponsored Programs. The agreement that accompanies all research that is sponsored by external sources must address the certain elements, including:

1. Length and cost of project;
2. The University’s right to publish;
3. Intellectual Property (IP) ownership and disposition.

The IRB reviews all grant applications to ensure that the grant is consistent with the IRB application regarding study purpose, procedures, and budget. This review may be done by the Chair, or the IRB member acting as primary reviewer of the study.

**Sub-Awards for Human Participants Research**
Prior to releasing sub-award funds to a collaborator, the collaborating institution and PI must demonstrate/indicate to UConn that approval has been obtained from the collaborator’s IRB.
Conversely, in any situation where the UConn PI is the proposed sub-awardee, UConn will demonstrate to the prime that UConn has approved any involvement and use of humans through the UConn IRB.

**Process for Filing Complaints, Concerns or Suggestions**

**Participant Complaints/Concerns**

In the informed consent process and document, the person obtaining consent must inform participants that they may contact the IRB if they have concerns about their rights as a research participant. The phone number of the IRB and/or the email address must be provided.

The IRB staff member receiving the complaint/concern will gather preliminary information from the participant and refer the matter to the RCC, or in the absence of the RCC, the IRB Monitor. The RCC will complete the investigation by speaking to the participant and to other persons involved. Participants may be asked to submit their complaint/concern in writing (e-mail is acceptable) but this is not required. The RCC will contact the PI to solicit additional information. The RCC will inform the IRB Monitor, DRC and the IRB Chair of the complaint and the investigation.

The Chair may: 1) request additional information from the RCC or contact the parties him/herself, 2) refer the matter to the full board for consideration as an unanticipated problem involving risk to participants or others or serious or continuing noncompliance, or 3) require the PI or IRB staff to take corrective action to resolve the complaint/concern. If any corrective action requires a change to previously approved IRB documents, the IRB Chair will request in writing that the investigator submit an Amendment Review Form (IRB-3). When indicated, the DRC will take appropriate administrative action.

The Chair, with the assistance of the RCC, may issue a letter to the participant in response to the complaint. The PI and DRC will be sent copies of such letters.

**Participant Suggestions**

Any participant in a research study who wishes to provide feedback to the RCS/IRB on their experience as a volunteer research participant may do so by contacting the IRB using the phone number or email address provided on the consent form. Whether the feedback is provided anonymously or in an identifiable format, it will be forwarded to the RCC and to the IRB Monitor for preliminary consideration and where appropriate, reported to the DRC and to the IRB Chair for additional action.

**Participant Log**

A central log of complaints, concerns and suggestions received by research participants will be maintained in the RCC’s office. The RCC is responsible for logging the information and follow-up activity. The log will contain the date of receipt and, as applicable, the PI involved, the participant’s name when provided, the nature of the complaint, concern or suggestion and the outcome.
The above process will be followed for all types of review: full board, expedited, or exempt determination.

Participant complaints will be reported as part of the protocol continuing review process. In this way, the IRB will be informed of study complaints that were resolved without the involvement of the full IRB.

Investigator Complaints/Concerns
Complaints or concerns about the RCS/IRB process or staff should first be directed to the RCC. The investigator may choose the initial means of communication. If the investigator is not satisfied with the response of the RCC, the complaint may be addressed to the DRC or to the IRB Monitor. The IRB Monitor may recommend, and the DRC may require, that the IRB implement corrective action. No requirements can be made that would change or influence a decision of the IRB.

Complaints about the review of an investigator’s protocol by the IRB should first be directed to the IRB Chair. The investigator may choose the mechanism of communication. The Chair will follow through as appropriate based on the magnitude of the complaint. The investigator may be invited to attend an IRB meeting to express the concern. The Chair may involve the IRB Monitor, the RCC and/or the DRC. The Chair or DRC may advise the IRB staff and/or IRB members to implement corrective action. The DRC may require corrective action. No requirements can be made that would change or influence a decision of the IRB as related to a research study.

If the investigator does not feel that the complaint was adequately addressed by the IRB Chair, s/he may inform the IRB Monitor or the DRC. The IRB Monitor may make recommendations to the DRC. The DRC may act or may bring the concern to the VPR. DRC with the VPR will make the final determination how to respond.

Investigator Suggestions
All research personnel are invited to provide suggestions for improvement to the RCS/IRB. Individuals may choose the mechanism for communication. The individual who received the suggestion will bring it to the attention of the RCC or the DRC. Investigators will be informed of the outcome of the suggestion via e-mail or phone. The RCC will maintain a central log of suggestions filed by research personnel.

Miscellaneous Complaints
All other types of complaints or concerns raised by investigators or third parties about the RCS/IRB or a human participant research protocol will be referred to the RCC or to the DRC and evaluated in keeping with the above stated guidelines.

Repositories and Databases
Database records and repositories may be created and used for research purposes.
An individual or individuals must be designated as the data manager for repositories. Only those designated as the data manager will be allowed to de-identify data for release in research projects. Only those designated as the data manager may contact individuals regarding consent for additional studies. This contact for additional consent may only occur if the participant has consented to being contacted for such purposes.

For the HIPAA covered entities on campus, authorization to continue to store data that existed prior to April 14, 2003 need not be obtained. However, the use of such data will be in accordance with the HIPAA regulation. If data or samples will be stored at an external site, the IRB may require that a copy of that site’s policies for use of the samples and protection of the participant’s privacy be submitted for review.

Creating Research Databases
IRB approval must be obtained via submission of an IRB-1 protocol application for the creation of a research registry or bank at UConn Storrs. IRB approval must also be sought for specific projects which will make use of the individually identifiable information in the registry or of the banked material prior to any research being implemented.

Identifiable data or samples collected solely for research purposes may not be added to a databank or repository at UConn for on-going storage without the authorization of the participant. During the consent process participants must be presented with the following options:

- declining the storage of identifiable data and/or sample beyond the requirements of the research study, or
- authorizing the on-going storage of identifiable data and/or sample beyond the research study.

If on-going storage at UConn is authorized in an identifiable manner the participant must also be informed of the following:

- who will have access to the data and/or sample, and
- that they may in the future request that identifiers be removed from the data and/or sample.

The identifiable data may not be used for future research purposes without a consent from the participant to do so, or approval from the IRB to waive the need for a consent and HIPAA authorization (if applicable). Alternatively, the administrator of the data or samples may de-identify information for researchers. The data may be coded such that the administrator can link the information back to the individual. The code cannot be comprised of any identifiable information. The researchers cannot at any time know the mechanism for creating the code or how to link the code to the individual. The administrator cannot be a part of the research team.
Accessing Databases for Research Purposes
Investigators who wish to access databases owned and operated by other institutions must agree to abide by the requirements of those institutions. In some instances, it is required that a Confidentiality Agreement be signed by the PI, and sometimes co-signed by the IO. The IRB will review the protocols that involve accessing external databases to determine whether the plan to access the data and/or combine datasets may lead to the deductive disclosure of individually identifiable information. If so, a plan must be in place to ensure that the confidentiality of the data is maintained.

The UConn Storrs Monitoring Program for Research with Human Participants*
*Storrs and the regional campuses, the School of Social Work and the School of Law

Goals of Monitoring Program
The goals of the Monitoring Program are:

1. Protect the rights and welfare of human research participants by determining if a study is being conducted in compliance with federal regulations, state law, Institutional Review Board (IRB) policies and with the currently approved protocol and by correcting noncompliance through education.
2. Assist investigators and the IRB by implementing a systematic, internal process for identifying areas of IRB and investigator non-compliance and working with investigators and the IRB to resolve those areas, thereby preventing situations that might increase risks to participants or lead to regulatory citations.
3. Provide current information to investigators, students, and the IRB related to relevant regulations and policies governing the protection of human participants in research.

Audit Categories:
1. Routine: Studies selected for these audits will primarily be randomly selected, however, selection may include elements in 3. Selection of Studies, below. They will focus on compliance with the federal regulations and with IRB policies by reviewing IRB and Investigator files. They will include a review of: 1) the roles and responsibilities of research team members, 2) consent form elements and consent process; 3) participant recruitment and eligibility; 4) participant files for agreement with the approved protocol; 5) data collection and security; 6) adverse events (AE) and protocol deviations, and 7) other relevant aspects of the study.
2. Informed consent: This type of review is intended to support researchers in conducting the informed consent process. It may include: 1) observation (when possible) of the consent process; 2) verification that the person consenting the subject is qualified and designated by the principal investigator (PI); 3) review of the consent form for IRB approval date and signatures; 4)
documentation of consent, and confirmation that a copy was given to subject; 5) review of the consent form for required elements.

3. For-cause: Under 45 CFR 46.113 "an IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects." This review is performed when concerns regarding compliance, protocol adherence, or subject safety are brought to the attention of the IRB or Office of Research Compliance. This is an on-site review that may include the elements described in Routine & Informed Consent.

4. Investigator Initiated: A PI may request an on-site review to help keep records and procedures in compliance with federal regulations and institutional policies or to prepare for an audit by a sponsor or federal agency.

Selection of Studies
Protocols selected for monitoring will focus on, but not be limited to any of the following:

1. Studies in which the probability and magnitude of anticipated harm or discomfort, (including loss of privacy or confidentiality) are greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests; or
2. Studies that were given full board or expedited review by the IRB; or
3. Investigator-initiated protocols, i.e., not peer-reviewed research; or
4. Studies that include participants from "vulnerable populations" identified in 45 CFR 46 subparts B, C, and D (pregnant women/fetuses/neonates, prisoners, and children), or other populations vulnerable to coercion or undue influence including: the mentally disabled, economically or educationally disadvantaged persons under 45 CFR 46.111(b), or others considered vulnerable by the University; or
5. Protocols that exhibit "for-cause" concerns; see description under Audit Categories above.
6. Examples of other elements that may be considered include:
   • Adverse event or Protocol Deviation reporting history,
   • Regulatory approval category,
   • Funding source,
   • Results of previous audits
   • Study topic

Arranging the Audits
Nothing in this policy will prevent the IRB or other university officials from intervening without notice where serious harm to subjects may be at risk or from taking any other reasonable action under the circumstances. Except in cases where the safety of subjects is a concern, written notification of an audit
will be sent from the Institutional Official or his designee. The IRB Monitor will contact the PI to arrange a visit to the department within the following estimated timeframes:

1. Routine: At least two weeks notice in advance of the audit.
2. Informed Consent: At least one week notice in advance of the monitoring.
3. For-cause: At least twenty-four (24) hours notice by a telephone call and email to the PI from the Institution Official or his/her designee.
4. Investigator Initiated: A time will be arranged by mutual convenience.

**Audits May Include Some Or All Of These Elements:**

1. Review of roles and responsibilities of investigators and key personnel including verification of:
   - Persons authorized to consent participants
   - Persons authorized to conduct study procedures
   - Human participants protection training (CITI Program)
   - Review by any other university compliance committee, e.g., Conflict of Interest, when applicable
   - Other relevant study or IRB materials
2. Review of Regulatory Compliance may include review of:
   b. IRB Documentation. The IRB Monitor compares the PI's records with the IRB's records.
   c. Consent/Assent Forms. The IRB Monitor examines the Consent/Assent Forms/Information Sheets used to enroll the participants to ensure that the appropriate form was used for the study and that the form had the current IRB stamped approval date on it. Where signed consent/assent was obtained, the IRB Monitor reviews whether the forms were properly signed and dated.
   d. Individual Participant Records. The PI may be asked in advance to randomly select a sample of participants' records for review. They are examined to determine if:
      - The participants met the inclusion/exclusion criteria for the study.
      - Study related procedures are performed according to the protocol.
      - Study related procedures are scheduled and performed per the study time line.
      - Data is recorded and stored securely as described in the Consent Form.
      - Adverse Events have been reported according to institutional policy.
      - Payments were made to participants as described in the protocol.
   e. Grant Application. If applicable, the grant application may be compared to the IRB approved protocol.
   f. The RCS/IRB File. IRB Meeting issues (quorum, diversity, expertise, conflict of interest); adequacy of review; IRB Minutes to assess requirements of IRB review.
3. Elements of Informed Consent/Assent:
   • Review of the required elements of informed consent according to the federal regulations and IRB requirements.

4. Informed Consent/Assent Process. Includes review of:
   • The timing of recruitment and screening in relation to informed consent.
   • The appropriateness of the person obtaining consent.
   • The appropriateness of the consent process to meet the needs of vulnerable populations.
   • Steps taken to aid participants who possess barriers to understanding or lack of capacity to consent (language, reading level, etc.)
   • Steps taken to determine that the participant understands the research study purpose, risks, benefits, voluntary participation, withdrawal, confidentiality, costs/compensation, contacts for questions or injuries.

5. Subsequent publications resulting from IRB approved protocols may also be reviewed.

Report of Findings

1. The IRB Monitor will report serious violations immediately to the IRB Chair and to the Institutional Official or his designee. In concert, they will determine whether regulations or policies require reporting the findings to external agencies or to individuals within the institution, including the Department Head or Dean.

2. A Summary Report of Routine Audits will be drafted by the IRB Monitor and sent to the PI for his review. The PI may discuss with the IRB Monitor any problems he has with the report and add his comments to it before signing it. When indicated, the PI will be invited to create his own corrective action plan. The IRB Monitor will sign the report and submit it to the Director of Research Compliance (DRC). The originals will be filed in the IRB Monitor's file for quality improvement purposes. Copies will be provided to the PI, the IRB Chair, and the DRC. At least quarterly, the IRB Monitor will present a list of Routine Audits at a regularly scheduled IRB Meeting. The Summary Report will also include a:
   • Statement describing the type of review, the date, location and procedure followed, who was in attendance and the PI's response;
   • Description of the PI's overall compliance;
   • Description of any noncompliance, (policies, regulatory or legal) or other deficiencies (as in documentation, etc.);
   • Recommendations of the IRB Monitor re: education for PI and/or research assistants, record keeping, etc.;
   • PI corrective action plan when necessary;
   • Optional section for PI comments;
3. For Cause and Consent Audits will usually be requested by the IRB. Summary Reports for these types of audits will generally contain the same types of information described above and will be reported on at regularly scheduled IRB Meetings.

4. The Summary Report for the Investigator-initiated audits will contain the same information as the Routine Audits but a copy of the report will only go to the PI. The IRB Monitor will keep a copy for quality improvement purposes.

5. Recommendations for the IRB and for the IRB staff will be made to the RCC or to the IRB Chair as appropriate.

6. The IRB Monitor will see to it that common problems noted during Routine Audits will be the subject of additional general training efforts at the university.

Regulatory Authority and References
The UConn Federal-Wide Assurance Agreement with the OHRP. The agreement's Terms of Assurance stipulates that the university must have procedures that "include formal mechanisms for monitoring compliance with human subject protection requirements."

- HHS, 45 CFR 46.109(a) "An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy."
- HHS, 45 CFR 46.109(e) and FDA, 21 CFR 56.109(f), "An IRB shall conduct continuing review of research... and shall have authority to observe or have a third party observe the consent process and the research."
- DHHS, 45 CFR 46.111(a)(6) and FDA, 21 CFR 56.111(a)(6) An IRB is required to ensure "when appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects."
- DHHS, 45 CFR 46.113 "An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects."

Training Requirements and Educational Activities

Training Requirements and Education of IRB Members, RCS Staff
At the time of appointment to the IRB, the RCC and/or Chair of the IRB meets with new members. A discussion is held covering the expectations of IRB members, the policies of the IRB, the ethical principles and regulations governing human research, and the review process. All newly appointed members are required to complete training in the protection of human participants before being assigned as a reviewer and are expected to read the Belmont Report.

All IRB members and staff are required to complete all modules of an on-line tutorial (currently the CITI course) covering the protection of human participants in Biomedical and Social/Behavioral research. The IRB Administrator ensures that all IRB members and staff receive a handbook that contains relevant
information such as Federal regulations and guidance, a listing of useful websites, a copy of The Belmont Report, the Declaration of Helsinki, and the Nuremberg Code. Relevant information is also available from the IRB website. List serves, e.g., the IRB Forum, are also used as a means of continuing education.

The VPR includes funds for IRB members and RCS staff to attend conferences and workshops as part of the RCS budget. Those who attend a conference/workshop will relay what is learned to other members and staff of the IRB and RCS through an oral and written report. Information may be shared at the next regularly scheduled meeting, or via electronic or hard copy distribution of materials.

As needed, the RCC will coordinate a meeting of the IRB for the purpose of educating members about policies and procedures, regulatory developments, and/or issues that have been raised since the previous policy meeting. Guest speakers may also be invited to attend these meetings.

**Training Requirements and Education of Investigators and Key Research Personnel**

All PIs, co-investigators, and key research personnel such as study coordinators or individuals obtaining consent, are required to complete training in the protection of human participants in research prior to obtaining IRB approval on a study. Training is required of all key personnel regardless of whether the study qualifies for exempt, expedited or full board review. The training requirement is satisfied through completion of an on-line training tutorial (e.g., the CITI course) approved by the IRB. Research personnel must renew their training every three years.

If an investigator is external to UConn Storrs, s/he must submit proof of having completed human participants protection training. A letter or certificate of completion from the respective institution or the NIH certificate may suffice. However, the IRB reserves the right to require the external investigator to complete some or all of the elements of the training module used to satisfy the UConn Storrs IRB requirement. If key personnel are external to UConn Storrs, they must complete the same on-line training tutorial required of UConn investigators.

The IRB staff will verify that all key personnel listed on an application have completed the training via the training website. If an individual on the application has not completed the training the IRB staff will notify the PI and the individual by e-mail. The PI may choose to remove the individual from the study and add him/her back via an amendment at a later date or to wait until the individual completes the training. Final IRB approval will not be granted until the requirement is satisfied.

The IRB Monitor serves not only to audit study compliance with policies and regulations but to educate investigators. The IRB Monitor will provide educational suggestions for improvements and, if needed, corrective actions necessary to protect participants and comply with policies and regulations. S/he will communicate the suggestions to the IRB Chair and the DRC, via preparation of the Audit Summary Report. The audit results will be conveyed to the PI via the final Audit Summary Report and a letter under the signature of the DRC or the IRB Chair.
The RCC and the IRB Monitor share responsibility for posting messages to the IRB web site and to the university list serves to share information with the research community at large. Messages may be in regard to changes in policies or regulations or to recent developments, internal or external to UConn Storrs.

**FDA-Regulated Research**

**Investigational Drug Studies**
Studies involving the use of an investigational drug will be conducted in compliance with 21 CFR 312 Subchapter D, Drugs for Human Use / Investigational New Drug Application (IND). An IND is required for experimental drugs if the drugs are used for the purpose of developing information about their safety or efficacy. Approved, marketed drugs also require an IND if the proposed use in research is different from its previously FDA-approved use or administered by an unapproved route or method of delivery or an altered dosage.

Investigators will be responsible for conducting the investigation in accordance with the signed investigator statement, the investigational plan, and applicable regulations and policies; and for protecting the rights, safety and welfare of participants in their care. Investigators are also responsible for the following:

- controlling of drugs under investigation;
- administering the drug only to participants under the investigator’s personal supervision or under the supervision of a co-investigator responsible to the investigator;
- supplying the drug only to persons authorized to receive it;
- maintaining adequate records for the disposition of the drug (dates, quantity, and use by participants);
- returning unused supplies to the sponsor or otherwise providing for the disposition in accordance with the direction of the sponsor;
- maintaining adequate and accurate case histories on each individual receiving the drug or employed as a control (all observations and other data pertinent to the investigation including case report forms and supporting data, e.g., signed and dated consent forms, medical records including progress notes, hospital charts and nurses notes);
- retaining records for 2 years after either the date a marketing application is approved for the drug for the indication under investigation, or, if no application is to be filed or if the application is not approved, until 2 years after the investigation is discontinued and FDA is notified;
- submitting progress reports and safety reports to the sponsor and IRB;
- providing financial disclosures to the sponsor and the IRB;
- storing drugs properly and securely;
obtaining IRB and FDA review and approval prior to initiating the research (including the consent process); and
permitting authorized individuals (RCS or IRB staff, FDA staff) to have access to and to copy relevant records.

The names of participants do not have to be disclosed unless the records of particular individuals require a more detailed study of the cases, or unless there is reason to believe that the records do not represent actual case studies, or do not represent actual results obtained.

In the event that a PI is also the sponsor of the IND, the PI must make arrangements with the IRB Monitor to request a pre-audit of the facilities that will be used to store the drug and to review the additional obligations of the sponsor. The audit must occur prior to the submission of the IRB application and the results of the audit must be submitted with the IRB application.

Exemptions from 21 CFR 312
The IRB may determine that a clinical investigation of a lawfully marketed drug(s) is exempt from the regulation if all of the following conditions apply:

- the investigation is not intended to be reported to the FDA as a well-controlled study in support of a new indication for use nor intended to be used to support any other significant change in the labeling for the drug;
- if the drug is lawfully marketed as a prescription drug product, the investigation is not intended to support a significant change in the advertising for the product;
- the investigation does not involve a route of administration or dosage level or use in a patient population or other factor that significantly increases the risk (or decreases the acceptability of the risk) associated with the use of the drug product;
- the investigation is conducted in accordance with the requirements of institutional review and informed consent as set forth in 21 CFR 50;
- the investigation is conducted in compliance with part 312.7 regarding the promotion and charging for investigational drugs.

A clinical investigation involving an in vitro diagnostic biological product (blood grouping serum; reagent red blood cells; and anti-human globulin) is exempt if it is intended to be used in a diagnostic procedure that confirms the diagnosis made by another, medically established, diagnostic product or procedure and it is shipped in compliance with the requirements set forth in 312.160.

Labeling and Dispensing of Research Drugs
All study drug labels must indicate:

- the name, address and phone number of the dispensing area;
- the participant’s name or identifying number;
• the name of the prescribing physician;
• the date of issue;
• the drug name and strength or study acronym; and
• directions for use.
• Labels for investigational drugs must also incorporate the following statements: "Caution: New Drug – Limited by Federal law to investigation use."

There must be an order from the physician (a standing order would be acceptable) if someone other than the physician is dispensing study drugs to participants. Per CT Law only those with prescribing authority may dispense drugs other than over-the-counter drugs. The IRB application must include the plans for dispensing of research drug.

**Drug Storage/Inventory**
Investigational drugs for outpatient use may be stored by the investigator. The IRB application must include the plans for storage and inventory and approval. The IRB must approve of the plans for storage and inventory control of research drug.

**Investigational Device Studies**
Clinical investigations of medical devices will comply with regulation 21 CFR 812 unless otherwise exempt, as noted below. The sponsor of the device will make the initial determination of whether the device presents a significant (SR) or non-significant risk (NSR). A SR device study is defined as a study of a device that presents a potential for serious risk to the health, safety, or welfare of a subject and 1) is intended as an implant, or 2) is used in supporting or sustaining human life, or 3) is of substantial importance in diagnosing, curing, mitigating or treating a disease, or otherwise prevents impairment of human health, or 4) otherwise presents a potential for serious risk to the health, safety, or welfare of a subject. A NSR device study is one that does not meet the definition of a SR study. NSR are not necessarily minimal risk studies.

For SR studies, the FDA must approve an IDE application submitted by the sponsor and the IRB must approve the study before it may commence. SR devices studies require review of the full board. In the event that a UCHC PI is also the sponsor of the IDE, the PI must make arrangements with a Research Compliance Monitor to request a pre-audit of the facilities and to review the additional obligations of the sponsor. The audit must occur prior to the submission of the IRB application and the results of the audit must be submitted with the IRB application.

NSR device studies do not require submission to the FDA. These studies must comply with the abbreviated regulations set forth in 21 CFR 812.2(b) that require that a device fulfill the following requirements:

• The device is not a banned device
• The sponsor labels the device in accordance with 21 CFR 812.5
• The sponsor obtains IRB approval of the investigation after presenting the reviewing IRB with a brief explanation of why the device is not a significant risk device, and maintains such approval.
• The sponsor ensures that each investigator participating in an investigation of the device obtains from each subject under the investigator's care, consent und 21 CFR 50 and documents it, unless documentation is waived.
• The sponsor complies with the requirements of 21 CFR 812.46 with respect to monitoring investigations;
• The sponsor maintains the records required under 21 CFR 812.140(b) (4) and (5) and makes the reports required under 21 CFR 812.15(b)(1) through (3) and (5) through (10);
• The sponsor ensures that participating investigators maintain the records required by 21 CFR 812.140(a)(3)(ii) and makes the reports required under 812.150(a) (1), (2), (5) and (7); and
• The sponsor complies with the prohibitions in 21 CFR812.7 against promotion and other practices.

Unless otherwise notified these NSR devices are considered to have an approved Investigational Device Exemption (IDE) if the sponsor fulfills the regulatory requirements of 21 CFR 812.2(b). While exempt from FDA approval, NSR studies must receive IRB approval prior to commencing. NSR studies generally will require full board review but may be approved through the expedited review procedure if the study falls within a designated approvable category and is minimal risk.

Exemption criteria for an IDE are as follows:

• A device, other than a transitional device, in commercial distribution immediately before May 28, 1976 when used or investigated in accordance with the indications in labeling in effect at that time.
• A device, other than a transitional device, introduced into commercial distribution on or after May 28, 1976, that FDA has determined to be substantially equivalent to a device in commercial distribution immediately before May 28, 1976, and that is used or investigated in accordance with the indications in the labeling FDA reviewed under subpart E of part 807 in determining substantial equivalence.
• A diagnostic device, if the sponsor complies with applicable requirements in 21 CFR 809.10(c) and if the testing:
  o Is noninvasive
  o Does not require an invasive sampling procedure that presents significant risk.
  o Does not by design or intention introduce energy into a subject.
  o Is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure
A device undergoing consumer preference testing, testing of a modification, or testing of a combination of two or more devices in commercial distribution if the testing is not for the purpose of determining safety or effectiveness and does not put subjects at risk.

- A device intended solely for veterinary use.
- A device shipped solely for research on or with laboratory animals and labeled in accordance with 21 CFR 812.5(c)
- A custom device as defined in 21 CFR 812.3(b), unless the device is being used to determine safety or effectiveness for commercial distribution.

The sponsor makes the initial determination of SR or NSR for the device. However, the IRB will make the final determination for NSR devices. If the IRB disagrees with the sponsor and designates the device as SR, the sponsor will be required to submit to the FDA for an IDE. The study will not be approved by the IRB until the IDE is obtained. The investigator will be informed of the IRB's determination in writing and the investigator must inform the sponsor.

In assessing the risk level of a device the IRB will consider information such as a description of the device and its proposed use, nature of the harm that may result from the use of the device or from procedures required for use of the device, e.g. surgical implants, reports of prior investigations conducted with the device, the proposed investigational plan, a description of subject selection criteria and monitoring procedures. The IRB should be provided with the sponsor's risk assessment and rationale for its determination as NSR. The sponsor must provide the IRB with the FDA's assessment of the device's risk if such an assessment has been made. The IRB may also choose to consult with the FDA.

A clinical study may be exempt from the regulation if the study involves the investigation of a lawfully marketed device.

The principal investigator of a device study must:

- obtain appropriate approvals (IRB, FDA) prior to obtaining consent and enrolling any subjects;
- maintain control of the device under investigation;
- conduct the study in compliance with the signed agreement with the sponsor, the investigational plan, applicable regulations and policies;
- protect the rights, safety and welfare of subjects under the investigator's care;
- make financial disclosures to the sponsor;
- supervise the device use, the device shall be used only with subjects under the investigator's supervision;
- supply the device to only authorized individuals;
- upon completion or termination of a clinical investigation, or the investigator's part of an investigation, or at the sponsor's request, return to the sponsor any remaining supply of the device or otherwise dispose of the device as the sponsor directs;
- permit authorized persons (e.g. HSPO / IRB staff, FDA staff) to inspect and copy records relating to the investigation;
- if authorized, permit authorized persons (e.g. HSPO / IRB staff, FDA staff) to enter and inspect any establishment where devices are held (manufactured, processed, packed, installed, used, or implanted, or where records of results from use of devices are kept);
- maintain adequate records including:
  - correspondence with another investigator, an IRB, the sponsor, a monitor, or the FDA;
  - records of receipt, use or disposition of a device that relate to the type and quantity of the device, the dates of its receipt, and the batch number or code mark, the names of all persons who received, used, or disposed of each device, why and how many units of the device have been returned to the sponsor, repaired, or otherwise disposed of;
  - each subject's case history and exposure to the device (include the case report forms and supporting data including, for example, the signed and dated consent forms, medical records including progress notes, adverse event reports);
  - the protocol and records of any deviations from the protocol; and
  - any other records required by the FDA or IRB or relevant to the study;
- submit reports of unanticipated adverse device effects to the IRB in accordance with the Adverse Event reporting policy and to the sponsor as soon as possible but within 10 days of becoming aware of the event;
- submit a report to the sponsor within 5 days of any withdrawal of IRB approval;
- submit progress reports to the IRB, sponsor, and monitor at least annually.

Investigators are to retain records for 2 years after the latter of either the date on which the investigation is terminated or completed, or the date that the records are no longer required for purposes of supporting a pre-market approval application or a notice of completion of a product development protocol. Transfer of custody of the records to another person/entity willing to accept responsibility for them may occur but requires that the investigator inform the FDA within 10 days of the transfer.

Names of subjects need not be disclosed unless there is reason to suspect that adequate informed consent was not obtained, or that reports required to be submitted by the investigator to the sponsor or to the IRB have not been submitted or are incomplete, inaccurate, false or misleading.

Types of research not conducted on the UConn Storrs campus

The following types of research are not currently conducted on the UConn Storrs campus:

- Humanitarian Use Device;
- Emergency Use of an Humanitarian Use Device;
- Emergency Use of Investigational Devices for Treatment;
- Emergency and Therapeutic Use of Investigational Drugs or Biologics;
• Planned Emergency Research.

Data Safety Monitoring Plans and Boards (revised 11-05-09)
The IRB is responsible for determining that a study requires formal ongoing monitoring of data to ensure that research participants are protected. This responsibility stems from DHHS and FDA regulations stating a criterion for study approval is "when appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure the safety of subjects" (45 CFR 46.111[a][6]).

Data Safety Monitoring Plan
This is a prospective plan set up by the study investigators to assure that adverse events occurring during studies are identified, evaluated and communicated to the IRB in a timely manner. Although the investigators initially propose a Data Safety Monitoring Plan (DSMP), the IRB must approve the plan and may require revision to the plan. A DSMP is required for all human studies at the University of Connecticut except for studies determined to be exempt from continuing review. For studies that present more than minimal risk to participants, the IRB will review and determine on a case-by-case basis whether a data safety monitoring board is most appropriate.

Issues that should be addressed in the DSMP include the frequency of the monitoring, who will conduct the monitoring, what data will be monitored, how the data will be evaluated for problems, what actions will be taken upon the occurrence of specific events or end points, and how communication to the IRB will occur.

Forms a Data Safety Monitoring Plan Can Take

Adverse Event Reporting to the IRB
For minimal risk or slight increase over minimal risk studies, the data safety monitoring plan may be as simple as acknowledging that when an unanticipated, serious adverse or unwanted event occurs that an adverse event report form will be filled out and sent to the IRB for review within the time frame specified by IRB policy. The IRB can then decide whether the protocol/informed consent require revisions, or if it is necessary to suspend or terminate the study.

Examples of such studies are as follows:

Mineral Risk:
• Study: Longitudinal on-line survey of undergraduate students regarding their transition from high school to college life.
• Data Safety Monitoring Plan: To ensure that the instrument used does not contain questions of an offensive or intrusive nature, it will be pilot tested with 10 students prior to being posted
online. If the pilot test results indicate that a question is problematic, the instrument will be revised and submitted as an amendment to the IRB for approval.

**Slight Increase Over Minimal Risk:**
- **Study:** Overweight and obese eighth graders at a middle school will be invited to incorporate 10 minutes of supervised physical activity into their recess time two times per week.
- **Data Safety Monitoring Plan:** The PI will review reports of study activity once per week to ensure that there are no unforeseen risks (i.e., physical injury, unintended consequences, etc.). Individual students will be removed from the study if necessary (i.e., they have received two verbal warnings but persist in unruly behavior). Study procedures will be revised if a greater than average injury rate is observed (e.g., 1 injury per 20 children in a 6 month time period). Events other than those anticipated will be submitted in a timely manner to the IRB on an adverse event form, and the protocol will be revised as appropriate.

**Data Safety Monitoring Officer**
In lieu of generating adverse event reports for each adverse event and sending them to the IRB, investigators can designate a Data Safety Monitoring Officer (DSMO), also known as an independent monitor, or the IRB can require that a DSMO be appointed. For research that is externally funded, the study sponsor may also require a DSMO. In determining whether an independent DSMO is required, the IRB will take into consideration the length of the study, the number of participants to be enrolled in the study, overall risk to participants, and other mechanisms for monitoring that are already in place. The DSMO must be a neutral party, and may not be involved in the research study in any capacity.

The DSMO must have expertise in the fields of medicine or science with a terminal degree, or equivalent professional experience, which are applicable to the study. For biomedical studies, the DSMO may be a physician licensed in the State of Connecticut and approved by the IRB. The DSMO reviews all adverse events occurring in a study to discern if they are anticipated or unanticipated. Anticipated adverse events are aggregated at specified times (e.g., every three months) and may be reported only during re-approvals as long as they remain below a pre-specified threshold (e.g., 1 event per 20 participants enrolled), which is determined by the IRB or the DSMO. Unanticipated adverse events are reported to the IRB in accordance with IRB policy. The IRB can then decide whether the protocol/informed consent require revisions, or if it is necessary to suspend or terminate the study.

**Data Safety Monitoring Board**
In certain studies, the IRB may determine that a Data Safety Monitoring Board (DSMB) must be appointed to monitor research data. The IRB must approve the composition of the board.

A Data Safety Monitoring Board (DSMB) is an advisory committee to the IRB that oversees interim analyses of safety and efficacy of research studies. They are charged with the responsibility of monitoring safety of the participants and efficacy of the treatments being tested. The DSMB helps to dissociate the principal investigator from the accruing data in order to maintain an unbiased review of
the safety of therapies or procedures being studied and to remove those with vested interest from deciding whether or not a study should be continued. The DSMB may determine that additional restrictions/warnings need to be added to the consent form to ensure informed consent.

In blinded studies, the DSMB reviews the reports of interim safety and efficacy analyses by the unblinded study administrator, asks for clarification and further data analyses from the unblinded study administrator, and makes recommendations if needed. The DSMB reviews the interim safety and efficacy reports at pre-specified times in a blinded manner so that the study investigators and data collectors do not know about the interim results unless the study needs to be revised in some way, be suspended or terminated, or upon the successful completion of the study. The times of the interim analyses need to be specified before the start of the study although the DSMB can ask for more frequent checks of data if required.

If a study is progressing well with no safety/efficacy concerns expressed by the DSMB, then the study may continue. The pre-specified interim safety and efficacy reports from the unblinded study administrator are sent to Research Compliance Services for review by the IRB when deciding whether to continue the project during the annual continuation review. A DSMB may recommend suspending a protocol if serious safety or efficacy concerns are raised, but the final determination to suspend will be made by the Chair, convened IRB, DRC, or VPR. If a study is suspended, a report summarizing the concerns is generated and submitted to the IRB for review at the next scheduled meeting.

The DSMB can recommend alteration of methodology (e.g., inclusion/exclusion criteria), updating the informed consent, suspension or termination of a study, but this is in an advisory capacity only. If the decision is split, a minority and majority opinion is written and transmitted to the IRB. The IRB has final say in whether these recommendations are carried out.

The NIH has stipulated that "The establishment of the data safety monitoring boards is required for multi-site clinical studies involving interventions that entail potential risk to the participants." - NIH Policy for Data Safety and Monitoring. June 10, 1998. The NIH further stipulates that: "For earlier studies (phase I and II), a data safety monitoring board may be appropriate if the studies have multiple clinical sites, are blinded, or employ particularly high-risk interventions or vulnerable populations." - NIH Policy for Data Safety and Monitoring. June 5, 2000.

A DSMB should comprise the following members:

- **Chair:** A chair should be selected who is an experienced researcher and, if appropriate, licensed clinician or practitioner (physician, clinical pharmacist, registered nurse or advanced practice registered nurse, psychologist, psychiatrist, social worker, or physical therapist) with a terminal degree, or equivalent professional experience.
- **Members:** Committee members should be selected and the size of the board can be based on the size or risk of the study. For most types of research, committee members should have at
least one person who is a researcher or clinician, statistician or researcher familiar with statistical analysis, and a lay person or someone outside the research area.

Overall, an odd number of committee members should be selected. A standard size DSMB will comprise three individuals (chairman, researcher with statistics experience, and lay person/ethicist/community advocate). Given the advisory nature of the DSMB, the board does not have to meet in person. They can review the safety/efficacy reports from the unblinded study administrator, communicate with other members via e-mail or telephone conference, and then vote on recommendations.

- Unblinded Study Administrator

The unblinded study investigator/administrator is a liaison that generates the data for the DSMB and responds to their data inquiries. The unblinded study administrator is a member of the research team and is paid or supported by the primary investigator's department or the research grant/contract. An unblinded study administrator needs to be experienced in human subject research and statistical analysis of data.

The unblinded study administrator is selected by the research team and may be paid by the research team or department conducting the research. This unblinded study administrator is responsible to the DSMO or DSMB as well as the IRB for providing prespecified interim safety/efficacy analyses and responding to their safety/efficacy queries in a timely fashion. The relationship is summarized by the following figure.

![Figure: Relationship among study entities germane to safety and efficacy.](image)

The UConn IRB acknowledges the contributions of the University of Minnesota for sharing of content in the Data Safety Monitoring Policy.
Adverse Events, Unanticipated Problems, Protocol Deviations, Noncompliance, and Suspensions or Terminations (revised 11-05-09)

DHHS and FDA regulations require prompt reporting to the IRB, appropriate IO, and appropriate federal departments or agency heads of 1) unanticipated problems involving risk to participants or others, 2) any serious or continuing noncompliance with regulations or the requirements of the IRB, and 3) any suspension or terminations of IRB approval.

It is the responsibility of the PI to assess events that occur during the course of a research protocol, and determine which of the following descriptions apply. The IRB will review reports and make a final determination, indicating agreement or disagreement with the PI's assessment, and why.

Adverse Events

An Adverse Event is an event that occurs during the course of a research protocol that either causes physical or psychological harm, or increases the risk of physical or psychological harm, or results in a loss of privacy and/or confidentiality to a research participant or others (such as family members).

An Anticipated Adverse Event is one that is reasonably expected and/or listed in the protocol and consent form as a risk of participating in the research. Examples of an anticipated adverse event include, but are not limited to, the following:

- A participant in an exercise physiology study experiences muscle strain following an exercise session;
- A participant in a study with blood draws experiences light headedness or fainting during the blood drawing process;
- A participant in a study of post-traumatic stress syndrome becomes upset during the re-telling the traumatic event and requires a referral to a counselor.

An Unanticipated Adverse Event is one that was not reasonably expected and/or is not listed in the protocol and consent form as a risk of participating in the research. Examples of an unanticipated adverse event include, but are not limited to, the following:

- A participant in a study of the benefits of eating strawberries experiences a previously undetected allergy to strawberries;
- A child participant in a study of how to improve classroom behavior experiences bullying by other students as a result of her participation in the study.

A Serious adverse event is one whose magnitude or frequency is above expectation. For example:

- Previous research data indicates that the expected rate of an injury from a certain interventional procedure is 1 in 1000, but the same procedure used in a protocol under review has a much higher rate (e.g., 1 in 100);
• An anticipated side effect of a certain dietary protocol results in a much more serious manifestation of that effect than would be expected (i.e., a high-fiber diet results in severe diarrhea and vomiting requiring hospitalization).

A Related adverse event is one that, in the opinion of the investigator, is likely caused by or affects the research.

• A participant in a study about post-traumatic stress disorder experiences a panic attack after telling the investigator about a incidence of childhood sexual abuse;
• A participant in a study about the benefits of a nutritional supplement on recovery from weight lifting experiences an allergic reaction to the product after it is ingested.

Events that are not related to study procedures and are not serious may be reported at the time of re-approval. Examples of unrelated events that may be reported at the time of re-approval include:

• A participant in a study gets the flu and has to withdraw from the study (report as a withdrawal);
• A participant in a longitudinal study of high school students’ transition to college life drops out of school and withdraws from the study (report as a withdrawal);
• A participant in an observational study of child behavior during recess falls on the playground and sprains her ankle (report in summary of findings);
• A participant in a study on the benefits of eating carrots on eyesight reports an incident of food poisoning from eating out at a restaurant and has to miss one of six scheduled visits to the laboratory. The protocol should accommodate for missed session make-ups. If not, this would be reported as a protocol deviation (missed session) but not as an adverse event (food poisoning unrelated to study procedures).

Examples of serious and related adverse events are:

The death of a research participant due to research procedure(s);

• Any change to the protocol made without prior IRB review to eliminate apparent immediate hazard to a research participant or others;
• Any event that requires prompt reporting according to the protocol or the study sponsor;
• A serious breach of privacy or confidentiality of research participants or others (such as family members);
• Any publication in the literature, safety monitoring report, interim result, or other finding that indicates an unexpected change to the risks or potential benefits of the research;
• Any complaint of a participant that indicates an unanticipated risk or which cannot be resolved by the research staff;
• Any other event or other problem which, in the opinion of the PI, was (1) previously unforeseen and (2) presents risks to research participants or others.
Reporting of Adverse Events

Using the Adverse Event Report Form (IRB-4), PIs are required to report to the IRB serious and related events no later than 2 working days after discovery of their occurrence. Events that are not related to study procedures and are not serious may be reported at the time of re-approval. All other events must be reported within 5 working days after discovery of their occurrence. This policy applies to events that occur at UConn or at an off-campus study site.

Unanticipated Problems, Protocol Deviations and Noncompliance

An Unanticipated Problem is defined as any unforeseen event that involves risk to the participant or others that is related to either a research intervention or interaction, or the conduct of the study in general. Examples of unanticipated problems involving risk include, but are not limited to, the following:

- an accidental or unintentional change to the IRB-approved protocol (e.g., the software program for an on-line survey study about college students' use of illegal drugs has a glitch that enables research participants to view other participants' identifiable survey responses);
- a complaint from a participant that indicates an unanticipated risk (e.g., loss of employment due to disclosure of data, etc.);
- unexpected changes to the risk/benefit profile of the study (e.g., based on literature, safety reports, interim results or other findings);
- unforeseen events involving the research team (e.g., the loss of a laptop computer with identifiable participant information, sudden unavailability of the PI and/or co-investigator, etc.);
- unexpected serious adverse events (internal or external) that in the opinion of the PI may be related to the study intervention;
- any change to the protocol taken without prior IRB review to eliminate apparent immediate hazard to a research participant when the immediate hazard is, in the opinion of the PI, related to the study.

Protocol Deviations and Noncompliance are defined as any action that is taken or occurs that is not in accordance with an IRB approved study, IRB policies or regulations, or failure to follow the requirements and determinations of the IRB. Protocol deviations and noncompliance may be minor (e.g., a participant is one day late for a study visit due to a family emergency and there is no impact on the safety of the participant due to the late visit), or may be considered serious or continuing.

Examples of protocol deviations include equipment failures during study procedures, the use of the wrong version of a form (including unvalidated consent forms), and enrolling study participants who do not meet the approved inclusion criteria.

Noncompliance and protocol deviations are considered serious when they create increased risks to participants, adversely affect the rights and welfare of participants, or affect the scientific integrity of a study. Willful violations of IRB policies and/or Federal regulations, including those pertaining to
obtaining informed consent, reporting of adverse events, and disclosure to participants of conflicts of interests and risks associated with a study, are also considered examples of serious noncompliance.

Noncompliance is considered to be continuing noncompliance when a pattern of noncompliance exists that, if allowed to continue, is likely to increase risks to participants, adversely affect the rights and welfare of participants, or affect the scientific integrity of the study. It may involve the same mistake being made repeatedly within one study or across studies (e.g., a co-investigator on two of the PI’s approved studies fails to document participant consent) or the same mistake being made after a corrective plan has been issued to the investigator for previous findings of noncompliance. The IRB will make the final determination as to what constitutes continuing noncompliance.

**Reporting Unanticipated Problems, Protocol Deviations and Noncompliance**

Unanticipated problems are to be reported to the IRB using the Adverse Event Report Form (IRB-4) and must be reported within 5 working days after discovery of their occurrence. This policy applies to events that occur at UConn or at an off-campus study site. The IRB will make the final determination as to whether an incident constitutes an unanticipated problem. Noncompliance and protocol deviations are to be reported to the IRB using the Protocol Deviation Report Form (IRB-6) and must be reported within 5 working days after discovery of their occurrence. The IRB will make the final determination as to whether an incident constitutes serious noncompliance.

**IRB Review of Adverse Events, Unanticipated Problems, Protocol Deviations and Noncompliance**

Adverse Event Report Forms and Protocol Deviation Report Forms are reviewed by the IRB Chair, Vice Chair, or a designated IRB member. Anticipated Adverse Events, Protocol Deviations, and reports of Noncompliance will be reviewed by the IRB Chair or a designee of the Chair within 5 working days of receipt of the report. If it is determined that the event did not represent an unanticipated problem involving risks to participants or others, a letter of acknowledgement is sent to the PI, and the report is filed.

If an Adverse Event, Unanticipated Problem, or Noncompliance is serious, related and unanticipated, or continuing, the IRB Chair or designated IRB member(s) will review the report within 5 working days of receipt of the report, and determine whether the event requires review by the full board. All reports requiring full board review will be placed on the agenda for the next fully convened meeting of the IRB. If necessary, an emergency meeting may be called. IRB members will be provided with a copy of the report and all supporting documentation to review. Pending review by the full board, the IRB Chair and reviewing member(s) will determine whether immediate action, such as suspension of new enrollment or termination, is warranted.

The IRB votes on whether the event is an Unanticipated, Serious or Related Adverse Event or Protocol Deviation, or Serious or Continuing Noncompliance involving risks to participants or others, and the determination of the IRB is recorded in the minutes. If the IRB determines that an event is an
Unanticipated Adverse Event involving risks to participants or others, the procedures outlined in the section of the University's IRB Policies and Procedures entitled "Reporting of IRB Findings to Federal Agencies" will be followed, and the IRB will consider taking the following actions:

1. No action;
2. Modification of the research protocol;
3. Modification of the information disclosed during the consent process;
4. Additional information provided to past participants;
5. Notification of current participants (required when such information may relate to participants’ willingness to continue to take part in the research);
6. Requirement that current participants re-consent to participation;
7. Modification of the continuing review schedule;
8. Monitoring of the research;
9. Monitoring of the consent;
10. Suspension or termination of the research;
11. Confiscation of data;
12. Referral to other organizational entities (e.g., Assistant Attorney General, Dean, Department Head, IO, or Sponsored Programs Services).

If no action is required, a letter of acknowledgement will be sent to the PI, and a copy of the letter filed in the protocol file. If the IRB takes any actions or imposes any requirements, the actions and requirements are documented in the minutes and in a letter to the PI.

**Suspensions and Terminations**

A Suspension of previously approved research is defined as a temporary hold on any or all research activity associated with a study, or a permanent stop to some portion of a previously approve research activity. For example, a hold placed on additional recruitment pending clarification of an adverse event would be considered a suspension of approval. Suspended protocols remain open and require continuing review.

Termination of previously approved research is defined as a permanent withdrawal of study approval that requires all study related activity to cease.

In the event of an unanticipated problem, serious or continuing noncompliance, or a suspension or termination of approval, the IRB may require corrective or disciplinary action including, but not limited to, the following:

- a modification of the protocol or information disclosed in the informed consent document and process;
- information be provided to past participants;
- current participants be informed if the information may relate to their willingness to participate;
• re-consenting of currently enrolled participants;
• more frequent continuing review
• monitoring of the consent process or research project by a third party;
• requiring additional education;
• barring an investigator from conducting human participant research.

The IRB or IO may seek counsel from other institutional areas (e.g., legal counsel) in determining corrective action plans. The IRB may make recommendations regarding employment status but has no authority over an individual’s employment status.

The DRC will also review the underlying reason that caused the noncompliance or unanticipated problem to occur or for which a suspension or termination is imposed and may require that additional corrective action be taken to prevent subsequent occurrences. Corrective action may include, but is not limited to, the following:

• requiring additional education of the investigator;
• clarifying existing policies or implementing new policies;
• enhancing overall educational activities provided to investigators.

Suspension or Termination of IRB Approval
The Chair, convened IRB, DRC, or VPR may suspend a study. The authority to suspend studies cannot be delegated to other individual members of the IRB, except the Vice Chair. The convened IRB or VPR may terminate a study.

Reasons for imposing a suspension or termination include, but are not limited to, learning of 1) previously unanticipated risks to participants, 2) findings of serious or continuing noncompliance, or 3) findings from the continuing review or internal monitoring process. The IRB or IO may also seek advice from other institutional areas (e.g., legal counsel) in determining whether to impose a suspension or termination of IRB approval. In addition, when imposing a suspension or termination, the IRB or IO will give consideration to the impact that the suspension or termination may have on participant safety and/or welfare. Consideration will include, but is not limited to:

• whether participation can be stopped safely;
• whether participants should be transferred to another physician for clinical care, if applicable;
• whether participants can be kept on study under the same PI;
• if kept on study under the same PI, whether additional monitoring is required;
• whether participants can be kept on study under another PI.

In the event of a suspension or termination of approval, the IRB or person imposing the suspension or termination will inform the investigator in writing. If immediate action is required, the person imposing the suspension or termination may give the directive verbally to the PI and the letter will follow. Letters
to the PI should be sent within 5 working days of the effective date of suspension or termination. Such letters will include:

- the effective date of suspension or termination;
- if notification was initially done verbally the letter will reference the date of verbal notification;
- the reason for the suspension or termination;
- for suspension, identification of the research activity, in whole or in part, that must stop;
- any corrective action or clarification that must occur;
- if the reason for suspension may bear on the participant’s decision to continue participation, a directive that currently enrolled participants be informed of the suspension;
- for terminations, a directive that all currently enrolled participants be informed of the termination;
- if applicable, a directive of how to deal with any currently enrolled participants; and
- a direction to the PI regarding to whom to submit responses.

The person or board imposing the suspension or termination will send a copy of the letter to:

- IRB Chair and Vice Chair;
- Director of Research Compliance (DRC);
- The IO (VPR); and, if applicable
- Office for Sponsored Programs;
- The Attorney General’s office; and
- The Dean of the PI’s school.

Letters issued by the IRB will be prepared by the IRB staff; reviewed, approved and signed by the IRB Chair; and sent by the IRB staff. If imposed by the IO, that individual is responsible for the preparation and sending of the letter. The IRB Chair is responsible for directing IRB staff to include any notice of suspension or termination on the next meeting agenda for presentation to and review by the convened board. The investigator is to direct a written response to the person who imposed the suspension/termination and copy the other individuals noted on the initial suspension/termination letter.

If an activity for which a suspension or termination has been imposed must continue, e.g., a research related treatment because it is in the best interest of the participant, the investigator must write a letter to the IRB Chair. The letter shall include:

- a justification as to why continuation is in the best interest of the participant;
- a request for approval for continuation of the specific activity either until the suspension is lifted or until alternate arrangements can be made for the participant;
- for terminations, confirmation that alternate arrangements are actively being sought and provide the anticipated time frame by which the arrangements should be finalized;
• confirmation that the investigator will inform participants that the study has been suspended or terminated but that permission for the activity has been obtained;
• confirmation that the investigator will direct participants to continue to report adverse events or unanticipated problems;
• confirmation that the investigator will continue to report all activity in accordance with policy.

Lifting a Suspension
Only the IRB can lift a suspension using either the expedited review process or full board review. If the DRC or VPR imposed the suspension, that person is responsible for notifying the IRB Chair in writing when s/he is satisfied that all concerns that led the suspension have been satisfied and to recommend lifting the suspension. That person must attach a copy of the responses from the PI to the letter to the IRB. The IRB Chair may use the expedited review process to lift a suspension:

• that was imposed by the Chair;
• that was imposed by the IO, providing the documentation noted above is received; or
• that was imposed by the convened board when the board specifically delegates to the chair the authority to lift the suspension;
• otherwise, the convened IRB will determine whether to lift a suspension.

The IRB will send written notification to the PI when the suspension is lifted. The letter will be prepared by the IRB staff, reviewed and signed by the Chair, and sent out by the staff. The IRB staff will also send a copy of the letter lifting the suspension to the individuals identified above.

Reporting of Unanticipated Problems, Noncompliance, Protocol Deviations, Suspensions or Terminations to the IRB
Events that may be considered unanticipated problems involving risk to participants or noncompliance that occurs within the control of the research team, or a suspension or termination of study approval, must be reported to the RCS within five business days of becoming aware of the event and at the time of continuing review. Events are reported to the IRB in one of four ways:

• the investigator self reports;
• the IO, DRC or IRB Chair refers an audit finding to the IRB for determination; or
• the IO issues a letter of suspension or termination and copies the letter to the IRB.

Self Reporting
Please note that PIs should not undertake any action with an external funding agency regarding an unanticipated problem or noncompliance without contacting the IRB Chair, the DRC or the RCC. Unanticipated problems and noncompliance should first be reported to an appropriate institutional official in order to determine the correct course of action.
PIs are to report to the IRB any serious noncompliance that occurs within the control of the study team or any unanticipated problem that may be related to the study within 5 days of becoming aware of the event. All instances of noncompliance or unanticipated problems are also to be reported at the time of continuing review. For example, if a participant is two days late for their visit because the participant canceled an appointment, the deviation would be reported at the time of continuing review. However, if the PI scheduled the participant’s appointment two days outside of the follow-up window the deviation should be reported within 5 days of becoming aware of it. The PI should use the protocol deviation report form for reporting to the IRB, or the adverse event report form, if applicable. If the PI proposes a corrective action that will require a change to the protocol or study related documents the PI must complete, sign and submit a request for approval of amendment form in conjunction with the protocol deviation report form.

Upon receipt of a protocol deviation report form, the IRB staff will forward the report and any supporting documentation to the IRB Chair or Vice Chair for review and determination of action. The IRB staff will also provide the Chair with the complete IRB file of the study to which the event relates. The IRB Chair may determine that the event does not constitute an unanticipated problem, or serious or continuing noncompliance, or the Chair may determine that full board review is required.

If the Chair determines that the event does not constitute an unanticipated problem, or serious or continuing noncompliance, that determination will be presented to the convened board for informational purposes at the next convened meeting. Any member of the board may request that the convened board review the report and corresponding information as noted below. In reviewing the events, the Chair may also require the PI to take corrective actions. Any required actions will be communicated to the PI via the IRB staff (by memo or e-mail) as directed by the Chair.

If full board review is required, the IRB Chair will direct the IRB staff to make additional copies of the form and the supporting documentation for distribution to each member of the IRB as part of the packet for the next regularly scheduled meeting. The Chair will also determine whether any additional supporting documentation is required and direct the staff to make copies accordingly. At a minimum, all IRB members will receive a copy of the protocol deviation report form, a copy of the current approved protocol, and copies of any supporting documentation that was submitted with the protocol deviation report form. The complete IRB file will also be available for review at the meeting. The Chair will lead the discussion of the report at the meeting.

If the protocol deviation report is accompanied by a request for modification form, the IRB staff will note the modification and discussion item on the agenda. Procedures previously described for the submission and review of amendments will be used for review and approval of the modification.

**Referral of Adverse Event**

When an adverse event is referred to the convened IRB by the IRB Chair, s/he is responsible for preparing the information for the IRB staff for inclusion on the meeting agenda and in the IRB packets.
All IRB members will receive at a minimum the complete adverse event report, the informed consent form, the approved protocol, and any additional material that was reviewed by the Chair. The Chair may elect to review additional material, including the protocol. The complete IRB file will be available at the meeting. Adverse events that may constitute unanticipated problems will be reviewed by the convened board. The Chair will lead the discussion of the event at the meeting.

**Referral of Audit Findings**

The IRB Monitor, who prepares the final audit correspondence for signature by the IRB Chair, is responsible for ensuring that audit letters containing a referral to the IRB are provided to the IRB staff for inclusion on the meeting agenda and in the packets distributed to members. All members will receive, at a minimum, the audit letter and the current consent form. The Monitor will coordinate with the IRB Chair to determine whether additional documentation should be included. The Chair may elect to review additional material, including the protocol. The complete IRB file will be available at the meeting. The Chair will lead the discussion of the audit finding at the meeting.

**Reporting Unanticipated Problems, Serious or Continuing Noncompliance, Protocol Deviations, Suspensions or Terminations to Institutional Officials and External Agencies**

Study suspensions or terminations, or determinations of unanticipated problems or serious or continuing noncompliance are communicated to the IO in one of two ways: via copy of a suspension or termination letter, and/or via copy of the IRB minutes. IRB staff complete and forward the minutes to the IO within one week of the meeting date.

The IO will report in letter format to the OHRP within the DHHS and when applicable to the FDA or other regulatory agency with oversight due to conduct or an assurance of compliance. The IO will copy the IRB Chair or Vice Chair, the PI, the DRC and RCS on such letters. The letter may be written by the IO or delegated to RCS staff with review, approval and signature of the IO. The letter will be mailed by the RCS staff. The letter will contain:

- the protocol number and title of the study;
- the name of the PI;
- a summary description of the problem and the cause;
- the date of occurrence;
- the corrective actions taken or to be taken;
- and any plans for ongoing monitoring.

Reporting to federal agencies is not required if the agency is already made aware of the event through other mechanisms, such as reporting by the investigator, sponsor or another organization. Letters will be issued within two weeks of the IRB determination, suspension or termination. The DRC will be responsible for informing any funding agencies.
Undue Influence
The DRC shall report to the IO any instance of an individual(s) attempting to influence the IRB staff, any IRB member or the IRB if, in the opinion of the DRC, the attempt to create the influence is willful and knowing. The DRC may exercise the authority to conduct an audit or investigation, suspend or terminate studies previously approved for that individual, or to suspend that individual’s involvement in studies for which s/he is not the PI. The DRC may also take other appropriate actions based on the findings, including recommending disciplinary action to the IO, including termination of employment. Such instances may be reportable as issues of serious noncompliance. If the DRC is the individual creating undue influence, the report is to be filed directly to the IO.

Allegations of Noncompliance with RCS/IRB Requirements
The RCS has the responsibility of dealing with reports of any known or suspected violations of laws, regulations, standards, policies and procedures that apply to UConn if the concern pertains to a human participant protection issue. The RCS retains the responsibility for ensuring that: 1) all activities are carried out in a fair and unbiased manner; 2) those reporting concerns are treated fairly and that their confidentiality is protected to the extent possible; and 3) no retaliation takes place.

Allegations of noncompliance with policies pertaining to human participant protection may be filed with the RCC, IRB Chair, or DRC.

Procedures for Filing an Allegation
Individuals can submit reports in writing or orally. Reports may be submitted anonymously. If a phone call is the initial method of communication, the person receiving the call will inform the caller that the content of the conversation is being documented and that while efforts will be made to protect the caller’s identity, protection cannot be 100% guaranteed. The reporting individual’s identity may become known during the normal course of an investigation. If the concern is received by the Chair, the Chair will share the information with the DRC and vice versa.

Allegations may encompass, but are not limited to, the following areas:

- performance of research on human participants without IRB approval;
- failure to conduct research in accordance with the terms of the IRB’s approval;
- failure to conduct research in accordance with regulatory requirements;
- failure to obtain informed consent from participants prior to involvement in the study;
- failure to report unanticipated problems or noncompliance in accordance with policy;
- failure of the IRB to act in accordance with its responsibilities to protect human participants; or
- failure of study personnel to act in accordance with their responsibilities to protect human participants.
Processing an Allegation

The RCS will process allegations to: •Evaluate the nature of the complaint to determine if participants may be at risk.

a. If participants may be at risk, an immediate suspension will be placed on the relevant research activities by notifying the PI. Policy for imposing a suspension will be followed and required reporting will occur.

• Exercise one of three options:
   a. Act alone to resolve the issue. The DRC or IRB Chair may exercise this option if the nature of the allegation is such that participants are not at risk, the integrity of the data is not compromised, or the resolution appears to be a simple matter of clarifying the issue with the investigator, and there does not appear to be knowing or willful noncompliance on the part of the investigator. The DRC or IRB Chair may still elect to exercise the options noted below after having exercised this option.
   b. Direct the IRB Monitor to conduct a for-cause audit (refer to monitoring of approved studies section). This option may be exercised by the DRC or IRB Chair if the nature of the allegation is such that participants may be placed at risk, the integrity of the data may be compromised, or the noncompliance appears to be knowing and willful. The DRC or IRB Chair may still elect to exercise the option noted below after having exercised this option.
   c. Conduct a full investigation. The DRC or IRB Chair may exercise this option based upon audit findings that appear to substantiate an allegation of willful and knowing noncompliance, or based upon the nature of the allegation and consideration as to whether similar allegation have been reported concerning the same individual. The DRC or IRB Chair may consult with the full board and/or counsel in determining whether to proceed with an investigation.

Option a or b is to be exercised within 5 business days of becoming aware of the event.

In general, when the option to investigate is exercised, the DRC or VPRGE will appoint an ad-hoc committee of at least three members to perform the investigation. One member will be charged with leading the investigation and may delegate tasks and determine how to approach the investigation, e.g., to have the entire committee interview study personnel, to have one committee member interview personnel and one review data, or to involve or not involve external collaborators or consultants in the investigation process. The committee will be comprised of individuals knowledgeable of the research topic and the regulations and ethical principles governing human research. The approach to be used must be approved by the DRC prior to starting the investigation. The investigation must start within 2 weeks of the date the decision to investigate is made.

Individuals about whom the allegation was made will be notified in writing by the DRC (or VPRGE if applicable) that the investigation is to be initiated and will be provided with an explanation of the
allegations. Investigations may encompass a review of all files (electronic and paper), and data that are relevant to the allegation, interviews with relevant personnel, or any other area deemed necessary to conduct the investigation.

Individuals about whom the allegation is made have the right to give testimony on all aspects of the report and on all of the evidence acquired by the investigation committee, to call witnesses and to be represented by legal counsel.

The DRC will instruct the committee to conduct the investigation in a confidential manner. In most circumstances, investigations should not exceed a two month period based on the date of initiation. If a longer time period is required, the reasons will be explained in the final report. The final report will be prepared and signed by the Chair of the investigative committee and sent to the VPRGE and DRC. The report will contain a summary of the allegation, a description of the investigative process, the findings, supporting information, and the suspected cause for the occurrence (e.g., deliberate choice by the investigator, lack of training of the investigator, confusing policies, etc.). If an allegation is unsubstantiated, the DRC will report back to the individual against whom the allegation was made via memo, with copy to the IRB Chair. If a suspension had been imposed, the letter will also be copied to the individuals identified in the section regarding imposing suspensions and the DRC will recommend lifting the suspension to the IRB.

If an allegation is substantiated via audit or investigation, the DRC will forward the final report from the audit or the investigation to the IRB staff for inclusion as a discussion item on the next agenda of the convened IRB. The final report from either the DRC or the investigative committee will be presented in memo format and will contain the information noted above. The IRB staff will distribute the final report and the currently approved consent form to all members of the IRB as part of the meeting packet. The Chair will facilitate the discussion at the meeting. The convened IRB will determine if the finding is one of serious or continuing noncompliance or unanticipated problems involving risks to participants or others. The IRB will also determine the course of corrective action and may recommend disciplinary action. Any member of the IRB may request additional material from the investigator, to review the complete IRB file, or previous meeting minutes.

Corrective actions include, but are not limited to, the following:

- modification of the protocol or information disclosed in the informed consent process;
- additional information be provided to past participants;
- current participants be informed if the information may relate to their willingness to participate;
- re-consenting of currently enrolled participants;
- more frequent continuing review;
- monitoring of the consent process or research project by a third party.
Any requirements for corrective action will be communicated to the investigator via memo from the Chair. The memo will be prepared by the IRB staff, reviewed and signed by the IRB Chair and sent by the IRB staff. The IRB staff will document required actions in the IRB minutes. Any corrective action requiring a change to the approved protocol must be submitted by the investigator via a request for approval of an amendment to the IRB. The IRB may also seek counsel from other institutional areas in determining a course of action (e.g., legal counsel). The VPR will follow through with any required reporting.

The DRC will review under what circumstances the situation occurred and when possible will take corrective action, such as developing or clarifying policies or providing additional training to investigators, to prevent similar occurrences.

**Responsibilities of Research Investigators and Research Study Personnel**

**Principal Investigator**

The IRB holds the PI responsible for the overall management of an approved study. Management of the study encompasses the ethical, technical, administrative, and fiscal elements of a project. The PI may delegate certain tasks, but retains ultimate responsibility and accountability. Research investigators are required to:

- Acknowledge and accept their responsibility for protecting the rights and welfare of human research participants, including the equitable selection of research participants, ensuring that risks to participants are minimized, and that the risks are reasonable in relation to anticipated benefits,
- Fulfill the training requirement for the protection of human participants in research (CITI on-line training modules, www.citiprogram.org), and to understand the ethical standards and regulatory requirements governing research activities with human participants,
- Supervise all study personnel and ensure that all personnel abide by the ethical principles of respect for persons, beneficence and justice, as outlined in the Belmont Report,
- Ensure that all study personnel are knowledgeable of, and conduct the study in accordance with the approved protocol (including approved amendments),
- Ensure that all research activities have IRB approval and other approvals required by the institution before human participants are involved, and implement the research activity as it was approved by the IRB,
- Report any real or potential conflicts of interests of the PI or any study personnel in compliance with conflict of interest policies and management plans,
- Obtain informed consent from participants before participants are involved in the research, and document consent as approved by the IRB. A copy of the IRB-approved informed consent document must be used at the time of consent. Participants must be provided with a copy of the form after it has been signed, unless the IRB has specifically waived this requirement.
Documented evidence of informed consent of the participants or their legally authorized representative is to be retained in a manner approved by the IRB,

- The consent process involves two required elements: 1) a discussion of the study by the person obtaining consent and the participants, and 2) an opportunity for participants to read the consent form. Please note that it is never appropriate to forgo the discussion, even if participants will then read the consent form. Participants must be given the opportunity to have the consent form read to them if they have difficulty reading,

- Maintain written records of IRB reviews, decisions, research records and informed consent documents,

- Obtain IRB approval for and notify the sponsor (if applicable) of any proposed change to the research protocol prior to its implementation, except when necessary to eliminate apparent immediate hazards to the participants,

- Should not undertake any action with an external funding agency regarding an unanticipated problem or noncompliance without contacting the IRB Chair, the DRC or the RCC. Unanticipated problems and noncompliance should first be reported to an appropriate institutional official in order to determine the correct course of action,

- Obtain re-approval by reporting progress of approved research to the IRB, in the manner prescribed by the IRB, but not less than once per year,

- Promptly report to the IRB any adverse events, protocol deviations or other unanticipated problems involving risks to participants or others,

- Verify that IRB approval has been obtained from all participating institutions in collaborative activities with other institutions, and that continuing review by other institutions is maintained,

- Ensure the confidentiality and security of all information obtained from and about human participants, and the privacy of participants is maintained,

- Use the most current version of IRB forms and document templates, which can be downloaded from the IRB website,

- Oversee the budget and expenditures related to the study to ensure that adequate resources are available, including staff, equipment supplies, storage space etc., to conduct the study at the University and any other performance site for which the PI is responsible,

- Ensure charges assessed to insurance carriers are for procedures for illness or injury directly resulting from the research procedures of the study, if applicable,

- Provide the IRB with audit or inspection reports or findings issued by regulatory agencies, cooperative research groups, contract research organizations, the sponsor or the funding agency,

- Communicate, when applicable, the investigator’s plans to meet with representatives of the community from which individuals will be recruited, about community concerns, values and expectations,

- Maintain, when applicable, accurate records on the receipt, use and disposition of excess drugs/devices,

All Study Personnel (including PI and co-investigators)
The IRB holds all study personnel responsible for meeting certain obligations. Study personnel are required to:

• Fulfill the training requirement for the protection of human participants in research (CITI on-line training modules, www.citiprogram.org), and understand the ethical standards and regulatory requirements governing research activities with human participants,
• Comply with applicable IRB policies and procedures,
• Document contact with participants, e.g., obtaining informed consent or informing participants of changes that may affect their willingness to continue participating,
• Provide a thorough explanation of the study in lay terms to the participant during the consent process,
• Provide the participant with an opportunity to ask questions and have them answered when obtaining informed consent and throughout their participation,
• Understand the appropriate use of an investigational intervention (drug or device) as described in the protocol, investigator brochures, product information/drug labeling, and various other available sources such as newsletters, safety alerts, or communications from sponsors, if applicable,
• Be familiar with and follow the adverse event and protocol deviation reporting requirements.

Record Retention
IRB staff will retain records in accordance with Federal regulations. Connecticut currently has no required retention period for IRB records.

IRB Study Records
The RCS will maintain complete files of all active studies on site.

The IRB staff arranges to have closed study files moved to a permanent, secure location in the basement of the Whetten Graduate Center for archiving. Files may not be destroyed until after Federal retention requirements are met. A list of closed files is available from the InfoEd database. Files are retrievable immediately for future reference to allow for inspection and copying by regulatory agencies, including the OHRP and FDA, at reasonable times and in a reasonable manner.
IRB Meeting Documentation
The IRB staff maintains a hard copy of the agenda and meeting minutes in 3-ring binders. Hard copies of the approved list of exempt and expedited protocols, a status report of protocols previously reviewed at IRB meetings, and educational materials are also attached to the minutes and retained in the binder. A hard copy of the minutes is also provided to the IO. The IRB staff also maintains electronic copies of the agendas and minutes for a given calendar year in a folder shared by the RCS and IRB staff. The IRB staff maintains hard copy files of meeting documentation on site for at least three years. The IRB staff may archive these files as dictated by space needs. Files are not destroyed. Files are retrievable immediately to allow for inspection and copying by regulatory agencies, including the OHRP and FDA, at reasonable times and in a reasonable manner.

Investigator Study Records
Per federal regulations (45 CFR 46.115(b) and 21 CFR 56.115(b)), investigators must maintain research records for three years beyond the completion/termination of the study.

Per FDA regulations for investigational new drugs (21 CFR 312.62) investigators must retain records for a period of 2 years following the date a marketing application is approved for the drug for the indication for which it was investigated; or, if no application is to be filed, or if the application is not approved for such indications, until 2 years after the investigation is discontinued and the FDA is notified.

Per FDA regulations for Investigational Devices (21 CFR 812.140) an investigator or sponsor shall maintain the study records during the investigation and for a period of 2 years after the latter of the following two dates: the date on which the investigation is terminated or completed, or the date that the records are no longer required for purposes of supporting a premarket approval application or a notice of completion of a product development protocol. An investigator or sponsor may withdraw from the responsibility to maintain records for the period required and transfer custody of the records to any other person who will accept responsibility for them (including the requirements of § 812.145). Notice of a transfer must be given to FDA no later than 10 working days after transfer occurs.