Standard Operating Procedures for the Institutional Review Board (IRB)

MEMBERSHIP
Membership is in accordance with 45 CFR 46.107 (see Appendix 1) and with current OHRP guidance. Membership shall include both scientists and non-scientists as well as general community members.

The Chair is appointed by the Provost.

University of Delaware faculty/staff members will be nominated by the Deans in concurrence with the Chair and will be appointed by the Provost.

Outside members, who are those members not affiliated with the University of Delaware community, will be nominated by the Chair and appointed by the Provost.

Members shall serve for terms of three years, renewable with concurrence of the Deans, Chair and the Provost. All members will complete human subjects protections and IRB training prior to starting each term. Members are expected to attend regularly scheduled IRB meetings.

When deemed appropriate by the Chair and the Provost (e.g. absence due to sabbatical), a member may have a designated alternate. In such cases, the alternate is expected to attend and fully participate in any IRB meeting the primary member is unable to attend. Alternate members must meet the same training requirements as the full member for which they serve. If a primary member and his/her alternate are both in attendance at a meeting, only one will count towards quorum and only the primary member’s vote will be counted. The exception will be that if a protocol under consideration involves prisoners, the prisoner advocate’s vote is the one which will be counted.

MEETINGS
Meetings are held monthly. Generally meetings will be at noon on the third Wednesday of each month. Meeting dates and times are posted on the Research Office web site.

A quorum consisting of 50% of current full membership + one is required for each meeting. A non-scientist member is required for quorum. Quorum will be verified at the start of the meeting and each time a member leaves during the course of the meeting.

Prisoner advocate attendance is required for the consideration of any protocol involving prisoners as research subjects.

IRB decisions will be made based on the vote of the majority of the eligible members present at the meeting.
It is important that members of the IRB avoid potential conflicts of interest. A potential conflict of interest occurs when a reasonable outside observer might perceive the circumstances as creating an apparent conflict of interest. Examples of such potential conflicts include an IRB member having a close personal relationship with a researcher submitting a proposal, an IRB member serving as a researcher on the proposed project, or an IRB member serving as a consultant to the project. In cases where a potential conflict of interest exists, the IRB member is expected to recuse from participating in the evaluation of the protocol (i.e. leaving the room and not participating in discussion of the protocol or voting).

**RECORDS**
The Federal-wide Assurance is signed by the Provost.

Various IRB authorizations including inter-institutional agreements exist in conjunction with the Assurance. Records related to these authorizations are maintained in the Research Office.

Meeting minutes are kept electronically, are provided to the IRB each month, and are available on the Research Office servers. Effective August, 2009, meeting minutes are stored on the IRBNet system.

Lists of newly approved expedited and exempt research protocols are provided to the full IRB each month at the monthly meeting.

Protocol files contain the correspondence and documents related to a specific protocol. Paper records of protocols approved before July, 2009 are maintained in the Research Office. Starting on August 1, 2009, protocol records for new protocols will be stored in IRBNet. Documents relating to protocols originally reviewed prior to August, 2009, but which are being renewed via annual review will be loaded into the IRBNet record for that protocol as a historical document. Protocol records are maintained for three years after the termination of all associated research activities. Researchers are expected to maintain consent forms related to the project for the same period. If a researcher leaves the University of Delaware, the records must be transferred to the central IRB office or, in the case of a student, to the research supervisor.

Information about all protocols active before August, 2009 including approval and expiration dates is maintained in a database in the Research Office. Starting in August 2009, protocol information is maintained in IRBNet.

**PROCEDURES FOR PROTOCOL REVIEW**
Protocols must be submitted via IRBNet.

Protocols will be classified as Exempt, Expedited or Full Board approval using the definitions provided in 45 CFR 46 (see Appendix 1). The IRB administrator and the Chair are responsible for the appropriate classification.

Research submitted as “Exempt” is reviewed and approved by the IRB administrator (a voting member of the IRB) in conjunction with the Chair if so determined to be Exempt.
research does not require continuing review. Exempt protocols are valid for a period of three years.

The categories of research eligible for Expedited Review are listed in Appendix 2. Research submitted as Expedited is reviewed by one or more voting members of the IRB. The review will include at least one IRB member with specific expertise in the area of the research. Expedited Reviewers may approve the protocol, approve the protocol with revisions, or refer the protocol to full board review. All Exempt and Expedited Review approvals will include a statement of the applicable exemption or expedited review category (effective 11/1/09).

Exempt and expedited protocol reviews are performed on a rolling basis. Due dates for full board protocols are posted on the Research Office calendar. Incomplete protocols will be returned without review.

Full board protocols will be made accessible to board members no less than one week prior to the monthly meeting. Members are expected to review all protocols and provide comments electronically via IRBNet to the Chair and the IRB administrator no later than noon on Monday before the Wednesday meeting. The IRB administrator is responsible for making sure that comments are compiled and provided to the researchers prior to the meeting.

Researchers will meet with the board to discuss any concerns about the protocol. Student researchers are expected to attend with their research supervisors. The IRB administrator is responsible for communicating the results of the review to the researchers and for overseeing the completion of any requested modifications prior to final approval of the protocol. This communication will take place via IRBNet.

When a protocol is approved by full board review, the board shall also make a determination of risk using the definition of 45 CFR 46.102(i) Minimal Risk. If the board determines that the proposed research meets the definition of Minimal Risk, it will further make a determination of whether continuing review of the project may be Expedited under Category 9 if no new risks are identified. If any member requests full board continuing review or if new risks are identified prior to or at the time of the renewal, the continuing review will be considered by the full board at a convened meeting.

The protocol approval date will be the date on which the final approval of the documents is made, and the expiration date will be no more than one year – one day from the date the protocol was reviewed by the IRB.

The IRB may use outside consultants in the review of protocols in the event that no member has particular expertise required to address human subjects protection concerns associated with such protocols.

CONTINUING REVIEW AND AMENDMENTS TO PROTOCOLS
All amendment requests will be made through the IRBNet system using the protocol amendment form. The IRB administrator will determine the level of review and appropriate reviewers required for the amendment.
Notification of the pending expiration of protocols is sent via email to the researcher two to four weeks prior to the expiration date along with the Protocol Renewal Form. Notification will come from the IRB administrator or support staff.

A copy of the original approved protocol will be made available to the IRB reviewers at each continuing review.

Continuing review of protocols will occur within one month prior to the expiration date. In accordance with OHRP guidance, renewed protocols will retain expiration one year from the original expiration date.

**DETERMINATION OF WHICH PROJECTS REQUIRE MORE THAN ANNUAL REVIEW**

The IRB will determine the need for more frequent review on a case by case basis. The IRB may request that the PI report back after a fixed period of time (3 or 6 months) or after a specific number of participants have been enrolled. The shorter review period will be used only when the IRB agrees that the proposed procedures are in compliance with 45 CFR 46, but there may be some concern about the activity or recruitment.

**PROCEDURES FOR AUDITING**

Random auditing will be performed to ascertain general compliance with approved procedures. In addition, all protocols determined to have more than minimal risk will be audited at regular intervals. Any continuing review indicating that changes to the protocol might have been made without prior approval will be audited prior to renewal of the protocol. Any documented unapproved changes in protocols will be referred to the full IRB for consideration.

**REPORTING UNANTICIPATED ADVERSE EVENTS AND SERIOUS OR CONTINUING NON-COMPLIANCE**

Researchers are required to report any unanticipated problems (see Appendix 3 for OHRP guidance) involving risks to subjects to the IRB administrator within 24 hours of the event. The administrator will work with the Chair to determine what further actions are required, including suspension of the protocol until the matter is fully investigated. Notification of protocol suspension and reinstatement will be made to the PI in writing.

If the IRB administrator or Chair receives a report or by way of audit determines that there is serious or continuing non-compliance with an approved protocol, the IRB administrator and the Chair will work together to assess the nature of the non-compliance, and any mitigating factors. The issue may be addressed by the full IRB. Protocols may be suspended during the investigation process. The Chair and the IRB administrator will prepare a report for the Institutional Official, who will report the event and findings to OHRP and appropriate funding agencies as required.