1.0 POLICY

1.1 Policy Statement

1.1.1 All protocols submitted for full Institutional Review Board review must be received sufficiently in advance to allow adequate review.

1.1.2 Protocols submitted for full board review must satisfy criteria for completeness before they are assigned to full board meeting agenda.

1.1.3 If research is supported by a federal agency with specific requirements, such as the U.S. Department of Defense (DoD) or the U. S. Department of Energy (DOE), the research compliance staff will inform the IRB of those requirements for the review and conduct of the research.

1.1.4 Each new protocol will be assigned to a primary reviewer.

1.1.5 Primary reviewers will present an in-depth review of the protocol at the convened meeting, including a description, an evaluation of the validity of the research protocol, an evaluation of the adequacy of the proposed consent process and documentation, conformity to applicable regulations, the presence of a declared or undeclared conflict of interest by the investigator, an estimation of potential risk to participants, and evaluation of any requests for waivers.

1.1.6 All board members are responsible for reading of each protocol in preparation for the full board meeting and for contributing to the discussion.

1.1.7 All conflicts of interest regarding the review of protocols will be identified in advance of discussion and recorded.

1.1.8 The opinions and advice of consultants will be sought when IRB membership lacks adequate expertise or credentials to adequately review human subjects research. Consultants may but do not have to attend the meeting and do not vote on the proposal.

1.1.8 The identity of board members making comments will be confidential. Speakers may not be identified in the minutes or by members outside of the IRB meeting. IRB chairs and members will sign a pledge of confidentiality regarding IRB applications and deliberations at the first IRB meeting of the academic year (September).

1.2 Objective
1.2.1 To ensure that a complete and systematic review of human subjects’ research is performed by individuals with adequate expertise.

1.3 Responsibility.

1.3.1 The Director of Research Compliance (DRC), Research Compliance Specialists (RCS), and IRB Chairs are charged with ensuring that protocols are complete and ready for review by the convened IRB. The same are responsible for providing complete materials for review in a timely fashion to the members of the IRB as well as obtaining consultants as necessary to provide adequate review of human subjects’ research. All board members are responsible for full review of each protocol in preparation for the full board meeting, including the existence of declared and undeclared conflicts of interest for PIs and research staff and its impact on participant safety and research integrity. All IRB members, legal counsel and consultants are responsible for disclosing their own conflicts of interest.

2.0 PROCEDURE

2.1 Applications for approval of research involving human subjects must be submitted to the Office of Research Compliance (ORC) by the 15th of the month prior to the convened meeting at which they are reviewed. This includes original submissions, modified and renewal applications that originally received full board review, and proposals originally submitted for expedited review that were judged ineligible for that level of review.

2.2 The Research Compliance Specialists for each IRB will review the submitted applications for completeness using FORM: Completeness of IRB Application and notify principal investigators of any missing elements. Proposals must be complete before any further processing.

2.3 The DRC, the IRB Chair, and the appropriate Research Compliance Specialist will meet prior to convened meetings (“the preparation meeting”) in order to designate primary reviewers with the necessary scientific expertise and to identify any need for additional expertise beyond the capacities of the IRB membership. The IRB Expanded Member Rosters and the DRC’s and IRB Chair’s personal knowledge of the members will provide the basis for reviewer designations and their seeking of consultation.

2.4 At least one IRB member is provided sample consent documents (when applicable), an approved protocol (when applicable) and any relevant grant.

- least one member is provided and reviews the investigator’s brochure (when one exists).

2.5 At least one member is provided and reviews the investigator’s brochure (when one exists).

2.6 After at least two months of board membership (three for members without previous IRB experience), new members of IRB will be given opportunities to serve as primary
reviewers and gain experience. To promote adequate reviewing, an experienced member will assist the new member to prepare the review.

2.7 The RCSs will deliver protocols to all board members at least 5 working days prior to the convened meeting at which they are reviewed. Such delivery will be satisfied by providing board members with access to an electronic copy of each protocol. All members receive all materials submitted by the investigator.

2.8 Primary reviewers will be asked to review assignments immediately upon receipt, identify any actual or potential conflict of interest, and notify the IRB Chair. This may lead to reassignment of the protocol.

2.9 Members of the IRB who are not primary reviewers will declare actual conflicts of interest or appearances of potential conflicts as soon as they are known in order to facilitate maintenance of a quorum, or at the latest, as each protocol is raised for discussion and before discussion begins. These declarations will be recorded in the minutes. The IRB Chair and the full board will decide whether the member in conflict may remain for the discussion in order to provide information about the proposal or whether the member should leave the room. In either case a member in conflict will not vote on the proposal.

2.10 If the Chair has a conflict, the Vice-Chair will preside over the discussion. If the Vice-Chair is unavailable, the DRC will preside.

2.11 Primary reviewers may also request external consultation before the convened meeting. (See FORM: Request for External Consultation).

2.12 Before the meeting is called to order, the IRB Chair will determine that a quorum is present. Consistent with federal regulations, a quorum is defined as a simple majority of members, one of whom is a nonscientist and one who represents an unaffiliated member. If proposals require a prisoner representative or a licensed physician with liability coverage, their presence will be verified. If proposals involve participants likely to be vulnerable to coercion or undue influence, the IRB Chair will verify that at least one IRB member knowledgeable about or experienced in working with such participants will be present at the meeting. If a quorum is not present, the meeting will be cancelled and rescheduled. If required members are absent, the proposal must be tabled and rescheduled for another meeting. (Meetings by telephone are also an option.)

2.13 Primary reviewers will be called on at convened meetings to present an in-depth review of their assigned protocols based on the criteria listed on FORM: IRB Checklist for Reviewers and Investigators. This synopsis includes a description of the study, an evaluation of the validity of the research protocol, an evaluation of the adequacy of the proposed consent process and documentation, conformity to applicable regulations, COI issues, and an estimation of potential risk to participants.

2.14 All IRB members will read all proposals and be prepared to participate in the discussion.

2.15 IRB meetings have equipment for teleconferencing and a laptop computer for displaying regulations or relevant criteria for the review or for projecting relevant sections of the IRB application for members.
2.16 Consultant participation will consist of judgments regarding the scientific soundness of a research protocol, risk-benefit analysis, review of the cultural appropriateness of the informed consent process, or other protocol-specific assessments. Consultant feedback must be written and may be delivered electronically prior to the meeting or read at the meeting by the IRB Chair or by the consultant if s/he is physically present. If the consultant attends the meeting, it will be only for the protocol for which consultation was requested. Consultants will not vote on protocols.

2.17 Following the primary reviewer's review the Chair will call for additional discussion of the protocol. Chairs will encourage participation by all. When discussion is finished, the Chair will ask the primary reviewer for a recommendation in light of the complete discussion. The Chair will then ask members to vote on the IRB Ballot Sheet. See GUIDANCE: IRB Determinations and Motions.

2.18 At the end of the meeting the Research Compliance Specialist will collect the IRB Ballot Sheets. For research to be approved it must receive the approval of a majority of members present at the meeting.

2.19 The Research Compliance Specialist prepares minutes of the meeting reflecting needed elements (See Policy “IRB Record Documentation”) and letters to investigators informing them of the Board’s decision and listing any needed changes to be signed by the IRB Chair. Minutes of the meeting are posted with the materials for the next month’s meeting. Investigator letters are usually sent within 5-7 working days of the meeting at which the proposal was reviewed.

2.20 Either the IRB chair or the Research Compliance Officer will sign letters to the investigator. The IRB chairs have designated the Research Compliance Officer to perform this function.

2.21 Investigators have 60 days in which to respond to IRB requests for additional information, revision, or resubmission. Applications for which no response is received in 60 days will be administratively withdrawn. If the investigator still wishes to receive board approval, s/he must submit a new application, incorporating the board’s requests.

3.0 REFERENCES

DHHS: 45 CFR 46.107(e), 108(b)
OHRP Guidelines on Written Institutional Review Board (IRB) Procedures
OHRP Guidance on IRB Approval of Research with Conditions: Nov.10, 2010
FDA: 21 CFR §56.107(e), 21 CFR 56.108(a); 21 CFR 56.109
ED: 34 CFR 356.3
Belmont Report

4.0 RELATED SECTIONS

4.1 FORM: IRB Checklist for Reviewers and Investigators

4.2 FORM: Reviewer Checklist for Full Board Reviews
4.3 POLICY: IRB and Investigator Responsibility for Applications Involving Declared or Undeclared Conflict of Interest

4.4 GUIDANCE: IRB Reviewer Determinations and Motions