

Human Subjects:

The human subject approval for this project will not have occurred at the time of application submission thus the Human Subjects section on the face page denotes "pending" awaiting protocol development and/or submission to the Human Investigation Committee (HIC) for review and approval. The HIC office currently provides protocol review, ensures human subject compliance, and the issuance of protocol approval letter(s) to faculty/funding agencies prior to any initiation of human subject services. Wayne State University's Federal Wide Assurance # is 00002460 (expires 09/21/2013). The HIC does have a "Human Research Protection Program (HRPP)" for research involving human participants and is briefly summarized below:

WSU complies with the Code of Federal Regulations (CFR), the Common Rule, as it applies to human participant research. These include the regulations from DHHS [45 CFR 46] and its subparts, the FDA regulations [21 CFR 50 and 56], the Veterans Administration regulations [38 CFR 46] including subparts and all other relevant federal regulations. All research that involves human participants will be reviewed and approved by the IRB (Institutional Review Board) of Wayne State University prior to the implementation of such research activities. The types of IRB reviews are based on the type of protocol that is submitted. The HIC will determine which type of review of a protocol is required once it is submitted. The types of IRB review are: 1) exempt review, 2) expedited review, and 3) full board review. In addition, IRB notification is required for the 4) emergency use of a non-approved investigational drug or biologic or a non-approved investigational device.

The criteria for initial review IRB approval of research protocols are set forth by HHS regulations at 45 CFR 46.111 and include: determining the level of risk to the participant, the potential benefits, the informed consent process and documentation, and safeguarding the subject.

Scientific Review is reviewed for scientific merit by the PI's department prior to submission to the HIC. Various departments conduct this scientific review in different ways and the IRB will accept any of these methods as long as the Chair and/or his/her designee certifies on the the Protocol Summary Form that the scientific review has been completed. In addition to scientific review, the department is responsible for certifying that appropriate support will be provided to conduct the study.

All general HIC guidelines will be adhered to: The materials for submission of a new protocol to HIC include: a completed Protocol Summary Form; a completed HIPAA Summary Form and other HIPAA documents (if applicable); the Informed Consent/ Assent /Information Sheet documents; a full protocol (grant proposal); an Investigator's Brochure, if applicable; any surveys, questionnaires, or other measurement tools; appendices; advertisements and other pertinent data which may assist in the decision making process.

The criteria used to determine the type of initial review a protocol submission will receive will be determined on the type of IRB review: 1) exempt review, 2) expedited review, and 3) full board review. When a submission is received in the HIC office, it is date stamped, checked for proper original signature, logged into the database, and assigned an HIC protocol number. The submission is then assigned to the appropriate IRB.

The Chair of the IRB or his/her designee then assigns protocols to the primary and secondary reviewers. The materials are routed to the appropriate staff members to prepare the packets for distribution to the IRB members prior to the meeting in sufficient time to allow them to adequately review the protocol. For all behavioral protocols, the Chair of the Behavioral IRB or his/her designee determines whether a protocol can be reviewed through the expedited process or be sent to full board for review.

The IRB members will evaluate each application and all documents for:
Merit-Sound research design that minimizes risk

- Risk/Benefit ratio
- Equitable selection of participants
- Consent process and documentation
- Safety monitoring
- The protection of privacy and confidentiality
- Adequate protections afforded to and the assessment of the potential for coercion in vulnerable participants

The results and recommendations are then communicated to the PI generally within a week of the formal decision. Details about the discussion of issues, concerns, major questions and recommendations are entered into the minutes for each new protocol after they are discussed separately.

The minutes of the IRB meeting are prepared for distribution to all committee members prior to a convened meeting. Copies are also forwarded to the appropriate institutional authorities as well as funding agencies.

Anyone who will be participating in any protocol will be expected to complete the on-line training program “Collaborative Institutional Training Initiative (CITI)” located at the following website: <http://www.hic.wayne.edu/mandatory-training.php>

(Include this statement with table if applicable)

A listing of all human protocols from training faculty with their HIC approval dates are shown below:

APPROVED HUMAN SUBJECTS PROTOCOLS FOR TRAINING FACULTY

Participating Faculty	Project Title/Protocol #	Role on Project (PI/Co-I/etc.)	Approval Date