WAYNE STATE UNIVERSITY

HIC Policy/Procedure

Wayne State University Human Investigation Committee	
SUBJECT	Outcome of Proposal Reviews By IRB
Section	
Form Date	04/25/98
Approvals	Office of General Counsel 11/20/06, Steering Committee 12/19/06, Administrative Approval 03/02/07

Background:

Pursuant to Federal Regulations [45 CFR 46.109(a), 38 CFR 16.109 (a), & 21 CFR 56.109(a)], the Wayne State University (WSU) Institutional Review Board (IRB) has the authority to approve, require modifications in (to secure approval) or disapprove all research activities involving human participants (subjects) conducted at the University and its affiliate institutions. IRB decisions to approve or disapprove research protocols are communicated to the Principal Investigator (PI) and institution in writing. [45 CFR 46.109(d), 38 CFR 16.109(d) & 21 CFR 56.109(d)].

Scope:

This Policy/Procedure applies to all human subject (participant) research (except for concurrence of exemption) submitted to the WSU IRB for review and approval and defines the types of outcomes of IRB decisions regarding human research protocols.

Definitions:

Approval- The full IRB Committee, IRB Chairperson, HIC Chairperson or his/her designee has approved the research protocol, for a period not to exceed one year.

Specific Minor Revisions- This outcome requires that minor changes (no new information required by the IRB to determine risk/benefit ratio) that must be made to the protocol before approval to begin can be granted. The minor changes must be made within 60 days of the initial outcome.

Tabled (Substantive Revisions) a number of significant questions and concerns regarding the risk/benefit ratio require resolution before the research protocol can be approved by the IRB.

Disapproval- The protocol as submitted is such that it cannot be reviewed in its current form and it requires complete revision and resubmission as a new protocol.

HIC Policy/ Procedures:

Proposal is Granted Approval:

The study may commence only upon written notice of approval from the HIC office. This approval does not replace or serve in place of any departmental or other approvals that may be required.

Specific Minor Revisions Required:

> The proposal may NOT commence under these conditions. Minor changes may include such things as typographical errors, minor re-wording of the consent form and clarification of statistical methods that do not alter the merit of the research design. If there are questions regarding the risk/benefit ratio, equitable recruitment, the consent process and documentation, safety monitoring, the protection of privacy or confidentiality, and the potential for coercion, this protocol may not be approved under the specific minor revisions category.
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> The PI is responsible for addressing the concerns of the IRB before approval can be granted. Once the concerns have been addressed and/or changes are submitted, the committee, committee chair or designee may grant approval if the changes are satisfactory. If the IRB committee's requests are not adequately addressed within 60 days of requested changes, the proposal must be withdrawn and the study must be resubmitted as a new proposal for full board IRB review.

Substantive Revisions Required:

> This proposal is in need of revision because there are a number of questions and significant concerns that require resolution. The HIC office will notify the principal investigator by letter indicating the issue(s) being raised. The PI is responsible for addressing the concerns of the IRB before specific minor revisions or final approval can be granted. These changes must be submitted in writing to the HIC office.
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> The proposal will be placed on the agenda for the next scheduled committee meeting upon receipt of the revisions. If the HIC office has not received a response within 60 days of notification, the proposal will be withdrawn and must be resubmitted as a new proposal if it is to be reconsidered for full board IRB review.

Protocol is Tabled:

> This proposal is in need of revision because there are a number of questions and significant concerns that require resolution. The HIC office will notify the principal investigator by letter indicating the issue(s) being raised. The PI is responsible for addressing the concerns of the IRB before specific minor revisions or final approval can be granted. These changes must be submitted in writing to the HIC office.

The proposal will be placed on the agenda for the next scheduled committee meeting upon receipt of the revisions. If the HIC office has not received a response within 60 days of notification, the proposal will be withdrawn and must be resubmitted as a new proposal if it is to be reconsidered for full board IRB review.

Proposal is Disapproved:

A proposal will be disapproved by the IRB for any of the following reasons:

1. The proposal is considered to be lacking key information by which to evaluate its objectives, methods, endpoints, benefits, or risks,
2. Protection of the research subject is not addressed,
3. The risks to the research subject appear to outweigh the benefits of the research study;
4. The proposal lacks merit or is designed such that the methodology is unlikely to yield useful data toward meeting the stated objectives; or
5. The proposed research is deemed unethical.

The HIC office will notify the principal investigator in writing outlining the reasons for disapproval. The proposal must be revised and resubmitted as a new protocol if it is to be reconsidered for full board IRB review. Please see the HIC Policy/Procedure entitled “Notification of IRB Decisions to Principal Investigator and PI Response Requirements”.