WAYNE STATE UNIVERSITY

HIC Policy/Procedure

Wayne State University Human Investigation Committee	
Subject	Notification of IRB Decisions to PI and PI Response Requirements
Form Date	November 3, 2006 (Rev. 7/12/10)
Approvals	5/17/06 Steering Committee , 5/18/06 Administrative Approval, 9/30/10 Administrative Approval

Background

In accordance with 45 CFR 46.109(d), all decisions of the Institutional Review Board (IRB) will be communicated to the principal investigators (PI) in writing.

General Procedures

Decisions of the Human Investigation Committee (HIC) and Institutional Review Boards (IRBs) will be communicated to the principal investigators (PI) via a letter, memorandum, or email. Collectively they will be called letters.

These letters will contain the following information:

- The results of the review of the protocol, amendment, continuation or adverse event.
- Comments/need for revisions or more specific types of information that may be required before HIC action can be taken.
- The PI or key personnel may not proceed with research until a written notification of final approval has been received from the IRB office.

It is the goal of the (HIC) to generate letters within 7 to 10 working days after decisions have been made.

Expedited/Exempt Approvals

Letters that acknowledge concurrence of exemption or an expedited approval will indicate the number of the category under which the exemption or expedited status was granted.

The date of expedited approval of the proposal and the date that the approval will expire will be included in the letter to the PI.

When the protocol meets the criteria for exemption, the letter will indicate that the HIC Chairperson concurs with the PI's determination and asks that the PI notify the IRB if modifications are made in the future that may require a higher level of review.

The approval of all expedited and exempt protocols will be added to the minutes of the appropriate IRB committee.

Approved Research

If the research protocol is approved, the letter will indicate that approval has been granted and that the research may begin. The approval letter will contain the date on which the research was approved and the date the approval expires.

Specific Minor Revisions Required

When minor changes are required before IRB approval can be provided, this decision and the specific changes that will be required will be communicated to the PI.

Investigators may not initiate a research protocol or a change to a previously approved protocol until final approval is granted and communicated to the PI.

The principal investigator is allowed 60 days to respond to the Committee's requests and must include a detailed response that addresses all of the IRB's concerns, questions, and requested changes. If 60 days elapse without a response from the PI, the IRB may require a new submission or the protocol may be referred back to the full committee.

When the responses are received, the Chair of the requesting committee or his/her designee will review them. Depending on the nature of the responses to the requested changes, the Chair or his/her designee may grant approval or refer the protocol to the full IRB. Please see the HIC Policy /Procedures: "Types of IRB Review" & "Conditional Approvals and Subsequent Decisions of IRB Chairs".

A letter of final approval of the project will be reflected in the minutes of the IRB meeting.

Substantive Revisions Required (Tabled)

The IRB may table a protocol when there are a number of significant questions and concerns that could not be resolved at the IRB meeting.

When substantive revisions are required before IRB approval can be provided, this decision, the issues that must be addressed before IRB approval can be provided, and the time frame for a response will be communicated to the PI.

A memo from the PI and when appropriate, a revised protocol, consent forms, assent forms, information sheets, and/or advertisement must be re-submitted to the full IRB which detail the PI's responses to the IRB's concerns, comments, recommendations and/or questions. The same IRB that conducted the initial review will review the revised materials. If the protocol and/or consent form is modified, the changes must be highlighted.

The PI may not initiate the study until a response from the PI has been received in the HIC Office, the revisions have been reviewed and approved at a subsequent IRB meeting, and final approval has been communicated to the PI.

If the PI has not responded to the concerns of the IRB within 60 days, the HIC reserves the right to terminate their review of the protocol, amendment, continuation, and/or adverse event.

Disapproved Research

The IRB may disapprove a research protocol based on their identification of major scientific or ethical problems, which, in the committee's opinion, cannot be readily resolved by the Principal Investigator. When a research protocol is disapproved by the IRB, the PI is not authorized to initiate the study. For protocols that have been disapproved, a letter is sent to the principal investigator that documents in detail the reasons for the disapproval. The letter must offer the investigator an opportunity to respond in person or in writing to the IRB's determination.

If the investigator wishes to pursue the research, the protocol must be revised and submitted as an entirely new protocol which addresses the IRB's concerns, comments, recommendations, and/or questions.