WAYNE STATE UNIVERSITY

HIC Policy/Procedure

Wayne State University Human Investigation Committee	
SUBJECT	Conditional Approvals and Subsequent Decisions by IRB Chairs
Section	
Form Date	
Approvals	7/19/06 Steering Committee, 7/20/06 Administrative Approval

Background

When a convened Institutional Review Board (IRB) sets conditions under which a protocol can be approved, the nature of these conditions govern whether or not the IRB Chair or his/her designee can subsequently approve the protocol alone, or whether the response provided by the Principal Investigator (PI) must be returned to the full board for review. The Office for Human Research Protections (OHRP) recommends the following guidelines in determining what type of review would be most appropriate:

- When the full board requests that substantive changes, clarifications, or modifications be made to a protocol or informed consent documents, approval by the IRB should be tabled pending further review of the PI's response by the convened IRB.
- Only when the convened IRB stipulates specific revisions requiring simple concurrence or minor changes (Specific Minor Revisions Required) by the PI may the IRB Chair or his/her designee approve the revised research protocol on behalf of the IRB under an expedited review procedure.

Regulatory Guidelines

In order for any research protocol involving human participants to be approved at Wayne State University (WSU), the following determinations are required (45 CFR 46.111) to be made by a convened IRB or the IRB Chair or his/her designee:

- Risks to subjects are minimized by using procedures consistent with sound research design and do not expose the participants to unnecessary risk and by using procedures already being performed on the participants, if possible;
- The risks to participants are judged to be reasonable in relation to anticipated benefits, if any, and reasonable in relation to the importance of the knowledge that may reasonably be expected to result;

- Participant selection is equitable;
- Informed consent will be sought from each prospective participant or their legally authorized representative (45 CFR 46.116) and appropriately documented as required by 45 CFR 46.117;
- Adequate provisions are made to monitor safety as needed;
- Adequate provisions are made to protect the privacy of the participant and confidentiality of data;
- Additional safeguards will be taken to protect potentially vulnerable participants.

If the IRB Chair does not agree with the decision made by the IRB Committee regarding substantive or minor revisions required, the IRB Chair shall determine if the decision by the Committee was in violation of 45 CFR 46.111 and if so, he or she will notify the Committee and the Institutional Official

The IRB Chair can override the Committee if he/she feels the investigator responses should be returned to full committee. The issue can be taken to the HIC Steering Committee for further discussion and a final decision, if needed.

HIC Procedures

During the initial review, continuation review, or review of protocol modifications by the full IRB, the committee determines if the required regulatory requirements have been met. When the convened IRB is not provided with information that satisfies the requirements specified above, the protocol must be tabled. In this case, the responses from the PI must be returned to the full board for their review at a subsequent meeting.

If, however, the revisions that the full IRB committee is requesting be made by the PI only involve minor changes or where the PI can provide simple concurrence with the changes made by the committee, it is appropriate for the protocol to be given provisional approval (Specific Minor Revisions Required). ***Only in this case can the response from the PI be reviewed by the IRB Chair or his/her designee on behalf of the IRB under an expedited review procedure.***

It is understood that the IRB Chair will determine if the concerns raised have been satisfactorily addressed by the investigator. If the IRB Chair determines that the changes made by the PI are not minor in nature or if the response raises questions not previously identified by the full board, the IRB Chair will return the protocol to the full committee for deliberation on the revisions.

All conditional decisions which are made by the IRB Chair on the recommendation of the full IRB Committee shall be entered into the minutes for that meeting.

Studies Involving an Investigational New Drug

If a convened IRB Committee votes to give a protocol that involves an investigational drug Specific Minor Revisions Required status:

- The IRB Chair or his/her designee can approve the protocol if response from the PI demonstrates a decrease in risks to the participants (all 7 criteria for approval under 45 CFR 46.111 are met) and the Investigational New Drug Exemption (IND) number has been provided to the HIC by the PI.
- The responses must be reviewed by the convened IRB Committee if they indicate that risks to the participant will be increased.
- If only an IND number is required for approval of a protocol, the IRB Chair or his/her designee may approve the protocol after the PI provides it to the HIC.

Studies Involving an Investigational Device

If the convened IRB committee has determined that an investigational device study involves a non-significant risk device and votes to give that protocol Specific Minor Revisions Required status:

- The IRB Chair or his/her designee may approve the protocol if the responses from the PI demonstrate that all 7 of the criteria for approval (45 CFR 46.111) are met after revisions and an Investigational Device Exemption (IDE) number has been provided.
- The responses from the PI must be reviewed by the convened committee if they indicate that the risks to the participant will be increased.
- If only an IDE number is needed for approval, the IRB Chair or his/her designee may approve the protocol after the PI submits it to the HIC.

If the convened IRB Committee has determined that a device study involves a significant risk device and votes to give the protocol Specific Minor Revisions Required status:

- The IRB Chair or his/her designee may approve the protocol if the PI's responses demonstrate that all 7 of the criteria for approval (45 CFR 46.111) are met after revisions and an Investigational Device Exemption (IDE) number has been provided.
- The responses from the PI must be reviewed by the convened committee if they indicate that the risks to the participant will be increased.
- If only an IDE number is needed for approval, the IRB Chair or his/her designee may approve the protocol after the PI submits it to the HIC.