WAYNE STATE UNIVERSITY

HIC Policy/Procedure

Wayne State University Human Investigation Committee	
SUBJECT	Minutes Requirements
Section	
Form Date	3/9/09
Approvals	Administrative Approval 03/11/09, Office of General Counsel Approval 03/12/09; Administrative Approval 4/26/10

Background & Scope

The purpose of the Human Investigation Committee (HIC) is to protect the rights of human research participants in compliance with Wayne State University policy and all applicable regulations. As a part of that commitment all deliberations, actions and votes of all HIC established Institutional Review Board Committee's (IRB's) must be documented in the meeting minutes and distributed according to this policy. The IRB meeting minutes must preserve an accurate record of IRB deliberations and actions and provide an accurate record for retrospective review. [38 CFR 16.115(a) (2)] [45 CFR 46.115(a) (4) [21 CFR 56.115(a) (3)]

Procedures

The minutes of each Institutional Review Board (IRB) committee meeting will be available for review within three weeks of the original meeting date for an approval vote at the subsequent IRB committee meeting. Copies of the approved minutes will then be distributed to the Detroit Medical Center, John D. Dingell Veteran Administration Hospital and to all the members of the IRB committee. The approved minutes will be retained in the HIC offices for three years. Approved minutes that document deliberations, actions and votes on Veteran's Administration (VA) protocols will be retained in the HIC offices for five years. Research that is approved contingent on specific minor revisions, which must be subsequently verified by the IRB Chair or designee, will be documented in the minutes of the first IRB meeting that convenes after the date of the approval of research with specific minor revisions. The IRB committee meeting minutes may not be altered by anyone, including the Vice President for Research, HIC Chair or higher WSU authorities or WSU affiliates, once approved by the members of an IRB committee. If errors are found in minutes after they were approved, the corrections must be resubmitted to the IRB committee for review, approval and signed by the IRB Chair.

IRB meeting minutes must document the following:

- The basis for requiring any changes in research;

- The basis for disapproving research;
- Rationale of any deletion or substantive modification of information concerning risks or alternative procedures contained in the Department of Health and Human Services (DHHS) approved sample consent document;
- Separate deliberations, actions and votes for each protocol review;
- The determination of the approval period for initial and continuing review;
- The determination of level of risk category;
- A written summary of the discussion of controverted issues and their resolution;
- The detailed revisions required to secure approval;
- The rationale for significant risk/non-significant device determinations;
- The rationale concerning parental approval (default is both parents);
- Determination that assent is not required;
- The approval of exempt reviews by the Chair, or designee (must be documented in the minutes of the first scheduled committee meeting with the appropriate expertise, e.g. children, behavioral); and
- The approval of required protocol revisions, by the Chair or designee, must be documented in the minutes of the first IRB meeting that takes place after the date of the approval.

IRB meeting minutes must also document committee members' attendance with respect to the following:

- Attendance at the meeting;
- Attendance of alternate members at the meeting and name of the person for whom they are substituting;
- Member's absence from the discussion, deliberation and vote on specific protocols because of financial or non-financial Conflict of Interest;
- The presence of a quorum at the meeting including the presence of one non-scientific member; and
- The participation of a member or alternate member via video or teleconference and that the member or alternate member received all pertinent meeting material before the meeting and that they were able to participate in all discussions.

IRB meeting minutes must also document the voting results for each IRB committee action as follows:

- Number of votes including;
    - Total votes In Favor (For),
    - Total votes Opposed (Against),
    - Abstained,
    - Recused (due to Conflict of Interest), and
- The name of IRB members who recused themselves due to Conflict of Interest.
  The name of IRB members leaving the room or not present for vote or discussion

Protocol specific findings that justify determinations on any of the following must be documented in the meeting minutes:

- Research involving pregnant women/neonates;
- Research involving prisoners;
- Research involving children; and
- Waiver or alteration of the consent process and documentation of the four requirements for waiver of consent

Documentation of any and all Conflicts of Interest must be recorded in the minutes and must include:

- The name of members who have a Conflict of Interest (COI); and
- Notation that those members having a COI recused themselves from the discussion, unless asked by the IRB to provide information and recused themselves from the vote..

Documentation of research "Non-Compliance" must be recorded in the minutes and must include:

- The determination of whether non-compliance is serious or continuing; and
- Any committee actions including research oversight, remedial action or termination or suspension of research.

Adverse Reactions and Unexpected Events must be documented in the meeting minutes and must include:

- The report of the adverse reaction or unexpected event;
- The IRB's determination on necessary and/or remedial action; and
- A report of any emergency or preliminary action taken prior to the IRB meeting.

Veterans Administration Research must be documented and must include:

- Protocol specific justification for research involving the cognitively impaired;
- Statements of significant new findings provided to participants when reviewed at an IRB meeting;
- Determination on whether the patient record must be flagged; and
- The level of risk must be noted. The determination of the level of risk may not be altered in the minutes after approval.

IRB Chair and Research Compliance Administrator (RCA) Signature:

- When the IRB Chair and RCA sign the minutes that they have reviewed, it certifies that they concur with the accuracy of the minutes