

Wayne State University Human Investigation Committee (HIC)	
SUBJECT	Suspension and Termination of Research Protocols
Section	
Form Date	10/06/06
Approvals	02/16/05 Steering Committee, 03/14/05 Administrative, Revision 11/17/06 Steering Committee, 12/05/06 Revision Administrative Approval

Background

"An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and to the Department or Agency Head." [45 CFR 46.113; 38 CFR 16.113]

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To fulfill this regulatory mandate, Wayne State University (WSU) has authorized the IRB committees, the IRB chair, or the Assistant VP for Research to suspend or terminate a research project in order to protect the safety and welfare of human research subjects. This would occur when there are issues of continuing or serious noncompliance with HIC and federal requirements, when the research is associated with unexpected serious harm to research participants or when there are immediate serious issues involving participant safety. (See Identifying, Defining, and Managing Non-Compliance in Human Research, Adverse Reactions and Unexpected Events SOP)

Scope

This Policy and Standard Operating Procedure applies to all activities being conducted by WSU (faculty, staff, and students) and its affiliate institutions that meet the definition of human participant (subject) research. (See HIC website Home page for "Definition of Human Subject Research").

Definitions

Committee – Committee refers to the HIC Steering Committee or the four Institutional Review Board (IRB) committees at WSU. The HIC Steering Committee is considered a stand-alone IRB, in addition to the other IRB committees at WSU.

Designee – a person appointed by the HIC Chair or IRB committee chair, acting on his/her behalf.

Non-Compliance – Non-compliance occurs when research involving human participants is conducted in a manner that disregards or violates federal regulations, institutional, and/or IRB policies and procedures governing research and human research protection. This can include, but is not limited to:

- failure to obtain IRB approval for research involving human participants;
- inadequate or non-existent procedures for informed consent;
- inadequate supervision in research involving drugs, devices or procedures;
- failure to follow recommendations made by the IRB to insure the safety of participants;
- failure to report adverse events or proposed protocol changes to the IRB; and
- failure to provide ongoing progress reports (See HIC Policy/SOP “Defining & Managing Non-Compliance in Research”).

Suspension – A suspension occurs when the Assistant Vice President for Research (AVPR), HIC Chair, IRB Committee or IRB Chair places a temporary hold on the research that had been previously approved so that no new participants can be accrued, no research interventions may occur (unless necessary for the safety and well-being of the enrolled participants) and no follow-up can be conducted unless it is in the best interest of the participant and approved by the IRB.

Termination of a previously approved protocol – Termination of a previously approved protocol occurs when the IRB withdraws approval or stops all research activity permanently. No new participants may be enrolled and no additional research interventions can occur. However, future follow-up may be conducted with the approval of the IRB to monitor the well being and any potential risk to participants.

On the occasion when research activities have occurred that did not receive prior review and approval from the IRB, the HIC shall stop all such activities permanently. **None of the data collected in this activity can be used in any future publication or presentations.**

Unexpected Event – An unexpected event is an unanticipated problem associated with any aspect of the research study that may involve not only risks to the participant enrolled in a research study, but to other individuals who may or may not be directly associated with the research study. Unexpected Events may occur in non-clinical (behavioral or social science) as well as clinical research studies (See HIC Policy and Procedure on Identifying, Reporting & Reviewing Adverse Reactions and Unexpected Events).

HIC Policy and Procedures

Prior to, during, or after the process of suspending or terminating a previously approved research protocol or research activities that have been conducted without prior approval, a for-cause audit will be conducted. The results of this audit will be provided to the Assistant Vice President for Research (AVPR), the Human

Investigation Committee (HIC) Steering Committee and/or the Institutional Review Boards (IRB) as a part of their decision to suspend and/or terminate a research protocol (See HIC Policy/SOP For-Cause Audit).

When other administrative groups within the University have suspended a research activity for an issue involving human participants, they are required to notify the HIC in writing within five (5) business days and an audit will be conducted by the HIC as part of their decision to suspend and/or terminate the research protocol. These actions may range from corrective or educational measures for the researcher up to and including the termination of all research activities. Further, the IRB may suspend the approval of research projects at anytime during an inquiry or investigation to assure the protection of human participants.

Procedures for Suspension of a Research Protocol

When reviewing an adverse reaction or unexpected event (AR/UE), the AVPR, HIC Chair, the IRB or IRB designee may determine that the protocol associated with the AR/UE should be suspended.

In addition, when information is received in the HIC office concerning research that is being conducted that is not in compliance with an approved research protocol, HIC Policy requirements or federal regulations, the AVPR, HIC Chair, the IRB chair or designee may suspend the research protocol until an internal audit has been completed. The completed audit report will be reviewed by the appropriate officials within the office of the AVPR, the HIC Chair and/or IRB Steering committee to determine whether or not to terminate the IRB approval.

In lieu of termination, the IRB may impose additional remedial actions to bring the research activities into compliance with the IRB and federal requirements and to reduce the risk to participants. When the IRB has determined that all remedial actions have been implemented satisfactorily, the IRB may withdraw the suspension and the research may resume.

Procedures for Termination of a Research Protocol

A research protocol is terminated:

- When the IRB determines that it is in the best interest of the safety and welfare of research participants.
- When a remedial action plan approved by the IRB has not been implemented in a complete or satisfactory manner.

Due to safety issues and full disclosure, as outlined in the informed consent process, participants in the research must be notified in writing of all terminations. This written notification must be approved by the IRB before it is sent to participants.

In addition, a detailed plan for safe withdrawal of participants from the research must be developed, considering their rights and welfare, and this also must be submitted to the IRB for review and approval. (See Adverse Events/Unexpected Events Policy and SOP)

1. If follow-up of the participants for safety and effectiveness reasons is permitted or required by the IRB, the participants should be informed after obtaining IRB review and approval of the notice. Any adverse events or other outcomes identified during follow-up should be reported to the IRB, the

research study sponsor, The Office for Research Protection (OHRP), the Food and Drug Administration (FDA), and other appropriate federal authorities, as applicable.

If the investigator wishes to resume a research protocol that has been terminated, it must be submitted as a new protocol.

Procedures for Terminating Research Activities Conducted prior to IRB Review and Approval

When research activities have begun without prior IRB review and approval, the following actions are required:

- An AR/UE Report must be submitted to the HIC Office for IRB review. The report must contain a detailed accounting of what research activities occurred and when. This is to be submitted according to the HIC Policy and Procedure on Identifying, Reporting, and Reviewing Adverse Reactions/Unexpected Event.
- An audit of all research activities will be done at the request of the AVPR, HIC Chair, IRB Chair, or IRB Committee.
- All data collected during these activities must be destroyed.
 - Hard copies must be submitted to the HIC office and will be shredded.
 - A written statement from the PI must be submitted to the HIC office verifying the date, and method of removing all data from a computer hard drive.
- The written statement must also include a statement that the PI will never use the data for any future research or publications.

Reporting of all IRB Suspensions and/or Terminations

The suspension and/or termination of IRB approval of a research protocol will be promptly reported to the investigator by courier within 24 hours if possible, but within two business days and will include a written statement of the reasons for the IRB's actions.

When the AVPR, the HIC Chair, an IRB, or an IRB Chair or designee has suspended and/or terminated a research protocol, the HIC Steering Committee will be notified. The HIC Steering Committee will review all suspensions and terminations at a regularly scheduled meeting or at an emergency meeting, if needed. After review, the HIC Steering Committee will report the suspension and/or termination to the AVPR who will report the termination to appropriate regulatory agencies (e.g., Office for Human Research Protection, FDA, Veterans Affairs, the study sponsor) within 60 days of the suspension or termination (See the related HIC Policies and SOPs: "Reporting of Unanticipated Problems, Terminations, Suspensions, and Non-Compliance", "Identifying and Managing Non-Compliance", "Identifying, Reporting, & Reviewing Adverse Reactions and Unexpected Events", and "For-Cause Audits").

PI Recourse

The Principal Investigator may request a meeting with the AVPR, HIC Chair, the HIC Steering Committee, IRB Committee, or Chair regarding any decision to suspend and/or terminate a protocol.

Disciplinary Action

While the IRB shall have the authority to suspend and/or terminate a research protocol, all disciplinary action taken against an individual for being out of compliance with institutional policies regarding the protection of human participants shall be the responsibility of the institution. The AVPR shall be responsible for reporting the termination to other institutional officials (department chairs, deans, the provost, etc. as required) and to assist in taking appropriate institutional disciplinary action.