

SUSPENSION AND TERMINATION OF IRB APPROVAL

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| SOP #: | 410 | VERSION #: | 1 | EFFECTIVE DATE: | 05/01/09 | SUPERSEDES DOCUMENT: | / / |
| THIS POLICY PERTAINS TO: | | | ALL RESEARCH CONDUCTED UNDER THE JURISDICTION OF THE IRB | | | | |
| RESPONSIBILITY FOR EXECUTING POLICY: | | ASSOCIATE VICE PRESIDENT FOR RESEARCH AND ECONOMIC DEVELOPMENT, IRB CHAIRPERSON, IRB MEMBERS, INVESTIGATOR | | | | | |
| LAST REVIEWED ON: | | / / | | RESULTS: | REVISED | | |
| APPROVAL AUTHORITY: | | Associate Vice President for Research and Economic Development | | | | | |
| APPROVED BY: | | | | | | DATE: | / / |

1. POLICY

The IRB shall have the authority to suspend or terminate approval of research that is not being conducted in accordance with IRB, federal, state or local requirements, or has been associated with unexpected serious harm to participants. A project may be suspended or terminated for the following reasons, including but not limited to:

- Serious and continuing non-compliance with federal regulations and IRB policy.
- Failure to submit a complete Research Project Review and Progress Report in sufficient time to allow an appropriate review to be conducted.
- Failure to submit a termination form after multiple attempts.
- Failure to obtain appropriate informed consent.
- Change in the risk: benefit ratio of the research.
- New information regarding the increased risk to the participant.

2. SPECIFIC POLICY

2.1 Definitions

Suspension: An action issued by the IRB that all or some of the research activities must stop until issues have been satisfactorily resolved. Suspended projects still have IRB approval.

Termination: An action issued by the IRB that all or some of the research must stop permanently except for the continuation of follow-up activities necessary to protect the participants' safety.

2.2 Suspension and Termination

2.2.1 At a convened meeting of the IRB, the IRB Chairperson or IRB Vice Chairperson will present the facts for consideration and vote. The IRB will review a study for suspension or termination for the following types of conditions, including but not limited to:

- Falsification of study safety data;
- Failure to comply with prior conditions imposed in writing by the IRB;
- Repeated or deliberate failure to obtain or document informed consent from human participants, which may include:
 - Repeated or deliberate omission of a description of serious risks of the experimental therapy when obtaining informed consent; and/or

- Repeated or deliberate failure to provide informed consent in a language understandable to the subject;
- Repeated or deliberate failure to limit administration of the investigational drug or device to those participants under the Investigator's supervision;
- Repeated or deliberate failure to comply with conditions placed on the study by the University, IRB, sponsor, or FDA;
- Repeated or deliberate failure to obtain prior review and approval of new protocols and on-going human subjects research by the IRB;
- Repeated or deliberate failure to follow the signed Investigator Letter of Assurance or protocol, e.g., by enrolling participants who should have been excluded which put those participants at greater risk;
- Repeated or deliberate failure to maintain accurate study records, submit required adverse event reports, report changes to the research or report unanticipated events to the IRB;
- Repeated or deliberate falsification or concealment of study records, e.g., by substituting in study records the results of biological samples from participants who met the inclusion criteria for samples of participants who did not meet the inclusion criteria, or by fabricating participants.

2.2.2 The IRB will decide on a course of action and establish a time line for the completion of that action. The discussion, action and vote will be recorded in the meeting minutes. The IRB may act at any time during the investigation to modify the terms of the suspension or termination.

2.2.3 Until a review can be done by the Full IRB, the IRB Chairperson may act alone to temporarily suspend or terminate previously approved human research or an Investigator's privilege to conduct human subject research if the alleged serious or continuing non-compliance with the requirements or determinations of the IRB, or any incidence that has been associated with the unexpected serious harm to participants appears to pose imminent threat to subject safety. Suspensions and terminations by the IRB Chairperson, acting alone, are reported to and reviewed by the convened IRB.

2.2.4 The IRB may request an ad hoc review from an independent source with expertise in the type of research being conducted or expertise in the specific area of concern.

2.2.5 For suspensions, the IRB deliberates and determines the category(s) of suspension, which are:

- Suspension to recruitment;
- Suspension to screening and enrollment;
- Suspension to interaction and intervention; and/or
- Suspension to follow-up.

2.2.6 The IRB notifies the Investigator in writing of its decision by letter (within 5 business days) and a copy of the unsigned letter will also be emailed by the IRB office. The letter will include:

- Reason and rationale for the suspension or termination
- IRB action plan and established timeline for response and reporting progress to the IRB
- If appropriate, require the Investigator to submit:
 - Procedure for the withdrawal of currently enrolled participants that considers their rights and welfare.
 - Letter or script notifying all currently enrolled participants that are affected by the suspension or termination.

- A reminder that all study activities such as, reporting adverse events, revisions to investigator brochures, and updated package inserts must still be reported to the IRB.
- If appropriate, require the Investigator to:
 - Complete additional training in Human Subject Research
 - Provide a plan for oversight for current and future research
- Notification that an internal audit of the study will be conducted by the Research Development and Compliance office
- If appropriate, inform current participants of the termination or suspension.

2.2.7 To reinstate a project that has been suspended, the Investigator must satisfactorily resolve any pending issues required by the IRB. If the issues have not been resolved after one year, the study will be terminated.

2.2.8 To reinstate a project that has been terminated, the Investigator must submit the project to the IRB as new and past issues must be resolved to the satisfaction of the IRB.

2.3 Reporting Suspension and Terminations

All suspensions and terminations will be reported to the appropriate individuals and agencies per SOP 409 Reporting Requirements.

3. RESPONSIBILITY

The IRB Chairperson or IRB Vice Chairperson is responsible for presenting the facts to the IRB at a convened IRB meeting.

The IRB Chairperson or IRB Vice Chairperson is responsible for notifying the appropriate individuals and agencies of the suspension or termination.

IRB members are responsible for determining if the facts are sufficient to require suspension or termination of the research.

IRB members are responsible for determining course of action and establishing a timeline for completion of that action.

The IRB Coordinator and/or IRB Secretary are responsible for sending out letters to Investigators and appropriate individuals and agencies.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.113
21 CFR 56.113

5. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

| Who | Task |
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| <i>IRB Chairperson and/or IRB Vice Chairperson</i> | Present the facts to the IRB at a convened IRB meeting |
| <i>IRB Members</i> | Review the facts and make determination, establish an action plan and timeline for the Investigator. |

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| <i>IRB Coordinator, IRB Secretary</i> | After IRB meeting, notify the Investigator within 5 business days of IRB determination. |
| <i>Associate Vice President for Research and Economic Development</i> | Notify within 5 business days all appropriate individuals and agencies of IRB determination. |