SOP 1.5.3 Suspension/termination of IRB review

General Description/Definitions

Suspension – is an action taken by the IRB which constitutes a temporary or permanent withdrawal of approval of all or some specific research activities after evaluation of unanticipated problems involving risks to subjects or others, evaluation of substantive allegations of serious and/or continuing non-compliance, or findings of serious and/or continuing non-compliance arising from post-approval monitoring or other ongoing review of research activities.

Termination – A study may be terminated when it no longer constitutes human subject research. The IRB may also terminate a study for cause or event, therefore halting further research.

A study may be suspended or terminated if there are serious concerns about the protection of the rights and welfare of human research participants or in instance of ongoing (continuing) noncompliance. The procedures described in this document are based on the regulatory requirements outlined in 45 CFR 46.113[1] and 21 CFR 56.113[2] and apply when an IRB suspends or terminates a human research study.

Procedures:

IRB Review of Study Suspension

The review process will begin by reviewing all pertinent information from the PI about the particular event per GMU's reporting policies (see related SOPs listed at end of document). The IRB reviews all available information and determines and documents during a full convened board meeting whether serious and/or continuing noncompliance occurred, whether or not to suspend or terminate the research, the reason for suspending/terminating the research, and the activities to stop (e.g., recruitment, enrollment, some or all interventions or interactions, follow-up, data analysis, or all research activities).

Review materials will be distributed to all IRB members as described in SOP 2.5.1 Full board review. Appropriate review materials may include:

- Study protocols and procedures
- IRB application along with all attachments and notices
- Study related correspondence and other pertinent documents

During review, the IRB will consider the following actions to protect the rights and welfare of subjects, including, but not limited to:

- Halting participant enrollment
- Halting study treatment and/or intervention
- Prohibition of use of data for analysis
- Notification of subjects of the suspension through appropriate communications (oral or written) approved by the IRB;
- Requiring withdrawal of current enrolled subjects;
- Changes to the protocol, consent form or other documents to correct any insufficiencies.

[1] 45 CFR 46.113. Department of Health and Human Services, Office of Human Research Protections. Code of Federal Regulations. http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.113
[2] 21 CFR 56.113. Federal Drug Administration. Code of Federal Regulations. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=56.113

The suspension of a single aspect of the research (i.e. new participant enrollment) will not be considered a suspension of IRB approval unless it is associated with an unanticipated problem, serious noncompliance, and/or continuing noncompliance. The convened IRB may consider alternatives to termination as an approach to protect currently enrolled participants who may be at risk if the research is terminated.

IRB Communication

The IRB will notify the PI in writing of the determination. The communication will include the following as appropriate:

- Determination of serious and/or continuing non-compliance;
- Determination of suspension or termination;
- Reasons for the suspension or termination;
- Description of the research activities that are suspended or terminated;
- Corrective actions mandated by the IRB and actions needed to lift a suspension;
- Timelines for implementing the proposed actions and follow-up reporting to the IRB.

This information will be reported promptly to the investigator, appropriate institutional officials, Office of Human Research Protections (OHRP) and the Food and Drug Administration (FDA), as described in applicable regulations and this SOP. This information may also need to be reported the funding agency as appropriate agency regulations and guidelines.

Review of Response by IRB

A convened IRB will review the response to concerns from the PI, and may subsequently lift the suspension, require additional changes, or require termination of the study. If the concerns are not addressed, the IRB may terminate the research or take other action to protect the rights and welfare of subjects or others. Communications will include all pertinent information, as described in this SOP and will be reported promptly to the investigator, institutional officials, OHRP and FDA as proscribed in applicable regulations and this SOP.

Termination of study by the PI and closure of study file

Continuing IRB review and approval may be required as long as a covered study activity is ongoing, including intervention or interaction with subjects and collection or use of identifiable information. Only when all study activity has ceased should an investigator close a research study. At that time, the PI must submit a termination report (continuing review form) to close out a study which includes the reasons for termination and a summary of the progress of the research activity. Once the study is terminated, the study records will be stored in accordance with the George Mason University data storage and retention policies. See "SOP 2.7 -Project Close-out Procedures" for additional information on study closure by the PI.

IRB Reporting

Reporting to Office of Human Research Protections (OHRP)[3]
To fulfill the regulatory requirements for reporting incidents, the IRB will include the following information in a report submitted to OHRP:

[3] Office of Human Research Protections, Department of Health and Human Services. Incident Reports. http://www.hhs.gov/ohrp/policy/incidreport_ohrp.html

- Name of the institution conducting the research;
- Title of the research project and/or grant proposal that was suspended or terminated;
- Name of the principal investigator on the protocol;
- Number of the research project assigned by the IRB that was suspended or terminated and the number of any applicable federal award(s) (grant, contract, or cooperative agreement);
- A detailed description of the reason for the suspension or termination; and
- The actions the institution is taking or plans to take to address the suspension or termination (e.g., investigate alleged noncompliance, educate the investigator, educate all research staff, require monitoring of the investigator or the research project, etc.)

The regulations at 45 CFR 46.103(a) and (b)[4] do not specify a time frame for reporting, but reports to OHRP will generally occur between 2-10 business days after study suspension or termination, depending upon the seriousness of the events or risk to subjects. If necessary, an initial report will be sent, indicating that a follow-up or final report will follow by either a specific date or when an investigation has been completed or a corrective action plan has been implemented.

Reporting to Food and Drug Administration (FDA)
Reporting to the FDA will only occur for studies that are regulated by the FDA. 21 CFR 56.108(b)[5] which requires that the IRB promptly report the following to appropriate institutional officials and the FDA:

- Any unanticipated problems involving risks to human subjects or others;
- Any instance of serious or continuing noncompliance with these regulations or the requirements or determinations of the IRB; or
- Any suspension or termination of IRB approval.

When reporting suspensions or terminations of IRB approval to the FDA, the IRB will include the IND or IDE number, the full name of the research protocol, the name(s) of the investigators, and the reason(s) for the suspension or termination. These reports will be submitted in the appropriate format to the appropriate FDA contacts identified on the website:
http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ReportProblemstoFDA/ucm136102.htm.

References:

45 CFR 46.103
45 CFR 46.113
21 CFR 56.113
21 CFR 56.108
Guidance on Reporting Incidents to OHRP

Related Forms, Guidance, and SOPs:

- SOP 1.5.1- Noncompliance and Deviations
- SOP 2.5.1 Full board review
- SOP 2.6.5- Adverse Event Reporting Policy
- SOP 2.7- Project Close-out Procedures

[4] 45 CFR 46.103. Department of Health and Human Services, Office of Human Research Protections. Code of Federal Regulations. http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.103
[5] 21 CFR 56.108. Federal Drug Administration. Code of Federal Regulations. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=56.108

Responsibility:

Principal Investigators
Research Team Members
IRB office
Institutional Review Board

Approval and Version History:

Please contact irb@gmu.edu if you have any questions about this policy or the version and approval history.

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Approved By	Title and Division	Date Approved
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Greg Guagnano	IRB Chairperson	06/25/2014