Title: SUSPENSIONS AND TERMINATIONS OF IRB APPROVAL
Version No.: 1.4
SOP No.: FO-310
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1. Purpose

This policy establishes procedures for documenting the requirements for suspension or termination of IRB approved human research activities.

2. Policy

Federal regulations authorize the IRB to suspend or terminate human research protocols. In addition to the IRB, Memorial Sloan Kettering Cancer Center (MSK) authorizes the Institutional Official (IO) to suspend and/or terminate human subject research protocols. Suspension or termination of IRB approval may occur when research is not being conducted in accordance with IRB requirements or has been associated with unexpected serious harm to participants. If suspension or termination of IRB approval occurs, the reporting requirements of IRB SOP CO-602 will be followed.

The Senior Vice President, Clinical Research, may administratively close studies for institutionally directed purposes. This closure is not considered termination of research and will not be reportable to OHRP or FDA. This is in contrast to reporting that must occur pursuant to HHS and FDA regulations if a study is suspended or terminated for cause by the IRB. Administrative closures will be reported to the IRB by the HRPP.

3. Specific Procedures

3.1 Definitions

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

Authorized Organizational Officials: For the purposes of this policy, this means those individuals authorized by the institution to suspend or terminate IRB approved research. Those individuals include the Institutional Official and the IRB Chairs.

3.2 Suspension or Termination by the IRB

3.2.1 The MSK IRBs are authorized by the federal regulations to suspend or terminate approval of research that is not being conducted in accordance with regulatory requirements, MSK IRB policies and procedures, determinations of the IRB, or have been associated with unexpected serious harm to participants.

3.2.2 Notification of suspension or termination of IRB approved research must include a statement of the reasons for the IRB's action and shall be reported in accordance with the requirements as set forth in IRB SOP CO-602.

3.2.3 The MSK IRB will determine and inform the Principal Investigator (PI) of steps to be taken as a result of suspension or termination of the research. Steps could include:

- Notifying current participants that the study has been terminated;
- Presenting to the IRB procedures for withdrawal of participants that will consider the rights and welfare of those participants;
- Informing the participants of any follow-up procedures permitted or required by the IRB for their safety; and

- Reporting to the IRB and the sponsor of any adverse events/outcomes that happen during that follow up period.

3.2.4 The communication to the PI, and to participants if applicable, should explain the suspension or termination and offer the PI an opportunity to respond to the IRB's decision. The communication will ask the PI to provide a plan for ensuring that the rights and welfare of all currently enrolled, or previously enrolled participants if appropriate, are protected.

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

3.2.6 To reinstate a project that has been terminated, the investigator must submit the project to the IRB as new submission and all issues identified in the past must be resolved to the satisfaction of the IRB.

3.3 Suspension by Authorized Organizational Officials

3.3.1 MSK authorizes the Institutional Official and the IRB Chairs to suspend human research projects on an urgent basis when required to mitigate immediate risk of harm to research participants.

3.3.2 When an authorized organizational official acts independently to suspend research, the IRB Chair will inform the PI of the suspension (within 24 hours).

3.3.3 Once suspended, the IRB Chair will determine if immediate action is required to alleviate harm to participants. The suspension decision and subsequent requirements to alleviate harm to participants will be promptly (within five days of the action) communicated to the PI and the IRB in writing by the IRB Chair or HRPP Director.

3.3.4 The IRB Chair or HRPP Director (or designee) will present the suspension and subsequent actions to the convened IRB during the next meeting.

4. Applicable Regulations and References

- 45 CFR 46.103(b)(5)(iii)
- 45 CFR 46.113
- 21 CFR 56.108(b)(3)
- 21 CFR 56.113

Revision History

Revision	Effective Date	Reason for Change
1.0	2/29/16	NEW
1.1	11/23/20	3.1 Removed individuals that can suspend or terminate as this is already covered in the policy statement; Added that authorized organizational officials can also terminate IRB approved research
1.2	1/23/23	2 Added a statement that the Institutional Official may administratively close studies for institutionally directed purposes and that this does not constitute termination of research and will not require OHRP reporting. 3.3.2 Removed the specific method of notification of suspension.

1.3	2/5/24	2 Updated staff titles 3.3.3 Clarified that, once suspended, the IRB Chair will determine if immediate action is required to alleviate harm to participants.
1.4	1/20/26	2 Clarified that MSK authorizes the IO to suspend and/or terminate human subject research protocols