

8.6 Study Hold, Suspension, and Termination

1.0 Purpose

The purpose of this policy is to describe the process for study holds, study suspensions, and study termination.

2.0 Policy

It is the policy of the Organization that:

- 2.1. The ORA has the authority to accept a study hold imposed by the PI, sponsor, DSMB, FDA or other funding agency, and the IRB Executive Chair or the IRB has the authority to release that hold.
 - 2.2. The IRB or the Executive Chair has the authority to suspend IRB approval of research, and the IRB has the authority to release that study suspension.
 - 2.3. The IRB or the Organization has the authority to terminate IRB approval of research.
 - 2.3. Suspensions or terminations of IRB approval as a result of noncompliance will be promptly reported to OHRP, FDA and sponsors or funding agency heads in accordance with the requirements of 45 CFR 46.108(a)(4), and 21 CFR 56.108(b), and the Organization's FederalWide assurance, as specified in [HRPP policy 8.7](#) (Reporting Incidents to Institutional Officials and Federal Agencies).
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3.0 Definitions

- 3.1. Study Hold: A planned or unplanned temporary halt to subject accrual and/or research activities, that is imposed by the PI, sponsor, DSMB, or FDA or other funding agency. A study hold may be full (affecting accrual and all study activities), or partial (affecting only accrual, or only some study activities).
Note: A study hold which is not imposed by the IRB does not constitute a suspension or termination of IRB-approval of research under 45 CFR 46.113; 21 CFR 56.113.
- 3.2. Suspension of IRB Approval: A directive of the IRB at a convened meeting, or a directive of the IRB Executive Chair or designee (in consultation with the IO as appropriate), that all or some research activities in one or more protocols must be temporarily suspended.

Note: interruptions in human research resulting solely from the expiration of the IRB approval period does not constitute suspension of IRB-approval of research under 45 CFR 46.113 or 21 CFR 56.113.

- 3.3. Termination of IRB Approval: A directive by the IRB at a convened meeting that all research activities must permanently cease in one or more protocols.
 - 3.4. Organization Directed Termination of IRB Approval: A directive by the Institutional Official (IO) that an IRB approved study be terminated.
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4.0 Study Holds by PI, Sponsor, DSMB, FDA or Other Funding Agency

- 4.1. The PI, sponsor, DSMB, FDA or other funding agency may place a study hold by contacting the ORA by email or letter. When the ORA acknowledges the study hold subject accrual and/or research activities will cease in accordance with the conditions of the study hold.
 - 4.2. The IRB will take appropriate action(s) to protect the rights and welfare of currently enrolled subjects.
 - 4.3. The PI will be responsible for notifying all study personnel that there is a study hold and subject accrual and/or research activities may be restricted.
 - 4.4. The IRB will be notified at the next convened meeting that a study hold was placed on the protocol.
 - 4.5. The PI, sponsor, DSMB, FDA or other funding agency may request a release of the study hold by contacting the ORA by email or letter.
 - 4.5.1. If the study hold was initiated for subject safety concerns only the convened IRB may release the hold.
 - 4.5.2. If the study hold was initiated for other non-safety concerns, the IRB Executive Chair/designee may release the study hold.
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5.0 Suspension of IRB Approval

- 5.1. The convened IRB or the IRB Executive Chair or designee may suspend IRB approval of research if such action is warranted due to concerns regarding the safety, rights, or welfare of human research subjects, investigators, research staff, or others, or due to noncompliance concerns, or other similar circumstances.
 - 5.1.1. The IRB Executive chair may exercise his/her authority to suspend research when, in his/her judgement, such action is necessary to protect the safety, rights, or welfare of human research subjects, investigators, research staff, or others before the next convened IRB meeting.
- 5.2. The IRB will take appropriate action(s) to protect the rights and welfare of currently enrolled subjects.
- 5.3. The PI will be responsible for notifying all study personnel that the study has been suspended and that all, or some, research activities are suspended.
- 5.4. The PI must report to the IRB any adverse events or outcomes associated with the suspension.
- 5.5. The PI must notify research subjects currently on study of suspension of IRB approval of research activities. Subjects should be advised of any follow-up necessary for safety

reasons.

- 5.6. The IRB, or the Executive Chair, has the authority to permit subjects currently on study to continue if it is in their best medical interest to do so.
 - 5.7. If the study was suspended by the Executive Chair, the IRB will be notified at the next convened meeting of the suspension.
 - 5.8. The PI may file a written appeal of the suspension to the IRB. The IRB has the final authority to act on any appeals and the decision of the Board cannot be overturned.
 - 5.9. The convened IRB has the sole authority to release a study suspension.
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6.0 Termination of IRB Approval

- 6.1. The convened IRB may terminate IRB approval of research if such action is warranted due to concerns regarding the safety, rights, or welfare of human research subjects, investigators, research staff, or others, which cannot be otherwise resolved, or due to serious or continuing noncompliance with the applicable federal regulations and HRPP policies, or due to other similar circumstances.
 - 6.2. The IRB will provide the PI with written justification for termination of IRB approval of the research.
 - 6.3. The IRB will promptly notify the IO and other appropriate Organization officials of the termination of IRB approval of research.
 - 6.4. The IRB will take appropriate action(s) to protect the rights and welfare of currently enrolled subjects.
 - 6.5. The PI will be responsible for notifying all study personnel that the study has been terminated and that all research activities must cease.
 - 6.6. The PI must report to the IRB any adverse events or outcomes associated with the termination.
 - 6.7. The PI must notify research subjects currently on study of termination of the study. Subjects should be advised of any follow-up necessary for safety reasons.
 - 6.8. The PI may file a written appeal of the suspension to the IRB within 30 days of the termination. The IRB shall give the PI an opportunity to appear before the Board. The PI will be afforded due process and may bring legal counsel who will be restricted to observation only. The IRB has the final authority to act on any appeals and the decision of the Board cannot be overturned.
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7.0 Organization Directed Termination of IRB Approval

- 7.1. In consultation with appropriate Organization officials the IO may direct that one or more of an investigator's approved studies be terminated.
- 7.2. The IO will provide the PI with written justification for termination of the research.
- 7.3. The IO will notify appropriate the IRB Executive Chair, and Organization officials of the termination of the research.
- 7.4. The IRB will take appropriate action(s) to protect the rights and welfare of currently enrolled subjects.
- 7.5. The PI will be responsible for notifying all study personnel that the study has been terminated and that all research activities must cease.

- 7.6. The PI must report to the IRB any adverse events or outcomes associated with the termination.
 - 7.7. The PI must notify research subjects currently on study of termination of the study. Subjects should be advised of any follow-up necessary for safety reasons.
 - 7.8. The PI may file a written appeal of the suspension to the IO within 30 days of the termination. The IO has full authority to act on the appeal and may at his/her discretion seek consultation with the IRB or any other persons. The PI will be afforded due process and may be offered the opportunity to meet with the IO. The investigator may bring legal counsel who will be restricted to observation only. The decision of the IO regarding any appeal is final.
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8.0 Reporting Suspensions and Terminations to OHRP, Department and Agency Heads, and FDA

Suspensions and terminations are reported in accordance with [HRPP policy 8.7](#) (Reporting Incidents to Institutional Officials and Federal Agencies).

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? Revised: 1/20/2023 - Simplified Purpose statement; revised section 2.0 to reflect specific authorities granted in the body of the policy; removed reference to appeals panel and substituted option to seek consultation with the IRB or any other persons (section 7.8); stylistic changes. {Approved Rusty McCulloh (Institutional Official), Bruce Gordon (Assistant Vice Chancellor for Regulatory Affairs, Executive Chair)}

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