

Administrative Hold, Suspension, or Termination of IRB Approval

Introduction:

The IRB conducts administrative holds, suspensions, and terminations in accordance with [45 CFR 46.113](#) and [21 CFR 56.113](#).

Definitions:

Administrative Hold: A voluntary action by an investigator to stop research activities in a currently approved protocol.

Continuing Review Reminder Notices are correspondences sent by the IRB to an investigator, as a reminder of the upcoming expiration of IRB approval of a protocol.

Expired Study is when continuing review of the research does not occur prior to the end of the approval period specified by the IRB, IRB approval expires automatically. No activities can occur after the expiration date.

Research Misconduct means fabrication, falsification, plagiarism in proposing, performing, or reviewing research, or in reporting research results.

Study Withdrawal is an action taken by the IRB to permanently withdraw a study, after it has been reviewed and given contingent approval (minor modifications required to secure approval); or been deferred with a request for additional information for review, and the investigator does not respond.

Suspension is when research on an approved protocol is partially or completely stopped pending future action by the IRB. Examples include: an unanticipated problem in research involving greater than minimal risks to subjects or others; unexpected serious harm to subjects; or when the IRB is investigating a research protocol for possible issues of human subject non-compliance or continuing non-compliance with federal regulations, or with the determinations of the IRB. Suspended protocols remain open and require continuing review.

Termination is when the IRB permanently stops some or all research procedures associated with an active approved protocol.

Policy:

The IRB has the authority and responsibility to suspend or terminate approval of research that is not being conducted in accordance with the IRB policies and procedures, or that has been associated with unexpected harm to participants or others. The IRB has the ability to temporarily or permanently suspend or terminate approval for some or all research activities. **Depending on the circumstances surrounding the suspension or**

termination action, the investigator may be required to submit a report to the IRB, detailing any adverse events and/or study outcomes that were previously unreported to the IRB for consideration. Any letter of suspension or termination of approval to an investigator must include a statement of the reasons for the action by the IRB ([45 CFR 46.113](#) and [21 CFR 56.113](#)).

The IRB Chair, Vice-Chair, or the Vice President for Research of the Center for Clinical Research is authorized to suspend or terminate the enrollment of subjects; and the ongoing involvement of subjects in research, as it deems necessary to protect the rights and welfare of participants. This also includes compelling and urgent instances when subject safety is of concern. The IRB will review such suspensions and terminations at a subsequent convened meeting. A plan will be developed that takes into account the rights and welfare of currently enrolled subjects and those subjects who may need to be withdrawn from the study. If the IRB determines that a suspension or termination of the research will place subjects at risk of harm, the investigator will be requested to submit a proposed script or letter for participants for IRB review and approval. The IRB determines the information that is to be provided to subjects and the method of their notification e.g., in writing or by telephone. This includes appropriate subject follow-up and notification of the reasons for the action. All protocol suspensions or terminations are reviewed at a subsequent IRB meeting.

Depending on the reasons for the suspension or termination and the design of the protocol, the IRB may require that the following subjects be notified of the suspension or termination:

- All subjects who have been or are enrolled
- Subjects currently on protocol; or
- Subjects who participated in a certain aspect of the protocol

The IRB will ensure prompt reporting to the following:

Notification of the IRB members: As required in [45 CFR 46.110\(c\)](#), the Vice-President of Research of the Center for Clinical Research will keep all IRB members advised of activities occurring outside of the full board meetings including protocols that have been suspended or terminated. The IRB members are advised of activities occurring outside of the full board meetings in a monthly written report, which is presented at a convened meeting.

During an investigation for human subjects' non-compliance, the IRB Chair or a Vice-Chair will notify the principal investigator of such terminations or suspensions by letter and will include a statement of the reasons for the IRB's actions. The investigator will be provided with the opportunity to respond in person or in writing. The IRB chair reviews and signs the letter. The letter includes:

- The nature of the event
- Name of the institution conducting the research

- Title of the research project and/or grant proposal
- Name of the principal investigator on the protocol
- A detailed description of the problem including the findings of the organization and the reasons for the IRB's decision.
- The activities to be stopped
- Actions to be taken by the investigator; including those to protect the rights and welfare of currently enrolled subjects.
- A request to immediately notify the IRB chair with a list of names of participants who might be harmed by stopping research procedures and a rationale why they might be harmed.
- In the case of a suspension or termination of IRB approval by an IRB designee, the date and time of the IRB meeting at which the suspension or termination will be reviewed by the convened IRB; and the actions required to protect the rights and welfare of currently enrolled participants.
- An offer for the investigator to respond to the convened IRB in writing

The IRB may find it in the best interest of the enrolled subjects to allow continued participation in the research interventions or interactions, but enrollment of new subjects cannot occur during IRB suspension. The convened IRB will determine the appropriate actions and if a study is to be terminated, or may continue with enrollment at the completion of the human subjects non-compliance investigation ([IRB Policy, Non-Compliance with Human Subjects' Regulations](#)).

Reporting to Regulatory Agencies, Department Heads and Institutional Officials:

The IRB will report events of suspensions or terminations of IRB approval to Regulatory Agencies, Department Heads and Institutional Officials as established in [IRB Policy, Reporting to Regulatory Agencies, Department Heads and Institutional Officials](#).

Lapse in Continuing Review:

The IRB and investigators must plan ahead to meet required continuing review dates specified by the IRB. The IRB has an established Continuing Review Notice system which reminds the IRB and its investigators when an approved IRB research protocol is due to expire. The notices are sent ten and six weeks in advance of IRB expiration. A notice is also issued the week of IRB protocol expiration, which notifies the principal investigator that the protocol will expire and once expired, all research activities including enrollment of new subjects must cease (*see* [IRB Policy, Protocol Continuing Review](#), for more information).

In certain circumstances, the IRB has the authority to allow the continued participation of subjects in research for which IRB approval has lapsed while the continuing review process occurs, if there are overriding clinical or safety concerns or ethical issues that indicate it is in the best interest of the participants to continue (*see* [IRB Policy, Protocol Continuing Review](#), for more information).

The Federal regulations do not allow for the conduct of human subject research without IRB approval. Any report of continuation of study activities after IRB expiration (outside of the above noted exception) will be investigated as an matter of potential non compliance and may be reportable to the [Office for Human Research Protections](#) (OHRP), the Food and Drug Administration (FDA), the UH Compliance Officer, and Department Heads and other Institutional Officials, in addition to other applicable governing Federal Agencies.

References and/or Regulatory Citations:

[OHRP Compliance Activities: Common Findings and Guidance \(7/10/2002\).](#)

[OHRP Guidance on Continuing Review \(January 15, 2007\):](#)

[45 CFR 46.113](#)

[21 CFR 56.113.](#)

Related Policies:

[IRB Policy, Non-Compliance with Human Subject Regulations](#)

[IRB Policy, Protocol Continuing Review](#)