# Suspension or Termination

## Purpose

The purpose is to outline the policies and procedures for suspension or termination of human research approval.

## Definitions

***Continuing Noncompliance*** is any noncompliance that occurs in a persistent or repeated manner.

***Noncompliance*** is failure to comply with the regulations, institutional policies, laws or the requirements or determinations of the IRB or Exempt Review Committee (ERC).

***Serious Noncompliance*** is any noncompliance that adversely affects the rights and welfare of the subjects, increases risks to subjects or others, alters the risk/benefit ratio, compromises the integrity or validity, or results from intentional misconduct on the part of the investigator or research team.

***Suspension of research approval*** is when approval is placed on hold until a determination is made that research may resume. Suspension may include some research activities, temporarily or permanently, or all research activities temporarily, short of terminating all activities. Note: Similar actions initiated by investigators or sponsors to stop research activities are not considered to be suspensions as described in this policy.

***Termination of research approval*** is when approval for a project is permanently revoked, except for follow-up procedures that may be necessary to protect the health and/or welfare of participants. Note: Similar actions initiated by investigators or sponsors to stop research activities are not considered to be terminations as described in this policy.

## Policy

The Institutional Review Board (IRB) has regulatory authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects (45 CFR 46.113). Research that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB (45 CFR 46.112).

Research may be suspended or terminated based on information received during continuing review or annual check-in, from findings of a quality improvement visit, from an investigator's self-report of an unanticipated problem, serious adverse event, or major deviation, from continuing non-compliance, or from complaints made to the IRB Office by participants or others. Any suspension or termination of approval shall include a statement of the reasons for the action and shall be reported promptly to the investigator, appropriate institutional officials, and the department or agency head (45 CFR 46.113, if applicable).

In urgent situations, either the Provost (Institutional Official) or Assistant Provost has authority to suspend or terminate research between IRB meetings. Research may also be suspended for failure to submit mandatory reports (e.g., annual check-in, deviation, serious adverse event, etc.). In these cases, the suspension or termination is reported to the full board when it next meets.

See also our Mandatory Reporting Policy for information about unanticipated problems, adverse events, and deviations.

## Procedures

1. Noncompliance information is discovered or received by the IRB Office, in the following ways:

    1. During continuing review or annual check-in
    2. From findings of a quality improvement visit

    3. From an investigator's self-report of an unanticipated problem, adverse event or major deviation
    4. From continuing non-compliance
    5. From complaints made to the office by research participants or others
2. The convened IRB, or in certain cases, the Provost (Institutional Official) or Assistant Provost, reviews the information and considers the appropriate action, based on the rights and welfare of the participants, the integrity and validity of the research, and policies and procedures.
3. If the project is suspended, the reason(s) are communicated to the Principal Investigator (PI) via an official letter, along with any actions required to protect the rights and welfare of current or past research participants. Appropriate actions may include, but are not limited to:

    1. Notification of current and/or former participants
    2. Transfer of responsibility for the project and participants to another investigator
    3. Continuation of participants in the project with and independent monitor
    4. Withdrawal of current participants from the research
    5. Requiring or permitting follow-up of participants (e.g., for safety reasons)
4. Suspension may be lifted by the convened IRB, Provost (Institutional Official) or Assistant Provost once there are no longer concerns about the following. Once the suspension is lifted, it will be communicated to the PI via an official letter.
    1. Potential harm(s) to research participants
    2. Research noncompliance
5. If the project is terminated, the reason(s) are communicated to the PI via an official letter, which will include any actions required to protect the rights and welfare of current or past research participants. Appropriate actions may include, but are not limited to:

    1. Notification of current and/or former participants
    2. Transfer of responsibility for the project and participants to another investigator
    3. Withdrawal of current participants from the research

4. Requiring or permitting follow-up of participants (e.g., for safety reasons)

6. Suspensions or terminations are also promptly reported to the appropriate institutional officials and the department or agency head (if applicable).
7. Investigator Responsibilities: Upon notification that research has been suspended or terminated by the IRB, the PI is responsible for the following:

    1. Closing enrollment and research activities as communicated to the PI
    2. Cooperating with any investigation about the issue
    3. Assisting with and/or carrying out actions required to protect the rights and welfare of participants (e.g., notification, withdrawal, follow-up, etc.)
    4. Reporting to the IRB or ERC any adverse events or outcomes encountered during suspension or termination of the research

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## Related Policies & Procedures

- Approval of Research
- Closure or Withdrawal
- Mandatory Reporting
- Misconduct

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## History

07/19/2013 - Created
10/23/2014 - Format Corrected after Site Conversion
05/31/2019 - Updated as a result of the Revised Common Rule