Suspension or Termination of Previously Approved Research

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Policy Statement

The UIW IRB has the authority to suspend or terminate approval of research that is associated with serious or continuing noncompliance with regulations and/or UIW IRB requirements, or that has been associated with serious harm or risk to participants. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, regulatory authorities, and the department or agency supporting the research.

Definitions

Suspension of previously approved research: The suspension of previously approved research is defined as temporarily discontinuing approved interventions with human participants for research purposes. Options include: 1) suspension of new enrollment but continuation of previously enrolled participants, 2) suspension of research activities at specific research site(s) under UIW jurisdiction, 3) suspension of a particular activity within the approved research protocol, or 4) suspension of all research activity.

Termination of previously approved research: The termination of previously approved research is defined as indefinitely (possibly permanently) discontinuing any interventions with human participants for research purposes.

Description and Procedures

A. Consideration of Suspension or Termination

Circumstances (including allegations with supporting evidence) that may result in suspension or termination of previously approved research include

1. when research is not conducted in compliance with IRB requirements. If such noncompliance is determined to increase participant risk(s) beyond what was reviewed and approved and/or continuing, the IRB will take action to protect human participants, which may include suspension or termination.

2. when research is associated with serious unanticipated risk or harm to participants or others. If the IRB determines that risk, harm or the unanticipated problem seriously threatens the

health status or well-being of participants or others, the study may be suspended or terminated.

Alternatively, when the conduct of the research rises to the level of either of the above two circumstances, the investigator may voluntarily stop research activities and notify the IRB, thereby preventing an imposed suspension or termination, until such time as the circumstances are resolved. Upon favorable IRB evaluation of the circumstances, the investigator may be permitted to continue research activities with or without modification. If the IRB's evaluation is not favorable, suspension or termination of research activities may be issued by the IRB.

B. Suspension/Termination Procedures and Documentation

One of the following three methods are used for suspending or terminating previously approved research. Each method allows for the group or individual to take swift and immediate action in order to ensure the immediate protection of research participants:

- Administrative Suspensions and Terminations can be put into effect by the Associate Provost for Research and Graduate Education. The preceding events and the imposed action are reviewed for on-going status at the next convened IRB meeting.
- Expedited IRB Suspensions and Terminations can be put into effect by the IRB Chair. The preceding events and the imposed action are reviewed for on-going status at the next convened IRB meeting.
- IRB Full Board Suspensions and Terminations are put into effect by board action within a board meeting, where the board members vote to take this action.

In all cases, regardless of the point of origin of the suspension or termination, the following procedure, which is overseen by the ORSPO, applies: Every effort should be made to contact the principal investigator promptly. Official written notice of the suspension or terminations must be provided to the principal investigator within 3 working days of informal communication of same. If a suspension or termination is imposed by Administration, the IRB Chair, or the convened IRB and Chair together with ORSPO ensure that the PI is quickly informed according to the criteria below:

- effective date of suspension or termination;
- reason for suspension or termination;
- corrective actions necessary, request for corrective actions, or instructions for closure of the study, as appropriate;
- who the notice is copied to (including Departmental Chairperson or Dean, IRB, ORSPO Director, and federal oversight agencies as required); and
- specific instructions pertaining to currently enrolled research participants, including language to ensure that:
    a. current participants are notified that the study has been suspended and/or terminated;
    b. procedures are in place to ensure that withdrawal of enrolled participants considers the rights and welfare of participants;
    c. when follow-up of participants for safety reasons is permitted/required by the IRB, the participants should be so informed; and

d. when follow-up of participants is permitted/required by the IRB for safety reasons, any unanticipated events/outcomes should be reported to the IRB and the sponsor.

Suspension imposed on some or all of the research protocol may be lifted when, and if, the IRB finds that participants are adequately protected from risk in order to continue in the study safely. Suspension may also be lifted when, and if, the IRB finds that the corrective action plan has been adequately addressed such that participants are fully protected and events preceding the suspension are unlikely to recur.

Effective Date

August 24, 2020

Revision History