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| Suspension or Termination of IRB Approval | Effective Date | 5.31.2018 |
| | Revisions Date | 6.10.2021 |

1.0 Purpose: The purpose of this standard operating practice (SOP) is to establish guidelines for suspending or terminating University and Medical Center Institutional Review Board (UMCIRB) approval of human research activities. The convened IRB, an IRB Chairperson (or designee) or the Institutional Official (IO) or designee may impose these actions on approved research when, in their judgment, this is necessary to protect the rights or welfare of research participants.

2.0 Persons Affected:

- 2.1 Individuals engaged in human research activities
- 2.2 UMCIRB Members
- 2.3 UMCIRB staff
- 2.4 Participants in previously approved human research studies

3.0 SOP: The UMCIRB has the authority to suspend or terminate approval of human research that is not being conducted in accordance with the IRB's requirements, institutional rules and regulations, state laws, or federal regulations or that has been associated with unexpected serious harm to participants. Participants may not be enrolled or receive research interventions (unless there is scientific or medical justification) during a period of suspension or termination. Certain parts of a research study may be allowed to continue when determined that it is in the best interest for these activities to continue or when there is possible increased risk to participants if certain procedures do not continue.

4.0 Definitions:

- 4.1 **Suspension of Research Activities:** A directive of the convened IRB, the IRB Chairperson (or designee), the Institutional Official (IO), the sponsor or other oversight body to temporarily stop some or all previously approved research activities. Suspension can be applied to such activities as recruitment, enrollment, or specific research procedures. Suspended protocols or protocols with specific suspended procedures remain in an “active” status and require continuing review.
- 4.2 **Suspension of Research Personnel:** A directive of the convened IRB, after a thorough investigation has been deliberated at a convened meeting, to temporarily or permanently suspend limited or full research activities of an individual associated with human research. The suspension can be the result of actions that can be verified:
 - 4.2.1 Scientific misconduct, e.g., determined falsification, fabrication, or plagiarism;
 - 4.2.2 Actions that resulted in increased risks to participants or others;
 - 4.2.3 Actions that purposely skew research results; or
 - 4.2.4 Actions that do not meet the ethical standards of ECU and the person’s academic or scientific discipline.
- 4.3 **Termination:** A directive of the convened IRB to permanently cease all activities in a previously IRB-approved research protocol. Terminated protocols are considered closed and will require a final report.

5.0 Responsibilities:

5.1 Principal Investigators (PI) are responsible for:

- 5.1.1 Abiding by all IRB determinations and decisions;
- 5.1.2 Notifying the IRB of the following:
 - 5.1.2.1 Suspensions, terminations, or other limits on their participation in IRB approved human research imposed by study sponsors or oversight/regulatory agencies;
 - 5.1.2.2 Unanticipated problems involving risks to human research participants or others; and/or
 - 5.1.2.3 Any problem with the conduct of the IRB approved human research which may impact the rights or welfare of study participants or impact the IRB's determinations.
- 5.1.3 Notifying the study sponsor(s) when IRB approval is suspended or terminated;
 - 5.1.3.1 For Food and Drug Administration (FDA) regulated research involving an investigational drug or device, an investigator shall report to the sponsor, within 5 business days, a withdrawal of approval by the reviewing IRB of the investigator's part of an investigation;
- 5.1.4 Notifying currently enrolled participants when IRB approval is suspended or terminated as instructed by the UMCIRB; and
 - 5.1.4.1 The UMCIRB must review and approve the communications to research participants from the PI.

5.2 IRB Chairperson (or designee) is responsible for:

- 5.2.1 Determining if immediate actions are needed to protect the rights and welfare of study participants prior to the item(s) being reviewed by the next available fully convened IRB;
 - 5.2.1.1 The IRB Chairperson or designee may determine that immediate suspension of the research or specific research procedures is necessary to protect study participants or others from harm;
 - 5.2.1.2 The IRB Chairperson or designee will report this action to the fully convened IRB at the next available meeting after the suspension; and
 - 5.2.1.2.1 The IRB will be provided all information which was available to the Chairperson or designee that led to the suspension of IRB approval and any subsequent information that has been brought to light.

5.3 UMCIRB is responsible for:

- 5.3.1 Suspending or terminating currently approved research that is not being conducted in accordance with the IRB's requirements, federal regulations or that has been associated with unanticipated serious harm to participants or others. This includes, but is not limited to, suspending or terminating research for the following reasons:
 - 5.3.1.1 There is apparent or perceived imbalance of risk to benefit ratio based on events that have occurred since IRB approval was granted;
 - 5.3.1.2 There is serious or continuing non-compliance that places participants or others at unnecessary risk;
 - 5.3.1.3 There is suspension of privileges for the PI at the site at which the research is conducted;
 - 5.3.1.4 The study has received an FDA Warning letter because of objectionable activity;

5.3.1.5 There is lack of appropriate oversight by the Principal Investigator or others responsible for the safety and well-being of participants.

5.3.2 Suspending a PI's ability to submit new human research studies for IRB consideration;

5.3.3 Considering whether procedures for withdrawal of enrolled participants take into account their rights and welfare;

5.3.4 Before a suspension or termination is put into effect, the convened IRB, or if time does not permit, an IRB Chairperson (or designee), considers whether any additional procedures are needed to protect the rights and welfare of current or previous participants. Such procedures might include:

5.3.4.1 Transferring the care of participants to another PI;

5.3.4.2 Making arrangements for clinical care outside of the research;

5.3.4.3 Allowing continuation of some research activities under the supervision of an independent monitor;

5.3.4.4 Notification of current participants;

5.3.4.5 Notification of former participants;

5.3.4.6 For terminated studies:

5.3.4.6.1 Requiring or permitting follow-up of participants for safety reasons;

5.3.4.6.2 Requiring reportable events or outcomes to be reported to the IRB and the sponsor.

5.3.4.7 The IRB may decide additional procedures are needed to protect the rights and welfare of current or previously enrolled participants.

5.3.5 The decision to suspend or terminate and the reason for the decisions are fully documented in the IRB meeting minutes and in the specific research file.

5.4 **UMCIRB Director or designee** will:

5.4.1 Assist IRB chairperson and IRB members by providing guidance and education;

5.4.2 Immediately notify the PI and study team, department head and appropriate institutional official(s), as applicable, of suspensions or terminations and the reason for the determination;

5.4.3 Record the IRB committee's decision to suspend or terminate a research study including the reason for their decision, within the IRB meeting minutes;

5.4.4 Compose and send reports to promptly notify the Office for Human Research Protection (OHRP), and other applicable agencies (see Distribution List below) and sponsors, of IRB suspensions or terminations.

6.0 Distribution List: List of agencies or institutional entities which, if providing financial support or have oversight responsibilities, would be notified in the determination of suspensions or terminations:

6.1 Agency for International Development (22 CFR 225)

6.2 Central Intelligence Agency (Executive order)

6.3 Consumer Products Safety Commission (16 CFR 1028)

6.4 Department of Agriculture (7 CFR 1c)

6.5 Department of Commerce (15 CFR 27)

6.6 Department of Defense (32 CFR 219)

6.7 Department of Education (34 CFR 97)

6.8 Department of Energy (10 CFR 745)

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- 6.9 Department of Health and Human Services (45 CFR 46)
- 6.10 Department of Homeland Security (6 U.S.C. section 112)
- 6.11 Department of Housing and Urban Development (24 CFR 60)
- 6.12 Department of Justice (28 CFR 46)
- 6.13 Department of Transportation (49 CFR 11)
- 6.14 Department of Veterans' Affairs (38 CFR 16), Office of Research Oversight
- 6.15 Environmental Protection Agency (40 CFR 26)
- 6.16 National Aeronautics and Space Administration (14 CFR 1230)
- 6.17 National Science Foundation (45 CFR 690)
- 6.18 Social Security Administration (42 U.S.C. section 901)
- 6.19 Food and Drug Administration (21 CFR 56)
- 6.20 Division, Department, or Unit Chairperson and Dean
- 6.21 Administrators at Affiliate site(s)
- 6.22 Any Compliance Officers, Risk Management, or State Agencies that may have a need to be informed
- 6.23 Biomedical and/or Social & Behavioral IRB members and ex-officios

Revision History:

| Date | Change | Reference Section(s) |
|------------|---|----------------------|
| 10.11.2013 | Updated to stand-alone document. | All |
| 5.31.2018 | Updated SOP to move procedures to section 5.0 and added 5.4 ORIC specific responsibilities. | 3.0, 5.0 |
| 6.10.2021 | Updated office name; Added new footer format. | Throughout |

References

FDA. Code of Federal Regulations:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50>

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=56>

DHHS, OHRP. Code of Federal Regulations:

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>