

Suspension and Termination of Research

Purpose

- 1) This policy describes the procedures for documenting the requirements for when the Chapman Institutional Review Board (IRB) suspends or terminates an approved research project.

Policy

- 1) Federal regulations allow the IRB to suspend or terminate human subject research ([45 CFR 46.113/ 21 CFR 56.113](#)).
- 2) The Chapman IRB may suspend or terminate approval when research is not being conducted in accordance with IRB requirements or has been associated with unexpected serious harm to participants.
- 3) In addition to the IRB, other Chapman University officials may suspend research. Such individuals include the Institutional Official or the IRB Chair.
- 4) During a suspension, all research activities must cease.
- 5) Only the convened IRB may terminate research.
- 6) If suspension or termination of IRB approval occurs, the reporting of the suspension or termination will be in accordance with applicable regulations ([45 CFR 46.113/21 CFR 56.113](#)) and Chapman IRB policies.

Suspension or Termination by the IRB

- 1) The IRB is authorized under federal regulations to suspend or terminate approval of research that is not being conducted in accordance with IRB policies and procedures or has been associated with unexpected serious harm to participants.
- 2) Reasons the IRB may suspend approved research can include, but is not limited to, the following:
 - a) A principal investigator (PI) fails to provide the IRB with information requested that can affect the safety, rights, and welfare of participants
 - b) New information about the research becomes available that could alter the determinations made by the IRB at initial review or renewal of the research
 - c) The PI fails to comply with federal regulations, state or local laws, and institutional policies regarding the conduct of research involving human participants
 - d) The PI fails to meet the stipulations imposed by the IRB at renewal within the timeframe designated by the IRB
 - e) During an investigation of an allegation of noncompliance or to evaluate a safety issue

- 3) Notification of suspension or termination of IRB approved research must include the reason for the IRB's action and shall be reported promptly, when applicable, to the PI and appropriate officials within Chapman (including the Institutional Official). The Chapman IRB will follow the policy for reporting suspension or termination of research to Office for Human Research Protections, the Food and Drug Administration, or any applicable federal funding agency, as appropriate.
- 4) The IRB shall determine and inform the PI of steps to be taken as a result of suspension or termination of the research, which may include:
 - a) Notifying current participants that the study has been suspended or terminated by communications that will be reviewed and approved by the IRB
 - b) Presenting to the IRB procedures for withdrawal or transferring of participants to another site that is participating in the research that will consider the rights and welfare of those individuals
 - c) Informing the participants of any follow-up procedures permitted or required by the IRB for their safety
 - d) Reporting to the IRB and the sponsor of any adverse events or outcomes that happen during the follow up period
- 5) The communication to the PI should explain the circumstances of the suspension or termination and offer to the PI an opportunity to respond to the IRB's decision. The communication will ask the PI to provide a plan for ensuring that the rights and welfare of all currently enrolled, or previously enrolled participants, if appropriate, are protected.
- 6) All suspensions and terminations of research will be documented in Cayuse IRB as an administrative closure. Decisions made by the convened IRB to suspend or terminate research will be documented in the meeting minutes.
- 7) To lift the suspension, the PI must satisfactorily resolve any pending issues identified by the IRB. If the issues have not been resolved after 60 calendar days, the study will be terminated.
- 8) To reinstate a project that has been terminated, the investigator must submit the research to the IRB as a new submission in Cayuse IRB and all issues identified from the previous study must be resolved to the satisfaction of the IRB.

Revision history:

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