

Research Noncompliance

Purpose

- 1) The purpose of this policy is to identify the standards and responsibilities for handling reports of noncompliance related to research involving human participants, and the action taken when the Institutional Review Board (IRB) makes a finding of serious or continuing noncompliance.

Policy

- 1) Federal regulations require the IRB to promptly report any incidence of serious or continuing noncompliance to the appropriate federal regulatory agency ([45 CFR 46.108\(a\)\(4\)](#), [21 CFR 56.108\(b\)](#)), the Institutional Official (IO) of Chapman University, the Principal Investigator (PI), and others as determined by the Director of Research Integrity and institutional policy.
- 2) Investigators, study personnel, and others share the responsibility to report incidences of noncompliance with the regulations, requirements, or determinations of the IRB.

Process to Address Allegations of Noncompliance

- 1) Information alleging or revealing noncompliance in studies that enroll human participants may come to the attention of the IRB through several pathways:
 - a) Initial submissions
 - b) Renewals
 - c) Internal audits or monitoring
 - d) Food and Drug Administration (FDA) audit or inspection reports (e.g., FDA form 483)
 - e) Sponsor audit reports
 - f) Adverse event/safety reports/incident reports
 - g) Reports from collaborators, employees, or participants
 - h) Any other sources
- 2) Examples of noncompliance can include but are not limited to:
 - a) Performing research activities such as consenting participants without first obtaining IRB approval or a determination of exemption from the IRB.
 - b) Deviating from or violating the provisions of the IRB approved research or procedures.
 - c) Violation of institutional policies, state and local laws, federal regulations, and any conditions placed upon the review, oversight, or conduct of the research. This example applies to both research team members and the Chapman Human Research Protection Program (HRPP), including the IRB.
 - d) Permitting an IRB approved protocol to expire without stopping all research activities, including data analysis.
 - e) Failure to obtain informed consent from research participants.

- 3) All reports of alleged noncompliance are forwarded to the Director for Research Integrity. Allegations are reviewed in a consistent, prompt, and professional manner and care is taken to maintain confidentiality.
- 4) Whenever necessary, Chapman University's Legal Affairs will be engaged to invoke attorney-client privilege.

Preliminary Determination to Suspend or Not Suspend the Research

- 1) The Director of Research Integrity is responsible for the initial review of all noncompliance allegations. Reports must contain enough information to determine whether the allegation is sufficiently credible and specific so that potential evidence of noncompliance may be identified and acted upon.
- 2) The Director of Research Integrity must report all credible allegations of noncompliance to the Institutional Official (IO) and IRB Chair.
- 3) For allegations of noncompliance associated with research team members, the Director for Research Integrity makes recommendations to the IRB Chair regarding possible immediate suspension of the research or enrollment of participants. These individuals should also consider whether the suspension of all research is warranted. This initial decision to suspend research is based on preliminary review of available information, communication with the PI involved in the alleged noncompliance activities, and the seriousness of the allegations. The decision to suspend can be made by the convened IRB or the IRB Chair. If research activities are suspended, the IRB will report the suspension in accordance with federal regulations and applicable Chapman University policies.
- 4) Any individual with a personal, professional, or financial conflict of interest must recuse themselves from the process of investigating the noncompliance and making recommendations.

Investigation

- 1) After the preliminary evaluation of the allegation, an investigation into the allegation is undertaken with the authority and oversight of the Director of Research Integrity. The investigation is initiated within five-working days of the recognized concerns. The purpose of the investigation is fact-finding and may involve examination of study records and discussion with research personnel, research participants, witnesses, the individual reporting the allegation, or others.
- 2) The Director for Research Integrity will communicate with and coordinate investigations with Risk Management, Institutional Compliance, Legal Affairs, and others to the extent required by applicable University policies.
- 3) Allegations that include issues that rise to the level of potential research misconduct will be reported to the Chapman University Research Integrity Officer (RIO) for further review and potential investigation in accordance with Chapman policy.

Resolution of the Investigation

- 1) Upon the review of the information obtained during the investigation, the Director for Research Integrity and IRB Chair provide an opinion as to whether the allegation of non-compliance has a basis in fact.
 - a) Allegations that are deemed to have no basis in fact require no further action.
 - b) Allegations of noncompliance that have a basis in fact are referred to the IRB for review.
- 2) Allegations of noncompliance that have a basis in fact are reviewed by the convened IRB. Details regarding the serious or continuing noncompliance and the corrective action plan are forwarded to the IRB for review at the next convened IRB meeting.

- 3) The IRB reviews all reports and the corrective action plan and determines if additional action is required to enhance protections to research participants.
- 4) The principal investigator (PI) and other individuals involved in the alleged noncompliance are notified by either the Director for Research Integrity or IRB Chair and provided the opportunity to discuss the allegations. The PI involved in the noncompliance is required to respond in writing to the findings of the investigation and may be invited to meet with the IRB to address the allegations.
- 5) Upon IRB review of the allegations, the following actions may be taken:
 - a) Additional investigation is needed. Should this occur, the IRB shall appoint a subcommittee to investigate the allegations further. The subcommittee will then communicate any additional information or findings to the convened IRB at a subsequent meeting.
 - b) No action required.
 - c) Suspend enrollment and/or all research activity for the research in question (in accordance with the Suspension and Termination of IRB approval policy).
 - d) Terminate the research (in accordance with the Suspension and Termination of Research policy).
 - e) Require a response from the investigator with a plan for corrective action and a proposed timeline for ensure compliance within 10 working days.
 - f) Initiate audits or monitoring of all or part of the PI's active protocols.
 - g) Request the PI modify the research protocol.
 - h) Require retraining of the PI and/or research personnel.
 - i) Require modification of the information disclosed during the consent process.
 - j) Require additional information be provided to past or current participants.
 - k) Require modification of the renewal schedule for the research (i.e., more often than annual).
 - l) Communicate with other IRBs involved with the research, as applicable.
 - m) Require current participants be informed and possibly undergo the informed consent process again when information might relate to the participant's willingness to continue to participate in the research.
 - n) Monitoring of the consent process.
 - o) Any other action deemed appropriate by the IRB.

Timeline for Reporting

- 1) Reports to the Office of Human Research Protections (OHRP), the Food and Drug Administration (FDA) and other federal agencies will be made promptly in accordance with the policy for reporting to federal agencies. In the event a situation requires extended time (i.e., greater than 90 calendar days) to investigate or resolve, a preliminary report will be sent to the agency followed by a final report.

IRB Noncompliance

- 1) Noncompliance on the part of the Chapman IRB is initially reviewed by the Vice President for Research (VPR) or Institutional Official (IO).

- 2) The VPR shall convene an ad hoc committee to review the noncompliance and make the appropriate determinations. The ad hoc committee shall include at least 3 individuals, which can include a member of the IRB, the Chief Compliance Officer, a consultant, or other individuals with appropriate expertise and experience to make the necessary determinations.
- 3) IRB noncompliance can include:
 - a) Failure of the IRB to document in its meeting minutes or supporting documents specific findings such as a waiver of the requirement to obtain informed consent from participants.
 - b) Failure to document determinations for approval of research and/or specific determinations required for vulnerable populations.
 - c) Misappropriation of categories for exempt determinations or review by expedited procedures.
- 4) Determinations of noncompliance on the part of the IRB will be reported to the convened IRB as information.
- 5) Processes for programmatic improvements are the responsibility of the Director for Research Integrity.
- 6) Determinations of noncompliance on the part of the IRB will be reported to the federal agencies in accordance with federal policy.