CHAPMAN UNIVERSITY | INSTITUTIONAL REVIEW BOARD

Incident Reports

Purpose

1) This policy sets forth the requirements to ensure that incident reports, including unanticipated problems involving risks to participants or others, are promptly reported to the Institutional Review Board (IRB), regulatory agencies, and appropriate institutional officials.

Policy

1) Principal Investigators (PIs) must promptly submit incident reports to Chapman's IRB within **5 working days** of when they discover or become aware of an incident.

Reportable Events

1) Chapman's IRB requires PIs to promptly report the following within **5 working days**:
    a) Any breach of confidentiality or release of identifiable participant information
    b) Any unforeseen and harmful/unfavorable event (e.g., injuries, negative experiences events) that research participants or others have experienced or suffered during the research.
        i) For example, a researcher conducting behavioral research collects individually identifiable sensitive information about illicit drug use and other illegal behaviors by surveying college students. The data are stored on a laptop computer without encryption, and the laptop computer is stolen from the researcher's car on the way home from work. This event should be reported to the IRB within 5 working days. Another example could include a research participant begins to cry uncontrollably when interviewed about high school experiences.
    c) Any information that changes the risks or benefits of the research. Examples might include:
        i) An interim analysis of the research or a safety monitoring report has concluded that the frequency and magnitude of harm, risks, and benefits have changed.
        ii) Another research study has published a paper offering evidence that the research-related risks or potential benefits are different from what the PI had originally submitted to the IRB.
    d) Any changes to the approved research that the PI implemented without first obtaining IRB approval to eliminate an apparent immediate hazard to research participants and to protect their safety and welfare.
    e) Any incidents that involve data collection or data storage breaches or losses.
    f) Participants who become incarcerated while enrolled in research, and the research has not been approved to enroll prisoners.
    g) Participants who become pregnant while enrolled in a clinical trial involving greater than minimal risk to participants and the research has not been approved to enroll pregnant participants.
    h) Research participant complaints that convey unexpected research-related risks or discomfort.
    i) Any accidental or unintentional change to the IRB-approved research (commonly referred to as a ***protocol violation***) that harmed participants or others, or that indicates participants or others could be at an increased risk of being harmed.

IRB Review Considerations and Process

1) Upon receipt of an incident report, the IRB administrator will assign the submission to the IRB Chair and a designated IRB reviewer.
2) The IRB Chair and designated IRB reviewer are required to receive and review all incident reports for research involving human participants.
3) Chapman's IRB utilizes checklists to ensure that human participants will be protected while participating in research. When the IRB Chair and designated IRB reviewer review incident reports they determine whether the incident described is:
    a) Unexpected; and
    b) Related to, or possibly related to, the research; and
    c) A new or increased risk of harm to participants.
4) If the IRB Chair and designated IRB reviewer determine that an incident constitutes an unanticipated problem but is one that only presents minimal risks to participants or others, they will:
    a) Review the incident report in Cayuse IRB and record all decisions or findings to address the incident.
    b) Ensure that the fully convened IRB receives information about the incident at the forthcoming convened IRB meeting.
5) If the IRB Chair and designated IRB reviewer determine that an incident constitutes an unanticipated problem presenting risks that are greater than minimal risk to participants or others, they will:
    a) Refer the unanticipated problem to be reviewed at the forthcoming convened IRB meeting.
    b) Determine whether an immediate course of action is warranted (e.g., suspension of activities; notification to participants) to prevent an immediate hazard before the convened IRB reviews the incident.
6) For unanticipated problems referred to the convened IRB, the IRB will assess whether the incident introduces new or increased risk of harm to participants or others.
    a) IRB members will receive a copy of the:
        i) Incident report submission
        ii) Research-related materials that the PI provided
        iii) Any other documents required for the IRB to conduct a thorough review of the incident
    b) The full committee will document its determination and actions in the meeting minutes.
    c) If the convened IRB determines that the incident does not constitute an unanticipated problem introducing new or increased risk of harm to participants or others, then there will not be any further considerations or actions required.
7) The convened IRB has oversight to consider and require a range of actions to address the incident report that could include but would not be limited to:
    a) Modifying the IRB submission.
    b) Modifying what information is to be disclosed during the informed consent process.

c) Providing additional information about the incident and associated risks to previously enrolled participants.

d) Notifying currently enrolled participants when information about the incident could concern their willingness to remain enrolled.

e) Requiring that currently enrolled participants reconsent to participating in the research.

f) Modifying the interval period for renewal of research.

g) Monitoring the research.

h) Monitoring the consent process and documentation.

i) Suspending research.

j) Terminating research.

k) Referring the research to other institutional officials and authorities.

8) In all scenarios, the IRB will notify the PI of its determination.

9) Should the IRB determine that an incident meets the criteria for an unanticipated problem, the IRB will report it to the sponsor in accordance with the sponsor's requirements.