CHAPMAN UNIVERSITY | INSTITUTIONAL REVIEW BOARD

Incident and Research Noncompliance Reports

Purpose

1. This document outlines the reporting mechanism for incidents and for research noncompliance. Incidents and non-compliance do not necessarily co-occur. It is possible for an issue to be classified as an "incident" without it being "non-compliance" and vice versa, although they share a reporting workflow.
2. Submission of incident reports is not necessarily an admission of any wrongdoing by the research team and instead serves as a mechanism for the IRB to be aware of issues encountered while conducting human subject research.
2. Research misconduct is covered by the separate document, Integrity in Research Policy.

Definitions

1. **Incident**: An unfavorable event involving risks to participants or others.
    a. Some incidents are considered **unanticipated problems.** Unanticipated problem is an event that meets all these three criteria:
        i. Unexpected (in terms of nature, severity, or frequency) given the information provided in research-related documents and the characteristics of the subject population being studied
        ii. Related to, or possibly related to participation in the research; and
        iii. Suggests that the research places subjects or others at a greater risk of harm than was previously known or recognized

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b. Some incidents are **adverse events.** An adverse event in a human participant is medical in nature, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research.
    i. "**Serious adverse event**": any adverse event that:
        1. results in death;
        2. is life-threatening (places the subject at immediate risk of death from the event as it occurred);
        3. results in inpatient hospitalization or prolongation of existing hospitalization;
        4. results in a persistent or significant disability/incapacity;
        5. results in a congenital anomaly/birth defect; or
        6. based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition (examples of such events include allergic bronchospasm requiring intensive treatment in the emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse).

2. **Noncompliance:** failure to follow federal regulations (e.g., 45 CFR 46), institutional policies, or IRB determinations regarding human subject research. Noncompliance can range from minor to serious, be unintentional or willful, and may be an isolated incident or a continuing pattern.
    a. **Serious noncompliance**: any action or omission in the conduct or oversight of research involving human subjects that adversely affects the rights and welfare of subjects, increases risk of harm to subjects, or adversely affects the integrity of the data and research. An example is a protocol deviation (i.e., accidental or unintentional change to the IRB-approved research) that harmed participants or others or that indicates participants or others could be at an increased risk of being harmed, or impacted the integrity of the study data. Such protocol deviation is commonly referred to as a ***protocol violation***.

b. **Continuing noncompliance**: a pattern of repeated noncompliance that continues after initial discovery, including inadequate efforts to take corrective actions within a reasonable timeframe.

Policy

a. Federal regulations require the IRB to promptly report any unanticipated problem, serious or continuing noncompliance, or the IRB's suspension or termination of IRB approval for a study 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 Assistant Vice President for Research Integrity and Compliance (AVPRIC) and institutional policy.
b. Chapman University policy requires reporting certain incidents to the IRB that are not considered reportable by the federal regulations.
c. Investigators, study personnel, and others share the responsibility to report incidences of noncompliance with the regulations, requirements, or determinations of the IRB.

1. **Reportable Events**
    a. Any unanticipated problems have to be reported to the IRB within **7 calendar days from recognizing the event**.
        i. Examples:
            1. Research participants or others have experienced unforeseen outcomes during the research.
            2. Participants experienced a serious negative reaction to the study that is substantially more intense/severe, or more frequent than had been expected.
            3. Participant sends an email to the researcher stating that they experienced unexpected research-related risks or discomfort.
            4. Study data was handled and stored as required by the IRB-approved protocol, however the data was hacked.
    b. Any continuing or serious noncompliance has to be reported within **7 calendar days from recognizing the event**.
        i. Examples:
            1. A breach of confidentiality that results from not following an IRB protocol. For example, the protocol approved only sharing identifiable information with the research team, however

others gained access to the data (e.g,. accidental inclusion of identifiable information in the dataset in the repository; theft of the electronic device used for data storage when the device was stored in a location not listed in the IRB-approved protocol)

2. Participant was injured because the research team did not follow the IRB approved safety protocol
3. Participants were not consented following the approved research procedures
4. 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.
5. Permitting an IRB approved protocol to expire without stopping all research activities, including data analysis.
6. Conducting research activities without IRB approval.

c. Any information that changes the risks or benefits of the research **has to be reported within 7 calendar days from recognizing the new risk**.
    i. Examples might include:
        1. An interim analysis of the research or a safety monitoring repor t has concluded that the frequency and magnitude of harm, risks, and benefits have changed.
        2. Another research study has published a paper offering evidenc e that the research-related risks or potential benefits are different from what the PI had originally submitted to the IRB.
        3. Participants who become incarcerated while enrolled in resear ch, and the research has not been approved to enroll prisoners.
        4. Participants who become pregnant while enrolled in a clinical t rial involving greater than minimal risk to participants and the research has not been approved to enroll pregnant participants.

d. Research participant complaints that are unresolved have to be reported to the IRB within 7 calendar days upon failing to resolve the complaint

e. Adverse events that were *anticipated* and *did not* result from noncompliance have to be reported to the IRB within **30 calendar days of recognizing the event.**
    i. Examples:
        1. A participant suffers an injury as result of the experimental exercise. Risk of the injury (including the severity and probability of sustaining such injury) was listed on the consent form.
        2. A participant suffers severe but known side effects of the experimental drug. The risk for the side effects was listed on the consent form.

2. IRB Review Considerations and Process

a. Upon receipt of an incident report, the IRB administrator will assign the submission to the IRB Chair for review. A secondary reviewer may be recommended by the IRB Chair.

b. The IRB reviewer(s) will determine whether the incident described is an unanticipated problem, or a serious/continuing noncompliance, or data was breached, or a harm that was pre-determined by the IRB as more than minimal risk during protocol review.

c. If the IRB Chair and designated IRB reviewer determine that an incident constitutes either: an unanticipated problem but is one that only presents minimal risks to participants or others, or is a noncompliance that is neither serious nor continuing, or <u>does not</u> involve a breach of data, or is not a harm that was pre-determined by the IRB as more than minimal risk during protocol review they will:
    i. Review the incident report in Cayuse IRB and record all decisions or findings (if any) to address the incident.
    ii. Ensure that the fully convened IRB receives information about the incident at the forthcoming convened IRB meeting.

d. If the IRB Chair and designated IRB reviewer determine that an incident appears to constitute an unanticipated problem presenting risks that are likely greater than minimal to participants or others, or may be a serious or continuing noncompliance, or involves breach of data, or involves a serious anticipated harm on the IRB-approved protocol, they will:

   i. Refer the incident to be reviewed at the forthcoming convened IRB meeting.

   ii. 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.

e. For incidents referred to the convened IRB:

   i. IRB members will receive a copy of the:

      1. Incident report submission
      2. Research-related materials that the PI provided
      3. Any other documents required for the IRB to conduct a thorough review of the incident

   ii. The convened board will determine whether:

      1. The incident is a UAP that indicates that the increased risk is greater than minimal, or
      2. The incident constitutes serious or continuing noncompliance

   iii. The convened board will document its determinations and actions in the meeting minutes.

f. The convened IRB has oversight to consider and take a range of actions to address the incident report that could include but would not be limited to:

   i. Determining that no action is required.

   ii. Determining that 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.

   iii. Requiring a response from the investigator with a plan for corrective action and a proposed timeline to ensure compliance within 10 working days.

   iv. Initiating audits or monitoring of all or part of the PI's active protocols.

v. Requiring retraining of the PI and/or research personnel.

vi. Requiring the PI to modify the IRB submission (e.g., modification of the consent form).

vii. Requiring the PI to provide additional information about the incident and associated risks to past or current participants.

viii. Requiring the PI to notify currently enrolled participants when information about the incident could concern their willingness to remain enrolled.

ix. Requiring the PI to reconsent all currently enrolled participants in the research.

x. Modifying the interval period for renewal of research.

xi. Monitoring the research.

xii. Monitoring the consent process and documentation.

xiii. Suspending enrollment and/or research activity for the research in question.

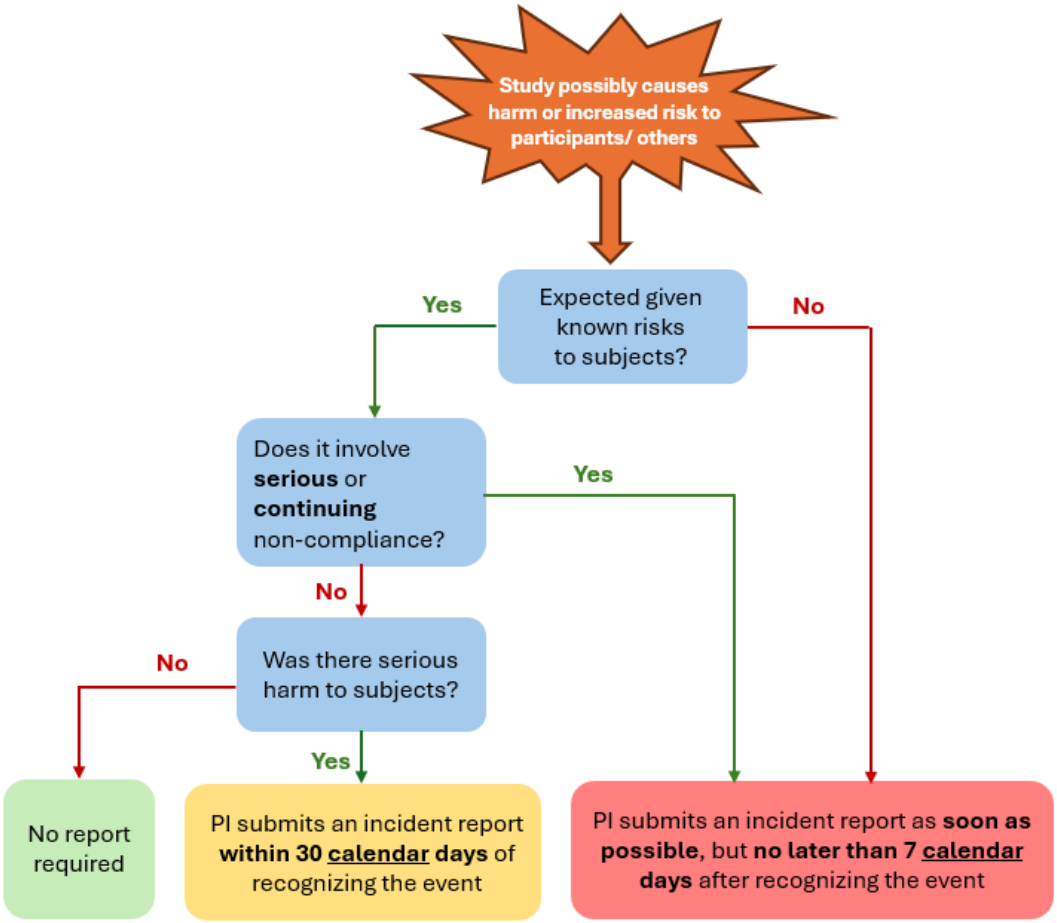
xiv. Terminating research.

xv. Communicating with other IRBs involved with the research, as applicable

xvi. Any other action deemed appropriate by the IRB (e.g., referring the research to other institutional officials and authorities).

g. In all scenarios, the IRB will notify the PI of its determination. The PI may respond in writing to the determination and may be invited to meet with the IRB.

Incident reporting to Chapman IRB



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Noncompliance

The IRB's Awareness of Noncompliance

Information alleging or revealing noncompliance in studies that enroll human participants may initially come to the attention of the IRB through several pathways:

1. Initial submissions
2. Renewals
3. Internal audits or monitoring
4. Food and Drug Administration (FDA) audit or inspection reports (e.g., FDA form 483)
5. Sponsor audit reports
6. Reports from collaborators, employees, or participants
7. Adverse event/safety reports
8. PI-submitted incident reports
9. Any other sources

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 (but is not limited to):
    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 Associate Vice President for Research Integrity and Compliance (AVPRIC).
6. Determinations of noncompliance on the part of the IRB will be reported to the federal agencies in accordance with federal policy.

Revision history:

11Dec2025 - original publication date; harmonized two superseded guidance documents Incident Reports ver. 09Aug2022 and Research Noncompliance ver. 17Jun2022

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