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# Yale University Institutional Review Boards Procedure

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## Procedure 700 PR.1 Reporting Noncompliance to the IRB

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### Overview

This procedure describes the process for reporting allegations of noncompliance with University, federal and state requirements for the protection of human participants including noncompliance with approved IRB protocols.

It is recognized that noncompliance with IRB approved protocols as well as with established regulations, policies and procedures may also occur during the course of a research study. Some sponsors and investigators refer to such incidents as deviations, while others would consider such events as noncompliance. The Yale IRBs consider all instances of protocol deviations as instances of noncompliance with the approved protocol and processes them as such.

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### Where to Report

Reports and allegations of serious noncompliance must be reported to the IRB office responsible for the oversight of the protocol within 5 working days. Generally, studies conducted by researchers from the School of Medicine and School of Nursing should be reported to the Compliance Manager located at the Human Investigation Committee (203-785-4688, [YSMhic@yale.edu](mailto:YSMhic@yale.edu)). Studies conducted by researchers from the remaining areas of the University should be reported to the Human Subjects Committee (203-436-3650, [human.subjects@yale.edu](mailto:human.subjects@yale.edu)). The IRBs will forward reports, when necessary, to the appropriate committee.

Minor noncompliance should be summarized for the IRB at the time of continuing review.

Reports of noncompliance involving the conduct of any of the IRBs or their staff should be reported to the Human Research Protection Administrator or designee (785-4688, [YSMhic@yale.edu](mailto:YSMhic@yale.edu)) or the Institutional Official for Human Research Protections (Deputy Provost for Biomedical and Health Affairs, 432-4446).

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### Format and Content of Reports

Allegations of noncompliance are best submitted in writing; however, they may also be presented verbally to the IRB.

Reports should include, to the extent possible:

- The study title, protocol number, and name of the principal investigator.
- A description of the event, or the sequence of events that led to the potential noncompliance and the reason why the event(s) is(are) considered noncompliance. (Example: indicate the procedures as outlined in the approved protocol to support the report of an incident of noncompliance.)
- An assessment of why the event occurred or may have occurred.
- An assessment of whether participants may have been adversely affected by the event or exposed to increased risk or reduced benefits or whether the event compromises the integrity of the study.
- An assessment of whether a deviation qualifies as being major or minor as defined in Policy 700 Noncompliance.

- A description of any changes to the protocol that will be made as a result of the event.
- A description of any corrective actions that can be, or have been implemented to ensure that similar events do not occur in the future.
- The name of the individual reporting the event. Note that the name of the individual reporting an allegation of noncompliance will be maintained confidentially by the IRB to the fullest extent practicable (see IRB Procedure 700PR.3 IRB Review and Investigation of Reports of Noncompliance)

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## **Examples of Noncompliance**

All instances of protocol deviations are by definition also an instance of noncompliance with the approved protocol. The term noncompliance, however, also includes violations of IRB or University policies and procedures or violations of federal regulations and state statute. Any difference between the IRB approved protocol and the actual activities performed during the conduct of research constitutes noncompliance.

Examples of reportable noncompliance include:

- Failure to obtain prior informed consent from participants.
- Conducting non-exempt research that requires direct interaction or interventions with human subjects without first obtaining IRB approval.
- Enrolling subjects who fail to meet the inclusion or exclusion criteria in a protocol that involves greater than minimal risk and that in the opinion of the IRB Chair, designee, or convened Committee, places the participant(s) at greater risk.
- Failure to report adverse events, unanticipated problems, or substantive changes to the proposed protocol to the Committee in accordance with IRB Policy 710 and Form 100 FR.4: Request for Approval of Amendment.
- Serious protocol deviations that place, or have the potential to place, participants and others at increased risk from the research.