

COMIRB Unanticipated Problem policy

Reporting requirements to COMIRB:

- The PI is required to promptly report to the IRB all problems listed below.

Note: This is a different obligation to report from that outlined in the contract or grant between the PI and the sponsor. The PI and/or sponsor will also have different reporting requirements for the FDA.

Definitions

Unanticipated Problem Involving Risks to Participants or Others

(Unanticipated Problem): Any event or information that was unforeseen and indicates that the research procedures caused harm (including physical, psychological, economic, or social harm) to participants or others or indicates that participants or others are at increased risk of harm than was previously known or recognized.

Adverse Event: Any unfavorable and unintended sign (including abnormal laboratory finding), symptom, or disease temporally associated with the use of a medical treatment or procedure, regardless of whether it is considered related to the medical treatment or procedure (attribution of unrelated, unlikely, possible, probable or definite).

Unanticipated event: Any adverse experience where the nature, severity or frequency is not identified in the investigational brochure described in the application form or detailed in the consent form. This can also include non-compliance issues such as over enrollment of subjects without prior COMIRB approval.

Possibly related: In the opinion of the PI, the adverse event is unlikely to be related to the study intervention, drug or device.

Probably related: In the opinion of the PI, it is more likely than not that the adverse event is related to the study intervention, drug or device.

Related to the research: An event is “related to the research procedures” if in the opinion of the principal investigator, it was more likely than not [probably] to be caused by the research procedures or if it is more likely that not [probably] that the event affects the rights and welfare of current participants.

Internal event / problem: An occurrence involving research subjects enrolled in a project approved by COMIRB and directed by a principal investigator employed by the University of Colorado Denver (or affiliate site) or one whose project is under the purview of the COMIRB).

External event / problem: An occurrence involving research subjects enrolled in multicenter research projects that do not fall under the purview of the COMIRB (i.e. sites other than UCD, UCH, VAMC, DHHA, and CPC).

Prompt Reporting: Reportable events must be submitted to COMIRB within 5 working days of the event or knowledge of the event.

Reportable Events

Investigators must report the following to COMIRB within 5 days:

- An actual unforeseen harmful or unfavorable occurrence to participants or others that relates to the research protocol (injuries, psychological events, drug errors).
- Adverse events which in the opinion of the principal investigator are both unexpected and probably related to the intervention/ drug or device.
- An unforeseen development that potentially increases the likelihood of harm to participants or others in the future.
- Information that indicates a change to the risks or potential benefits of the research. For example:
 - An interim analysis or safety monitoring report indicates that frequency or magnitude of harms or benefits may be different than initially presented to the COMIRB.
 - A paper is published from another study that shows that the risks or potential benefits of your research may be different than initially presented to the COMIRB.
- A problem involving data collection, data storage, privacy or confidentiality.
- Incarceration of a participant in a protocol not approved to enroll prisoners.
- Pregnancy of a participant or spouse in a protocol that specifically excludes pregnancy due to the potential risks of the intervention or treatment on the fetus.
- Change to the protocol taken without prior COMIRB review to eliminate an apparent immediate hazard to a research participant.
- Complaint of a participant when the complaint indicates unexpected risks or cannot be resolved by the research team.
- Protocol violation (meaning an accidental or unintentional change to the COMIRB approved protocol) that harmed participants or others or that indicates participants or others may be at increased risk of harm.
- Study related event that requires prompt reporting to the sponsor.
- Sponsor imposed suspension for risk.
- Non compliance by the PI or research team
- Any other problem that caused a risk to the participant or others

Related policies:

Safety report policy
Safety report decision tree

Forms:

Unanticipated problem form

Policy – COMIRB Unanticipated Problem Policy
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Continuing review form