

Events and Information that Require Prompt Reporting to the IRB

See related guidance [Data Monitoring Plans](#)

Note: Submit a narrative summary of all adverse events, (previously reported or not, serious or not), and submit routine, periodic reports (e.g. DMC reports that indicate no changes, sponsor annual progress reports) to the IRB at Continuing Review (renewal).

- Submit IRB Report Form – via eProtocol at <http://hs.stanford.edu/>
- Reporting an **unanticipated problem involving risks to participants or others (UP) or Internal Events that are unexpected and related to the research:**
 - **If PD is the only monitoring entity:** Items (1-6 below) should be reported directly to the IRB within 10 working days from when the PD learns of the event or new information.
 - **If there is a monitoring entity in addition to, or other than, the PD:** Report to the IRB using this form within 10 working days from receiving assessment from monitoring entity. Only when an event has been assessed by the monitoring entity to be a UP should the PD report it to the IRB. **Reportable information** (2-6 below) should always be reported by the PD directly to the IRB within 10 working days from when the PD learns of the event or new information.
- **Cancer Studies (including GCRC cancer studies):** Use the CCTO [Adverse Event Communication Form](#) to report to CCTO Safety Coordinator, M/C: 5548. *CCTO will instruct if must also submit to IRB*, and to GCRC if applicable.
- **GCRC Study “only” (not a Cancer Study):** Submit to the IRB and to GCRC Nurse Manager, M/C: 5251.
- **VA Studies:** Submit to IRB and a copy to the VA Research Administration Office, M/C: 151A

1) UNANTICIPATED PROBLEMS INVOLVING RISKS TO PARTICIPANTS OR OTHERS (UPS)

Report events to the IRB (including internal or external events, deaths*, life-threatening experiences*, injuries, breaches of confidentiality, or other problems) that occur any time during or after the research study, which *in the opinion of the Monitoring Entity or the PD* are:

- a. **Unexpected** - not in the consent form, investigator brochure, protocol, package insert, or label; or unexpected in its frequency, severity, or specificity, **AND**
- b. **Related** to the research procedures - caused by, or probably caused by research activity, or, if a device is involved, probably caused by, or associated with the device, **AND**
- c. **Harmful** - caused harm to participants or others, or placed them at increased risk of harm (including physical, psychological, economic, or social harm).

To qualify as a UP, an event must be Unexpected **AND** Related **AND** Harmful.

Unexpected deaths or life-threatening experiences related to the research (at STANFORD or when STANFORD is the coordinating institution in a multi-site study) **must be reported to the IRB within 5 working days from when PD learns of event.*

REPORTABLE INFORMATION (2-6) (other than UPS)

- 2) **New Information that indicates a change to the risks or potential benefits of the research**, in terms of severity or frequency. [E.g., Analysis indicates lower-than-expected response rate or a more severe or frequent side effect; Other research finds arm of study has no therapeutic value; FDA labeling change or withdrawal from market]
- 3) **Protocol Deviation or Violation. Only if:**
 - Intended to eliminate apparent immediate hazard to a research participant, or
 - Harmful (caused harm to participants or others, or placed them at increased risk of harm - including physical, psychological, economic, or social harm), or
 - Possible serious or continued noncompliance
- 4) **Complaint** that is unresolved by the research team, or that indicates increased or unexpected risks.
- 5) **Incarceration when in the opinion of the PD** it is in the best interest of the participant to remain on the study.
- 6) **Unanticipated adverse device effect.** New information about the effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence, or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

OTHER EVENTS OR INFORMATION E.G., INTERNAL EVENTS THAT ARE UNEXPECTED AND RELATED TO THE RESEARCH.

- 7) Report only after consulting with the HRPP Education Specialist (650-724-7141; IRBeducation@stanford.edu)