



UNANTICIPATED PROBLEM OR ADVERSE EVENT FORM

Please complete this form for each unanticipated problem, or adverse event, experienced by a research subject while enrolled in a research protocol.

Investigators only need to report to the IRB those problems or events that meet all **three** criteria in **Section A**.

For purposes of this form, examples of unanticipated problem or adverse event may include the following. These examples are intended as a guide, and may not be inclusive of all unanticipated problems or adverse events.

- A. any medical, psychological or behavioral event that is undesirable and unintended, although not necessarily unexpected;
- B. an event in which the outcome is fatal or life threatening, causes permanent disability, causes hospitalization or prolongation of hospitalization;
- C. an overdose; or
- D. a complaint by a research subject, or family member of a research subject, concerning the research or the protocol.

If, in the opinion of the principal investigator, a fatal or life-threatening event is likely related to the protocol, research activity should **stop** until the IRB has reviewed the adverse event, and consulted with the principal investigator. If you are not sure whether an event qualifies as a reportable event, it is recommended that you report it.

Investigators must notify the IRB according to the following timelines:

- Study-related death or Serious Adverse Event: within **24 hours**
- Any other Adverse Event or Unanticipated Problem: **5 business days from date of discovery**

Please indicate:

Initial Report OR Follow-up Report

Report #:

Protocol #:

Principal Investigator Name:

Protocol Title:

Sponsored/Funder, if applicable:

For Student Investigators, list your Faculty Advisor:

Section A

Describe the incident, experience, outcome, or adverse event being reported (*check all that apply*): **REPORT ONLY THOSE INCIDENTS, EXPERIENCES, OUTCOMES AND ADVERSE EVENTS WHICH MEET ALL THE FOLLOWING CRITERIA.**

- Unexpected in terms of nature, severity or frequency, given the research protocol, IRB-approved informed consent document, and given the characteristics of the subject population being studied (expected natural progression of subjects' disease, disorder or condition or predisposing risk factor profiles/cultural norms).
- Related or possibly related to participation in the research, i.e., is there a definite or reasonable possibility that the incident, experience or outcome may have been caused by the research procedures or research drug/device.
- Potentially place the research subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.



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Section B

TYPE OF REPORT (check all that apply):

- Adverse event or injury (Report only if serious, unexpected, and related.)
- Adverse device effect (Report only if unanticipated.)
- Breach of confidentiality
- Data and Safety Monitoring Board (DSMB) report, interim analysis, or other oversight committee/monitoring report (Provide report information/minutes, especially if altering the risk/benefit profile.)
- Event requiring prompt reporting (Report only when required by the protocol, sponsor, or funding agency.)
- New information (Report information indicating an unexpected change in risks or potential benefits, e.g., literature/scientific report or other published finding.)
- Subject of Family Member complaint (Report complaints indicating unanticipated risks)
- Other problem or finding (e.g., an unqualified subject was allowed to participate on project, loss of study data, a subject becomes a prisoner while participating in research). Please describe:

PLEASE COMPLETE THE FOLLOWING

1. Subject identification (e.g., a coded identifier, study ID#, etc., but do not include the subject's name).
2. Date of event:
3. Date the event was discovered by the Principal Investigator:
4. Was an investigational drug or device involved?
 Yes No
5. The event was (check one category):
 Likely related to the protocol Possibly related to the protocol Related to protocol
 Unlikely related to protocol or relationship is unknown
6. This determination was made by:
 Investigator Sponsor
7. What was the severity of the event?
 Mild Moderate Life threatening/serious Fatal
8. For adverse/unexpected events which were life-threatening or fatal, and were likely or possibly related to the protocol, provide information on the number of subjects enrolled study-wide and the number of subjects experiencing this side effect study-wide. (You may need to obtain this information from the sponsor if this is a multicenter trial.)

Number of subjects enrolled study-wide

Number of events as of (date)
9. Was the possibility of the adverse/unexpected event addressed in the protocol and consent?
 Yes
 No
10. Does this adverse/unexpected event increase the likely risk or decrease the likely benefit of the study?
 Yes
 No Please explain.



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11. The anticipated problem or adverse event will also be reported to (*check all that apply*):

- Sponsor
- Collaborating investigators
- Privacy Officer (if involving protected health information)
- Office of the Chief Information Officer (if security incident involving restricted data) No other reporting or unknown
- Other – specify:

12. Research Status:

The research participant(s) involved is/are:

- Still in study
- No longer in study
- N/A or unknown

Research recruitment is:

- Ongoing
- Temporarily Stopped/Placed on Hold
- Completed

Research interventions/interactions involving other participants are:

- Ongoing
- Temporarily Stopped
- Completed for all participants

Actions to be taken, as a result of the event (*check all that apply*):

- The protocol or study procedures will be modified.
- The consent process and/or research instruments will be modified.
- Additional information and/or follow-up will be provided to current and/or past participants.
- Current participants will be asked to re-consent to participation.
- The investigator has voluntarily placed the research on hold, pending more information or resolution of problem. (***This requires immediate reporting***)
- The Henry J. Austin Health Center research project (portion) is being stopped. (***This requires immediate reporting***)
- No action is planned. ***Provide explanation.***

Attach a full description of the event or problem being reported, any actions taken, and any known outcome (if applicable). Attach additional documents as necessary. Do not include (and remove where necessary) any participants' personally identifiable information from submitted material. Indicate if follow up reports will be submitted.

Printed Name of Principle Investigator

Signature of Principle Investigator

Date

NOTE: By e-signing this form you agree to abide by HJAHC IRB policies

→ For any document to be modified, please submit two electronic copies. One marked copy, with track changes to indicate revisions and deletions. And another final copy with all changes included without markings.

→ Questions about whether an event constitutes an adverse/unexpected event, or questions about completing this form, should be directed to the Chair of the Institutional Review Board using the Contact Form.