



Institutional Review Board

Unanticipated Problem Report for IRB-Approved Research

**** All research activities must be suspended until the problems are resolved with IRB approval ****

An *unanticipated problem* (UP) is any unexpected occurrence that increases risk to subjects. Federal regulations and the SEU IRB require the prompt reporting of research problems, incidents, or new risks to participants in an approved study. Reporting must occur via this form within five (5) business days of an event. Send this completed form to IRB@stedwards.edu.

Use this form when all of the following conditions are met:

- (a) the issue was not anticipated or foreseen (e.g. not described in the Consent form).
- (b) the issue involves risk or harm to research participant(s) or others.
- (c) the issue is probably or definitely related to or caused by the research.

Today's Date: _____

Date of Occurrence: _____

Date PI Notified of Occurrence: _____

Existing IRB Protocol ID (or "Exempt"): _____

Project Title: _____

Full Name of PI: _____

SEU Email: _____

Phone: _____

SEU Status: ☐ Faculty ☐ Staff ☐ Student

Faculty Advisor Name (if applicable): _____

SEU faculty advisors are responsible for reporting unanticipated problems of research under their supervision.

Faculty Advisor Email (if applicable): _____

Course ID and Semester/Year (if applicable): _____

EVENT REPORTING

1) Specify urgency:

In the PI's opinion, does this UP warrant immediate or urgent attention by the IRB and perhaps others?

☐ Yes ☐ No

2) Identify the type(s) of UP. Select all that apply.

- ☐ Adverse event.
- ☐ Unexpected increase in frequency or severity of an otherwise expected event.
- ☐ New information that increases risk.
- ☐ Breach of confidentiality.
- ☐ Protocol deviation.
- ☐ Protocol violation.
- ☐ Sponsor-imposed protocol suspension (due to harm or increased risk).
- ☐ Complaint by research participant indicating unexpected risk.
- ☐ Complaint by research participant that cannot be resolved by the research team.

3) Briefly summarize the Unanticipated Problem. Provide an assessment of increased risk or harm caused by the UP.

4) Describe any corrective actions taken and/or planned to specifically address the Unanticipated Problem. Explain the current status of the situation. If applicable, include descriptions of the protocol violation or deviation.

5) Will this incident result in modifications to the research protocol or its documentation?

Modifications to an existing IRB protocol must be submitted separately via the [IRB Application for Modifications or Continuing Review](#).

☐ Yes (see below) ☐ No (skip to question 6)

5a. Do you intend to activate an interim management plan prior to IRB modifications approval?

☐ Yes (see below) ☐ No (skip to question 5)

5b. Describe the interim management plan to ensure participant safety and/or inform participants of new research information in a timely manner:

6) Has the reporting deadline of five (5) business days been met?

☐ Yes (skip to question 7) ☐ No (see below)

6a. Please explain why the reporting timeline requirement was not met:

6b. Please explain what steps will be taken to ensure prompt reporting in the future in accordance with SEU IRB policy:

7) Do you anticipate submitting a follow-up report? Follow up reports or any subsequent relevant information can be emailed separately to IRB@stedwards.edu.

___ Yes ___ No

The SEU IRB will evaluate this report as soon as possible and, if necessary, refer to a full board review. You will be notified of the IRB's decisions when they occur.

ACKNOWLEDGEMENT & SIGNATURE

- I have suspended all research activities under this protocol and will not resume until the IRB reviews and approves a resolution to the reported unanticipated problem(s).
- I have personally reviewed each of the reported items and ensured correct classification in accordance with SEU IRB requirements.
- I understand my responsibility to provide follow-up information as it becomes available.

Signature of PI or Faculty Advisor

Date