Section 1: About the Report Form

The Report Forms (RF) application is used to submit problems, events, or information issues to the IRB for review. These may include Adverse Events, Protocol Deviations, Reports of Non-Compliance, and Unanticipated Problems.

Section 2: When to Use This Form

Use this report problems, events, or information issues for the IRB for review. These may include Adverse Events, Protocol Deviations, Reports of Non-Compliance, and Unanticipated Problems.

**Learn more at:**

* Adverse Events:

<https://oprs.research.illinois.edu/research-topics/adverse-events>

* Unanticipated Problems:

<https://oprs.research.illinois.edu/research-topics/unanticipated-problems>

* Deviations:

<https://oprs.research.illinois.edu/research-topics/deviations>

* Reports of Non-Compliance:   
  <https://research.illinois.edu/compliance-safety/research-integrity-ethics-and-misconduct>

<https://research.illinois.edu/compliance-safety/conflict-commitment-interest>

Section 3: Protocol Information:

Please complete the information below.

1) Principal Investigator:

Please enter the names of the PI’s.

2) Protocol Number:

Please enter the Protocol number. (If this is a new study application, the protocol number will be assigned and completed by OPRS once the application is submitted.)

3) Project Title:

Please enter the Project Title.

Section 4: Questions About the Event or Problem

1) Date of the Event or Problem:

Please enter the date(s) of the event or problem below:

Click or tap here to enter text.

2) Date that the Problem/Event was reported to the investigator (or when the information was received by investigator):

Please enter the date(s) of the event or problem being reported to the investigator below:

Click or tap here to enter text.

3) Event or Problem Reporting to IRB (within 10 days of Event or Problem)

3.1) Was this report submitted to the IRB promptly, within 10 working days of the event or problem?

Select Yes or No.

Yes  No

3.2) If you answered “No” above (in 3.1), please explain why the report is late:

Click or tap here to enter text.

4) Current Status of the Study:

Choose the answer that applies to the study at this time.

Open for Enrollment

Closed to Enrollment, study procedures are ongoing

Closed to Enrollment, study procedures are completed

Enrollment on Hold

5) Number of Enrolled Participants

If the current number for All Centers is not known, enter the most recent count you have on file. If this is not a multi-center study, enter N/A for All Centers.

5.1) Number enrolled at UIUC:

Click or tap here to enter text.

5.2) Number enrolled at all centers:

Click or tap here to enter text.

6) What is Being Reported:

Choose the answer(s) that apply, and complete the associated section(s) on this form.

Possible Unanticipated Problem (Complete Section A, if you check this)   
  
Examples: Adverse Event, Breach of confidentiality or Privacy, Complaints from participants or others, Other Problem or Event

Possible Serious or Continuing Non-Compliance (Complete Section B, if you check this)

Examples: Deviation or Violation

Information (Complete Section C, if you check this)

Examples: New Information, Data and/or Safety Monitoring report, Incarceration of participant, Other information

Section A: Possible Unanticipated Problem

Complete this section if you checked the “Possible Unanticipated Problem” option in question 6 (in Section 4).

A.1) Provide a narrative description of the problem/event, including where the event occurred:

Describe the event or problem below:

Click or tap here to enter text.

A.2) Any Previous Incidents of this Problem or Event

A.2.1) Has the same problem or event occurred previously?

Select Yes or No.

Yes  No

A.2.2) If you answered “Yes” above (in A.2.1), describe what happened (include a description of frequency):

Click or tap here to enter text.

A.3) Provide a narrative description of any corrective action, intervention, or treatment provided to alleviate the problem and the outcome of such actions:

Describe the event or problem below:

Click or tap here to enter text.

A.4) Provide a narrative description of any preventive actions that have been taken or are proposed in response to the problem/event:

Describe the event or problem below:

Click or tap here to enter text.

A.5) Problem or Event Reporting (for Unanticipated Problems)

The IRB uses the criteria below to evaluate any incident, experience, or outcome that may represent an unanticipated problem.

A.5.1) In the opinion of the local Principal Investigator, was the event or problem unexpected?

Unexpected may be in terms of nature, severity, or frequency, given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied. Select one option below.

Select one option:

Expected Event  Unexpected Event

A.5.2) In the opinion of the local Principal Investigator, was the event or problem related to research?

Related or probably related to participation in the research or if the event or problem probably or definitely affects the safety, rights and welfare of current participants.

Select one option below.

Related Event  Unrelated Event

A.5.3) In the opinion of the local Principal Investigator, does the event or problem suggest that the research places subjects or others at greater risk of harm?

Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic or social harm) than was previously known or recognized. This involves substantive harm, or a genuine risk of substantive harm, to the safety, rights, or welfare of human research subjects, research staff, or others..

Select one option below.

Greater Risk of Harm  No Greater Risk of Harm

Section B: Possible Serious or Continuing Non-Compliance

Complete this section if you checked the “Possible Serious or Continuing Non-Compliance” option in question 6 (in Section 4).

B.1) Location where the deviation occurred:

Describe the location below:

Click or tap here to enter text.

B.2) Reporting Deviation(s) to the Sponsor or Regulatory Agency

B.2.1 Has the deviation been reported to the Sponsor or Regulatory Agency?

Choose the answer that applies.

Yes

No

Not Applicable

B.2.2 If you answered “Yes” to B.2.1, please detail how the deviation was reported to the sponsor or agency, including when:

Click or tap here to enter text.

B.2.3 If you said “No” to B.2.1, please explain why the deviation was not reported:

Click or tap here to enter text.

B.3) Describe the deviation in detail, including situation and circumstances:

Describe the deviation below:

Click or tap here to enter text.

B.4) Any Previous Incidents of this Deviation

B.4.1) Has the same deviation occurred previously?

Select Yes or No.

Yes  No

B.4.2) If you answered “Yes” above (in B.4.1), describe what happened (include a description of frequency):

Click or tap here to enter text.

B.5) Describe the participant's condition before and after the identified deviation (if applicable):

Describe the participant’s condition below:

Click or tap here to enter text.

B.6) What was the net effect on potential risk or benefit?

Describe any potential risk or loss of benefit to the participant or corruption of scientific data due to the deviation.

Click or tap here to enter text.

B.7) Describe how this deviation was corrected:

Include details below.

Click or tap here to enter text.

B.8) Describe the plan to prevent this deviation from occurring in the future:

A preventive action plan should describe an active process addressing the causal elements so the IRB would conclude that the investigator has a serious and viable plan in place for assuring the safety of research participants and the oversight of data integrity.

Describe your plan below.

Click or tap here to enter text.

Section C: Information

Complete this section if you checked the “Information” option in question 6 (in Section 4).

C.1) Type of Information:

Choose the answer that applies.

Data and/or Safety Monitoring Report

New information that results in a change to the protocol, consent, or IRB application must also be submitted via an amendment

Incarceration of a participant in a protocol not approved to enroll prisoners

Warning or determination letters issued by any funding agency or regulatory body

Change in FDA labeling or withdrawal from marketing of a drug, device, or biologic used in a research protocol

Other Information

C.2) Describe the information being reported to the IRB:

Provide a description in your own words of what information is being submitted. Do not only refer to an attachment. Do not submit changes to IRB approved documents, such as the protocol, consent documents, investigator brochure, etc. If you are changing the study, you must submit an amendment.

Describe your plan below.

Click or tap here to enter text.

C.3) Risk of Harm and Actions Taken

C.3.1 Does the information indicate any increased risk of harm to the rights or welfare of study participants or others?

Choose the answer that applies.

Yes

No

C.3.2 If you said “Yes” to C.3.1, indicate action to be taken:

Choose the answer that applies.

Suspend study enrollment

Revise protocol (if this is checked, submit an amendment)

Revise informed consent document (if this is checked, submit an amendment)

Addendum to the informed consent document for current participants (if this is checked, submit an amendment)

Other corrective or preventive actions

C.3.3 If you answered “Other corrective or preventive actions” to C.3.2, please describe the other corrective or preventive actions below:

Note: A preventive action plan should describe an active process addressing the causal elements so the IRB would conclude that the investigator has a serious and viable plan in place for assuring the safety of research participants and the oversight of data integrity.

Detail below.

Click or tap here to enter text.