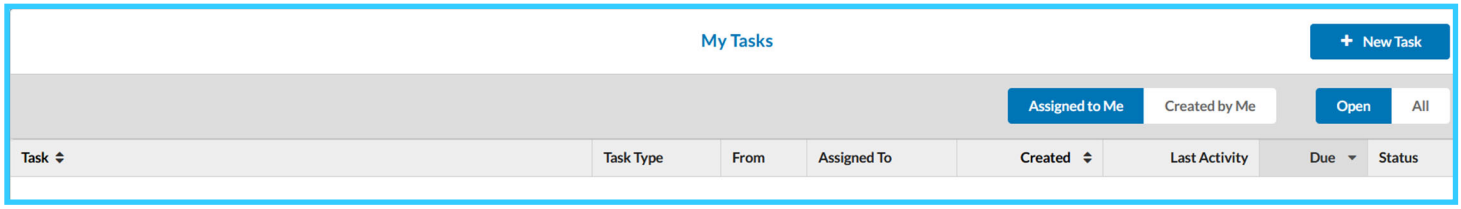
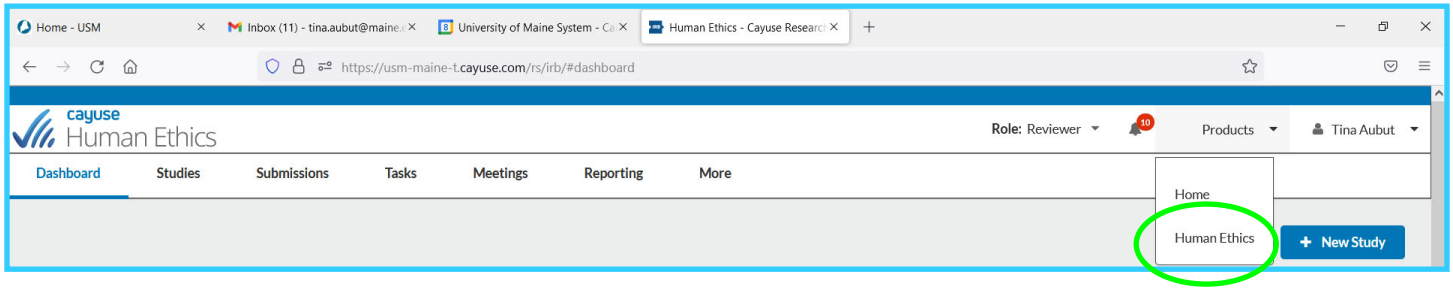
Incident Report

HRPP 002 Protocol Violations (pdf)
HRPP 004 Non-Compliance (pdf)
–Reporting Alleged Research Misconduct and Animal Protocol Violations
–Reporting Alleged Mismanagement of Federal Funds
HRPP 006 Unanticipated Problems & Adverse Events (pdf)
HRPP 039 Research Concerns (pdf)





Click on New Submission—Incident Report

* **Incident Type**

An incident/event (or series of related events) may fit into more than one category, so ***check all that apply****. Distinct or events unrelated to another should generally have separate Incident submissions.*

☐ **New or Increased Risk**

For example:

- *Unanticipated Problems*
- *Adverse events*
- *Serious adverse events (SAE)*

An unanticipated problem involving risks to subjects or others is any incident, experience, or outcome that:

1. *Is unexpected given*
   - *The research procedures that are described in the protocol documents; and*
   - *The characteristics of the subject population being studied;*
2. *Is related or possibly related to participation in the research; and*
3. *Suggests that the research places subjects at a greater risk of harm than was previously known or recognized.*

An adverse event is any untoward or unfavorable occurrence in a human subject, including any abnormal sign, symptom, or disease temporarily associated with the subject?s participation in the research, whether or not considered related to the subject?s participation in the research.

Certain information may indicate new risks or that subjects may be at higher risk than previously recognized.

- *Investigator's Brochure (IB) updates identifying new or increased risks*
- *New FDA Black Box Warning*
- *DSMB/C report identifying new risks*
- *Publications identifying new risks*
- *Unauthorized disclosures of subject information*
- *Unanticipated Adverse Device Effect*

☐ **The incident a result of protocol violation**

A protocol violation is any exception or deviation involving a single subject that is not approved by the IRB prior to its initiation or implementation.

☐ **Protocol Deviation and/or Noncompliance**

Noncompliance is conducting research in a manner that disregards or violates federal regulations or institutional policies and procedures applicable to human subject research.

- *Noncompliance does not include minor or technical violations which result from inadvertent errors, inattention to detail, or failure to follow operational procedures, which do not pose risk to subjects and/or violate subjects? rights and welfare.*

Deviation/noncompliance is conducting research in a manner that disregards or violates federal regulations governing human subject research, with the protocol, or requirements/determinations by the IRB. For example:

- *Events that harmed a subject.*
- *Events that increased risk of harm.*
- *Serious Noncompliance: where events may adversely affect subjects rights or welfare.*
- *Continuing Noncompliance: where a pattern of noncompliance is likely to continue without intervention, or failure to work with the IRB to resolve noncompliance*
- *Deviations from the research plan made to avoid apparent and immediate hazard to a subject.*

☑ **Written Reports**

Any of the following when conducted by a federal agency, funding agency, the IRB, monitor, state agency, or other oversight age

- *Audits*
- *Inspections*
- *Inquiries*

☑ **Suspension or early Termination of the Study**

This unplanned suspension or termination could be required by the sponsor, investigator, or institution.

☑ **The incident involves Protected Health Information under HIPPA**

☑ **The incident involves Student data under FERPA**

☑ **The incident involves identifiable information**

☑ **Other**

For example:

- *Unexpected incarceration of a subject when the study is not approved to include prisoners*
- *Data/security breach*
- *Significant or unresolved subject complaint*

☑ **None of the above**

Was this Incident report was created in error? Consider if you need to create a different type of submission.

* **IRB Oversight Arrangements**

Indicate how IRB oversight is organized for this study. This should match what is in the latest approved version of this study (latest approved Modification or Initial approval).

- ○ Study involving more than 1 site where each site will conduct their own IRB review
- ○ Study involving more than 1 site where this site is the Reviewing IRB (IRB of Record) for other sites
- ○ Study involving more than 1 site where this site is Relying on an External IRB
- ○ Multi-site study (multiple US sites participating in a research study using the same protocol) where this site is the Reviewing IRB (IRB of Record) for all sites
- ○ Multi-site study (multiple US sites participating in a research study using the same protocol) where this site is Relying on an External IRB

Reviewing IRB Determination & Documentation

Please upload documentation from the Reviewing IRB regarding their determination for this Incident and any supplemental documentation.
-Links to Google docs will not be accepted.

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Event Information

* **Event Description**

Please provide a detailed description of the event, incident, experience, or outcome. If applicable, provide the subject number/identifier of affected participants.

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* **Location(s) of Event**

State the location(s) the event(s) occurred, as applicable.

* **Date(s) of Occurrence**

Indicate when the event occurred. This may be a single date, a range of dates (start and end say for onset of adverse event), a series of dates for a recurring issue, etc.

Name(s) of research personnel present during incident:

FIND PEOPLE

Description of their role:

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* **Date of Discovery**

Indicate the date the study team discovered the event(s).

MM-DD-YYYY

New or Increased Risk Information

Expectedness

*** Expectedness Assessment**

Considering the research procedures described in the protocol and consent form AND the characteristics of the subject population being studied, is the event Unexpected in terms of ANY of the following:

- *Nature of the event*
- *Severity of the event (more serious than expected)*
- *Frequency of the event (more frequent than expected)*

(●) Yes
( ) No

*** Expectedness Rationale**

Explain your rationale for your assessment of expectedness.

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Relatedness

*** Relatedness Assessment**

Is the event EITHER related or possibly related to participation in this research (e.g., whether the incident, experience, or outcome may have been caused by the research procedures)?

(●) Yes
( ) No

*** Relatedness Rationale**

Explain your rationale for your assessment of relatedness.

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Risk of Harm

*** Risk of Harm Assessment**

Does this event suggest that the research places subjects or others at greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized?

NOTE: If the event is Serious, this answer should be Yes.

( ) Yes
( ) No

*** Risk of Harm Rationale**

Explain your rationale for your assessment of Risk of Harm.

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* **Is this a Reportable Event?**

- (●) Yes - (Expectedness, Relatedness, and Risk of Harm were ALL Yes)
  Indicating Yes to Expectedness, Relatedness, and Risk of Harm means this event is Reportable and subject to prompt reporting requirements.
- (●) No - (At least one was answered No for Expectedness, Relatedness, and/or Risk of Harm)
  This event may not meet the criteria for prompt reporting as a Reportable Event, and may therefore just need to be reported at time of Renewal. Please contact the IRB Office for guidance BEFORE submitting.

Risk or Harm to Subject

* **Risk or Harm to Subject Assessment**

Did the deviation or noncompliance harm the subject(s) OR increase risk to the subject(s)?

- ( ) Yes
- (●) No

* **Risk or Harm to Subject Rationale**

Explain your rationale for your assessment of risk/harm.

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Eliminating Hazard to Subject

* **Eliminating Hazard to Subject Assessment**

Was this a change in the research plan to eliminate apparent and immediate hazard to a subject?

- ( ) Yes
- (●) No

* **Eliminating Hazard to Subject Rationale**

Explain your rationale for your assessment of eliminating hazard to subject.

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Role of Researcher

* **Role of Researcher Assessment**

Did the deviation or noncompliance occur due to the action or inaction (regardless of intent) of the researchers?

"Researchers" includes:

- *When this institution is the IRB of Record for this site or others, anyone Engaged in Research under the IRB oversight of this institution.*
- *When this institution is relying on a Reviewing IRB, anyone Engaged in Research affiliated with this institution.*

- ( ) Yes
- ( ) No

* **Role of Researcher Rationale**

Explain your rationale for your assessment of the role of the researcher(s) in this event.

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Prompt Reporting of Reportable Information

Is this event being promptly reported per IRB Policy?

- ○ Yes
- ◉ No

Explain why this event was not reported within required deadlines.

Corrective Actions

Describe any changes to the protocol or other corrective actions that have been taken or are proposed in response to the event.

NOTE: Changes to the protocol MUST ultimately be submitted via a Modification.

Additional Information

Additional Information or Comments

If applicable, you can provide additional information that you think to be beneficial to review of this Incident.

Additional Documentation

If you have any additional documentation to provide for this Incident, upload it here (e.g., revised risk documentation, records on affected subject, Corrective Action Plan, etc.).
-Links to Google docs will not be accepted.

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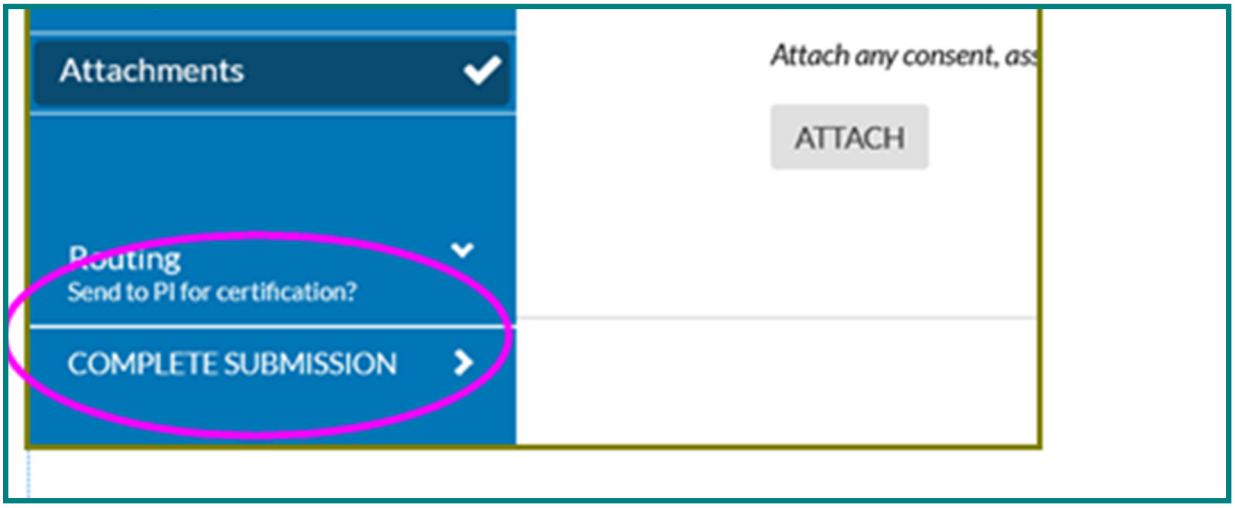
When done, click Complete Submission. Pop-ups will ask you to confirm.



Certify submission: PI, CO-PI, and Faculty Sponsor (Advisor) **ALL** must certify each submission.

When all certification routing is done, it goes into the que of an ORIO analyst for next steps.