MICHIGAN STATE UNIVERSITY

Click™: IRB

Quick Guide

How to Report New Information (RNI)

This quick guide provides information about how to report new information in Click. Examples of reportable events include unanticipated problems involving risks to subjects or others, subject complaints, noncompliance, etc.

DO NOT INCLUDE ANY INDIVIDUALLY IDENTIFIABLE SUBJECT INFORMATION IN THE REPORT. THIS INCLUDES PROTECTED HEALTH INFORMATION AS DEFINED BY THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA), INCLUDING HIPAA IDENTIFIERS (See HRPP Manual 7-6 Health Insurance Portability and Accountability Act Compliance in Human Research for more information).

For urgent situations, please call 517-355-2180. For more information on reportable events, please visit the HRPP Manual (https://hrpp.msu.edu/msu-hrpp-manual-table-contents-expanded).

WHO:

- Principal Investigators (PIs)
- Study Teams

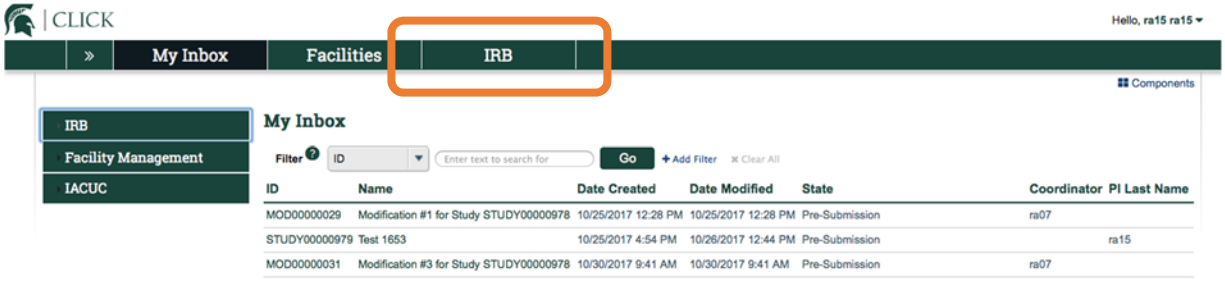
WHEN:

- Creating and submitting Reportable New Information (RNI)

HOW:

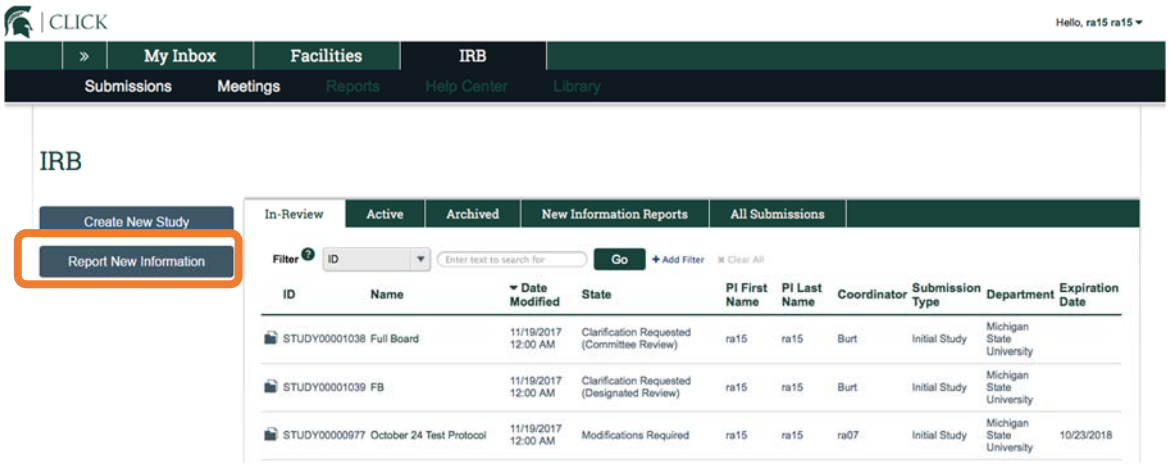
While any individual can Report New Information, based on the functionality of the Click system, we encourage the Principal Investigator to complete and submit the Reportable New Information when possible.

1. Click on the “IRB” tab.



2. Click “Report New Information.”

How to Report New Information



3. On the Reportable New Information SmartForm page, complete the required fields (indicated with a red asterisk: *).

Reportable New Information

1. RNI short title: (uniquely identify this new information report)

2. * Date you became aware of the information:

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3. Identify the categories that represent the new information: (check all that apply)

- [x] Potential unanticipated problem that may involve risk to subjects or others
  - [ ] Potential breach of confidentiality (e.g., lost or stolen research data)
  - [ ] Newly discovered information (e.g., from data analysis or publications) that indicates a greater risk to subjects than expected and that may affect adversely the safety of the subjects or the conduct of the clinical trial
  - [ ] An investigator brochure, package insert, or device labeling is revised to indicate an increase in the frequency or magnitude of a previously known risk, or to describe a new risk
  - [ ] Changes made to research without prior IRB approval in order to eliminate apparent immediate harm
  - [ ] Incorrect dosing or labeling that adversely affects the safety of subjects
  - [ ] Risk to others (e.g., research staff, investigators) related to the research (e.g., physical harm)
  - [ ] Adverse events that are unexpected, involve new or increased risk, and are related to the research, including unexpected serious adverse event or unanticipated adverse device effect
  - [ ] Withdrawal, restriction, or modification of a marketed approval of a drug, device, or biologic used in research protocol
  - [ ] Unsafe research environments or threats to subjects or others related to their participation in the research or changes in the research environment that increase the risk to subjects or others due to the research (e.g., political or social changes)
  - [ ] Higher occurrence of an adverse event or serious adverse event than expected
  - [ ] Any side effect not mentioned in the consent form or protocol
  - [ ] Incarceration of subjects
  - [ ] Other unexpected incidents
- [ ] Potential or confirmed noncompliance with a federal or state law, regulation, policy or the requirements and/or determinations of an IRB
- [ ] Subject complaints
- [ ] Unapproved change in protocol to eliminate a hazard to subjects
- [ ] Protocol deviations or violations: Any change, divergence, or departure from the study design or procedures of a research protocol that has not been approved by the IRB
- [ ] Suspension or termination: Premature suspension or termination of the research by the sponsor, investigator, or institution.
- [ ] MSU HRPP Compliance Office TEACH
- [ ] MSU HRPP Compliance Office Site Visit
- [ ] Audit or inspection by a federal or state agency

- [ ] New potential conflict of interest of a study team member
- [ ] Written reports of study monitors
- [ ] Emergency use of investigational drugs or devices
- [ ] Any activities or circumstances that affect the rights and/or welfare of research subjects
- [ ] Any information that could increase the risk to subjects

4. * Briefly describe the new information:

How to Report New Information

5. In the submitter's opinion:

a. * Does this information indicate a new or increased risk, or a safety issue?

○ Yes ○ No Clear

b. * Does the study need revision?

○ Yes ○ No Clear

c. * Does the consent document need revision?

○ Yes ○ No Clear

ⓘ If revisions are required, describe them above and submit a study modification for review.

6. Related studies and modifications: ?

ID	Short Title	Investigator	State	IRB Office

There are no items to display

7. Attach files containing supporting information:

+ Add

Name

There are no items to display

ⓘ Use one of these templates:

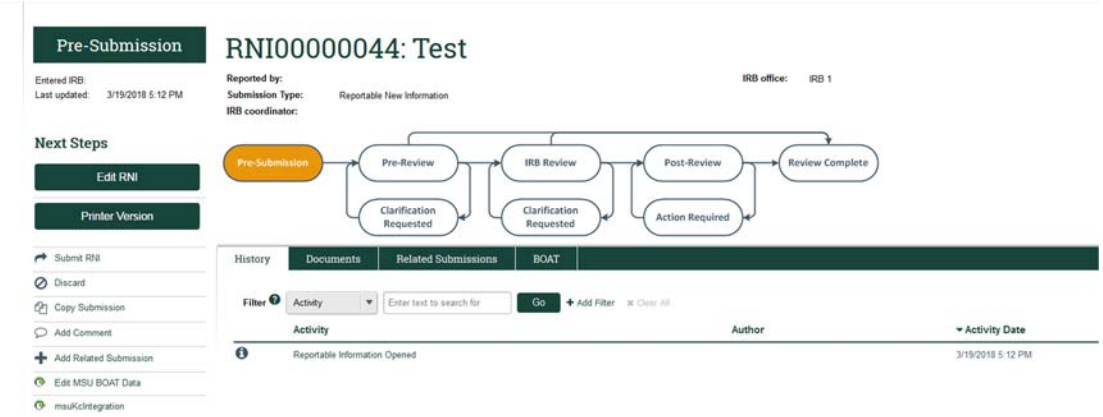
- HRP-531- Template - Unanticipated Problem Involving Risk to Subjects or Others
- HRP-532 - Template - Protocol Deviation or Violation
- HRP-533 - Template - Subject Complaint
- HRP-534 - Template - Emergency Use of Investigational Drugs or Devices

Note:

- DO NOT INCLUDE ANY IDENTIFIABLE SUBJECT INFORMATION IN THE REPORT.
- Question 1: The short title displays on the submission's workspace, My Inbox, and Submission lists.
- Question 6: Be sure to identify the specific study(ies) that this reportable event is related to, if known or any.
- Question 7:
  - If the RNI may be an unanticipated problem involving risks to subjects or others, complete and attach HRP-531 – Template – Unanticipated Problem Involving Risk to Subjects or Others

- If the RNI may be a protocol deviation or violation, complete and attach HRP-532 – Template – Protocol Deviation or Violation
- If the RNI is a subject complaint, complete and attach HRP-533 – Template – Subject Complaint.
- If the RNI is reporting emergency use of investigational drugs or devices, complete and attach HRP-534 – Template – Emergency Use of Investigational Drugs or Devices.

4. After you select “Continue” or “Exit”, you will be returned to the RNI submission’s workspace.



5. Select “Submit RNI” to submit the Reportable New Event to the Institutional Review Board office. Only the individual who created the RNI can perform the “Submit RNI” activity.