The eIRB Upgrade Webinar Series:
Changes in Reportable Event and Not-Human-Subjects-Research Review Processes

Emory IRB
○ Benefits of the new eIRB RNI (aka RE) submission form
○ Why the new form requires a process change
○ Changes in the Non-Human-Subjects-Research Determination Process
○ Tools and Resources
○ Questions
Problem with current RE submission forms: On the first page of the RE form, you have to select the type of event you are submitting

- If you make a mistake, the appropriate questions will not appear on subsequent pages.
- Causes confusion and more work for users

Solution in upgraded eIRB: The Reportable New Information (RNI) form is only one form, designed to capture any type of event
○ Problem with current RE submission forms: There are occasions when the PI is not available to submit a reportable event form.

○ Solution in upgraded eIRB: the PI is not required to submit the form!
  • In fact anyone can submit a RNI even if not part of the study team

○ Problem with current RE submission forms: You need to submit an RE form for each study affected.

○ Solution in upgraded eIRB: You can report the same event for all affected studies at the same time

Benefits of new RNI (RE) Form
Reportable New Information

BEFORE REPORTING TO THE EMORY IRB PLEASE REVIEW OF REPORTING REQUIREMENTS IN THIS CHART

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

2. **Date you became aware of the information:**

3. **Indicate if this event is internal or external**
   a. Internal
   b. External

4. **Identify the categories that represent the new information:** (check all that apply)
   **Risk:** Information that indicates a new or increased risk, or a safety issue. For example:
   a. New information (e.g., an interim analysis, safety monitoring report, publication in the literature, sponsor report, or investigator finding) indicates an increase in the frequency or magnitude of a previously known risk, or uncovers a new risk.
   b. 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.
c. Withdrawal, restriction, or modification of a marketed approval of a drug, device, or biologic used in a research protocol.

d. Protocol violation that harmed subjects or others or that indicates subjects or others might be at increased risk of harm.

e. Complaint of a subject that indicates subjects or others might be at increased risk of harm or at risk of a new harm.

f. Any changes significantly affecting the conduct of the research.

**Harm:** Any harm experienced by a subject or other individual that, in the opinion of the investigator, is unexpected and at least probably related to the research procedures.

a. A harm is "unexpected" when its specificity or severity is inconsistent with risk information previously reviewed and approved by the IRB in terms of nature, severity, frequency, and characteristics of the study population.
b. A harm is “probably related” to the research procedures if, in the opinion of the investigator, the research procedures more likely than not caused the harm.

**Non-compliance**: Non-compliance with the federal regulations governing human research or with the requirements or determinations of the IRB, or an allegation of such non-compliance.

**Audit**: Audit, inspection, or inquiry by a federal agency.

**Report**: Written reports of study monitors.

**Researcher error**: Failure to follow the protocol due to the action or inaction of the investigator or research staff.

**Confidentiality**: Breach of confidentiality.

**Unreviewed change**: Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a subject.

**Incarceration**: Incarceration of a subject in a study not approved by the IRB to involve prisoners in non-exempt research.

**Complaint**: Complaint of a subject that be negatively affect subject’s rights, safety, welfare or their willingness to continue study participation, or that may affect the integrity of the research data. If not, those reports should be forward to CTAC.
**Suspension:** Premature suspension or termination of the research by the sponsor, investigator, or institution due to risk.

**Unanticipated adverse device effect:** Any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

**Informed Consent/HIPAA issues:** Deviations involving the consent process involving the subject's lack of signature, missing forms or using the wrong/expired forms to consent a subject.

**Important!** Information that does not fit into one of the categories above does not need to be reported to the IRB as new information.
5. Briefly describe the new information:

6. 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.

7. Related studies and modifications: ⚫

   ID  Short Title  Investigator  State  IRB Office
   There are no items to display

8. Attach files containing supporting information:

   Name
   There are no items to display
To explain, let’s discuss the triage process for REs:

- Submitted REs are triaged and sent to 1) Expedited Reviewer to be acknowledged or 2) Compliance Review (CoRe) team

- We **acknowledge** events that are:
  - Not Unanticipated Problems
  - Minor Protocol Deviation/Protocol Non-Compliance (not reportable, but sometimes reported per sponsor requirements)
  - Events that are reportable but that the CoRe subcommittee considers noncompliance that can be acknowledged if the CAPA is adequate

- Once an event is **acknowledged**, it moves to a state called «Draft Letter». The event stays in the analyst inbox and it is closed with a manually-produced letter that details specific about the event.
Problem with new RNI form

- In the new system, acknowledged events are instead immediately closed, and leave the analyst’s inbox.

- We acknowledge dozens of events every week, so keeping track of this minor events will be hard for our staff.

- In addition, we have look at other universities processes and found that acknowledged events do not receive detailed letters. This takes a lot of extra effort when the information of what is being acknowledged is in the submission (the IRB is not making changes to CAPA plan or other information provided).
• Starting on July 15, 2019, the Emory IRB will no longer provide a letter for events that were acknowledged by an expedited reviewer

• Instead, the study team should print out the submission, that will indicate the event was acknowledged, for their records. This same process will be followed after moving to the new eIRB system

• The IRB has a memo posted in our website to explain our new process to sponsors or anyone else that may need it
Non-Human Subject Research Determinations
• Non-human subject research are projects that are not considered “research” with “human subjects” per the federal regulations

• Research is defined as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. (45 CFR 46.102(l))

• Human subject is defined as a living individual about whom an investigator obtains (1) information or biospecimens through intervention or interaction (2) uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens
• Non-human subject research does not need to be submitted to the IRB. Currently we accept request for NHSRD to help study teams. This request are received via an online form.

• This task has become a big part of our staff daily assignments, even though it is not required.

• We did a research of other institutions similar to ours, and we decided to make changes to this process
• Starting July 15, 2019, the IRB will no longer host the online form to submit determination requests to the IRB. Instead, we will have another form that will guide you to submit or not submit your project to the IRB.

• The form will send you an email you can print for your records, as well as a copy of your answers.

• Your information will be saved on an excel sheet automatically, so the IRB can perform routine reviews of studies that used our form.
NHSRD process-Changes

- If you truly do not know if your study is research with human subjects or not, the IRB staff can answer questions or meet with you, but formal determinations will not be provided in the form of a letter.

- If you require a formal determination, you will be required to submit a new eIRB submission.

- In case you needed, the IRB created a memo you could use if required by others.

- The NHSRD tool will be available until 7/12/2019.
Review of New NHSRD form

Located in our website under Does My Project Need IRB Review? Non-Human Subjects Research Determination Electronic Form
Thank You

Find our contact information under http://www.irb.emory.edu/about/staff.html