https://www.irb.northwestern.edu/reportable-new-information-2/

The following events are reported as a Reportable New Information and/or a Modification submission in eIRB+.

**Information that does not fit into one of the categories below does not need to be submitted to the IRB.**

- **Risk**: Information that indicates a new or increased risk, or a safety issue. This includes a chance that something bad could happen. For example:
  - 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.
  - 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.
  - Withdrawal, restriction, or modification of a marketed approval of a drug, device, or biologic used in a research protocol.
  - Protocol violation that harmed subjects or others or that indicates subjects or others might be at increased risk of harm.
  - Complaint of a subject that indicates subjects or others might be at increased risk of harm or at risk of a new harm.
  - Any changes significantly affecting the conduct of the research.

- **Harm/Death**: Any harm (including death) experienced by an NU subject or other individual(s) that, in the opinion of the investigator, is unexpected and at least probably related to the research procedures. **Harms can include psychological, economic, legal, and other non-physical harms.**
  - A participant at the Northwestern site has experienced a severe and unexpected reaction to the study drug. The PI thinks this is possibly related to the study drug.
  - An investigator finds out that the study involves a currently approved drug that may cause renal failure according to newly published literature. An interim analysis or safety monitoring report that indicates that frequency or magnitude of harms or benefits may be different than those initially presented to the IRB.
  - Change in FDA labeling or withdrawal from marketing of a drug, device, or biologic used in a research protocol.
  - An investigator realizes participants have accidentally been given study drug at a higher dose than was approved by the IRB. While no side effects were reported, the increase in dosage placed the subjects at potential risk of harm.

- Four weeks into the study of a new asthma drug, a participant informs the research staff that she is pregnant although the pregnancy test done at screening was negative. Pregnancy is an exclusion factor in the study.

- **(Reportable) Non-compliance:** Serious and/or continuing non-compliance with the federal regulations governing human research or with the requirements or determinations of the IRB that causes harm, increases the risk of harm, adversely affects the rights or welfare of participants or undermines the scientific integrity of the data, or an allegation of such non-compliance. **Incidents of non-compliance on the part of research participants which do not involve risk need not be reported to the IRB (i.e., failure to turn in medication diary).**

  **Examples of Reportable Non-compliance include, but are not limited to, the following:**

  - Human subjects research conducted without IRB approval.
  - Research personnel do not obtain written consent or assent for a study when the IRB has determined that consent or assent is required for a study that involves the collection of discarded tissue. While no harm occurred, failure to obtain consent/assent is a violation of the research participant's rights.
  - Enrollment of participants before IRB approval has occurred and/or after IRB approval has lapsed.
  - Continued treatment of participants after IRB approval has lapsed without first obtaining permission from the IRB.
  - PI enrolls a participant that does not meet all of the inclusion/exclusion criteria. The criteria that were not met puts the participant at risk of harm.
  - Enrollment of children, prisoners, pregnant women and fetuses, without prior IRB approval.
  - Use of an unapproved consent form.
  - Use of unauthorized study personnel to conduct study procedures, obtain informed consent, or have access to identifiable participant information.
  - A required lab test is not done whose omission, in the opinion of the PI, poses risk of harm to participants.
  - Assessment for any inclusion/exclusion criterion was not done prior to beginning if study procedures. The criteria that were not evaluated prior to study procedures puts the participant at risk of harm.
  - A procedure, treatment, or visit specified in the protocol is conducted outside of the required time frame and has clinical consequence; poses risk of harm to subject or others; and/or is thought to be impactful to the scientific integrity of the study.