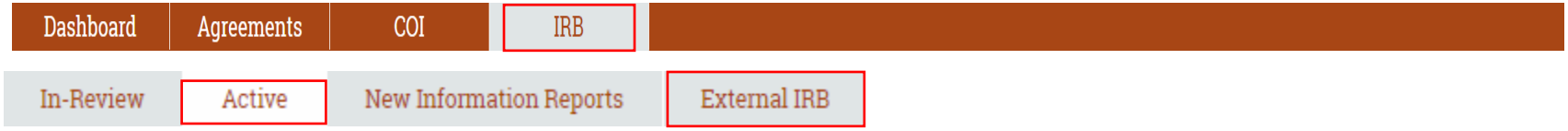
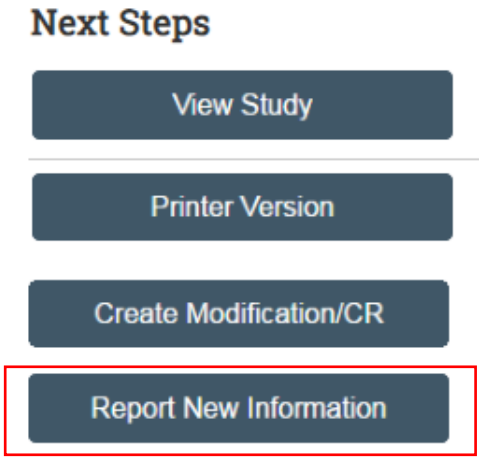
UT Health San Antonio | Enterprise Research Management System (ERMS)

Reportable New Information (RNI) Quick-Guide

1. On the IRB page, navigate to the **Active** tab, and select the approved study under Active or External IRB.



2. Select Report New Information.



3 Complete Reportable New Information.

Reportable New Information

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

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

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

Name	Description
☐ 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.

Need Help?

Identify the Categories That Represent the New Information

Identify the type of event from the list of categories below. You can select more than one category. Information that does not fit into any of the categories provided does not need to be reported to the IRB as new information.

Definitions: Violation: An ac t which had the potential to cause harm or increase the risk of harm to one or more research participants or has the potential to damage the scientific integrity of the data collected for the study; or impacts a subject's safety, rights, or welfare.

4 Select Continue and Finish.

5

Next Steps

Edit RNI

Printer Version

Submit RNI