CASE WESTERN RESERVE UNIVERSITY

How To Submit Reportable New Information (RNI) in SpartaIRB

For information on Reportable New Information definitions, examples, and reporting timelines, see the CWRU Investigator Manual, CHAPTER 27 – Reportable New Information.

Log in to https://spartairb.case.edu/ using your CWRU username and password. On the left side of the home page, select the Report New Information button. This will open the Smart Form with numbered fields to complete.

Fill out the RNI Smart Form as described below. Use the available Question Mark links to access clarifying information about the field.

1. **RNI Short Title**: Enter a brief, unique description that distinguishes it from other RNI submissions. You may use the IRB study ID as part of the description, e.g., "STUDY12345678 over enrollment of participants." Limit of 50 characters.
   The short title identifies the RNI throughout the SpartaIRB system, such as in your inbox and in the IRB's list of submissions to review. DO NOT INCLUDE IDENTIFIERS such as participant name, birth date, email address, etc.

2. **Date you became aware of the information**: Enter the date that the responsible party (i.e., the Principal Investigator) became aware of the information.

3. **Identify the potential categories that represent the new information (check all that apply)**: Select the category or categories that best describe the action or item. Choose from the following:
   - **Audit**: Audit, inspection, or inquiry by a federal agency. *(Note: do not select this for internal CWRU QIP Reviews)*
   - **Complaint**: Complaint of a subject that cannot be resolved by the research team.
   - **Confidentiality**: Breach of confidentiality.
   - **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.
   - **Incarceration**: Incarceration of a subject in a study not approved by the IRB to involve prisoners.
   - **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.
   - **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.
   - **Risk**: Information that indicates a new or increased risk, or a safety issue.
   - **Suspension**: Premature suspension or termination of the research by the sponsor, investigator, or institution.
   - **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.

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

4. **Briefly describe the new information**: enter a description of the event, including what happened, when it occurred and/or the number of times it occurred, where the event occurred (if applicable to the event), and who was involved. DO NOT INCLUDE IDENTIFIERS. Also include any actions taken or planned actions to address the event. Additionally, if applicable, include an explanation for any delay between (a) the date of the event and when the PI became aware of it and/or (b) a delay in the time that the PI became aware of the information and the RNI submission date. See the CWRU Investigator Manual, CHAPTER 27 – Reportable New Information, for requirements regarding reporting timelines.

5. **In the submitter's opinion**:
   a. **Does this information indicate a new or increased risk, or a safety issue?** Yes/No
   b. **Does the study need revision?** Yes/No
   c. **Does the consent document need revision?** Yes/No
   NOTE: if any are YES, a study modification will need to be submitted to address any study team or protocol changes, including consent form language, study procedures, data collection instruments, etc.

6. **Related studies and modifications**: Enter the IRB Study ID (e.g., STUDY12345678) as well as the ID of any Modification (e.g., MOD00012345) related to the actions taken in Item 4 and/or Item 5 above.

7. **Attach files containing supporting information**: upload any documents related to the RNI, such as QIP Review letters, DSMB reports, Corrective and Preventive Action (CAPA) Plans, etc. Make sure that any supporting documentation does NOT INCLUDE IDENTIFIERS.

Once the RNI Smart Form has been completed, select “Finish,” then select “Submit.” Respond promptly to any “Clarification Requested” communications.