IRB 8.2 Report New Information SmartForm

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| Reportable New Information BEFORE REPORTING TO THE EMORY IRB PLEASE REVIEW OUR REPORTING REQUIREMENTS | Green = Help Text |
| 1. **RNI short title:** (uniquely identify this new information report) | **RNI Short Title**  Select a brief description for this RNI submission that does not include subject's identifiers such as their names, initials or medical record number. You can use any unique title shorter than 50 characters. |
| 1. \* **Date you became aware of the information:** |  |
| 1. **Indicate if this event is internal (subject enrolled by Emory personnel or event is under Emory SI or IRB oversight) or external (if not). Check all that apply.**  * Internal * External  1. **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:   1. 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. 2. 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. 3. Withdrawal, restriction, or modification of a marketed approval of a drug, device, or biologic used in a research protocol. 4. Protocol violation that harmed subjects or others or that indicates subjects or others might be at increased risk of harm. 5. Complaint of a subject that indicates subjects or others might be at increased risk of harm or at risk of a new harm. 6. 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.   1. 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. 2. 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 that include findings that negatively affect subject's rights, safety, welfare or their willingness to continue study participation, or that may affect the integrity of the research data. As a reminder, all monitoring reports should be forwarded via email to CTAC regardless of findings.  **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 cannot be resolved by the research team. Such complaints generally affect the rights, welfare, safety of subjects or their willingness to continue with study participation.  **Suspension:** Premature suspension or termination of the research by the sponsor, investigator, or institution.  **ICF/HIPAA Deviations:** Deviations involving the consent signature(s), missing ICF/HIPAA 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. |  |
| 1. \* **Briefly describe the new information:** |  |
| 1. **In the submitter’s opinion:** 2. \* **Does this information indicate a new or increased risk, or a safety issue?** Yes  No        [Clear](http://hcapps6.huronclick.com/UHIRB/CommonAdministration/Choosers/Entity/CustomDataType/DataEntry/Form?postback=1&form=0&qualifiedAttributeName=customAttributes.externalSites&valueField=_IRBSubmission.customAttributes.externalSites_setItemAdd&typeName=_ExternalSite&entityview=com.webridge.entity.Entity%5BOID%5B0652F9BD4FBAFF47A37FE59BF2A6380C%5D%5D&displayField=_IRBSubmission.customAttributes.externalSites_setItemAddDisplay&_webrChangeTrackingParentTransID=f46f540967b24c8c864163c3efd961bd&showOkAndAddAnother=true&rootEntity=com.webridge.entity.Entity%5BOID%5B667648EB6E036E4C9E38C9EB3B45370E%5D%5D&WizardPageOID=com.webridge.entity.Entity%5BOID%5B57EF03344D669341897CC4CA7C13B7D4%5D%5D&aldOID=com.webridge.entity.Entity%5BOID%5B6D52AB3FE31D4C4FB11A671DECD8BE85%5D%5D) 3. \* **Does the study need revision?** Yes  No        [Clear](http://hcapps6.huronclick.com/UHIRB/CommonAdministration/Choosers/Entity/CustomDataType/DataEntry/Form?postback=1&form=0&qualifiedAttributeName=customAttributes.externalSites&valueField=_IRBSubmission.customAttributes.externalSites_setItemAdd&typeName=_ExternalSite&entityview=com.webridge.entity.Entity%5BOID%5B0652F9BD4FBAFF47A37FE59BF2A6380C%5D%5D&displayField=_IRBSubmission.customAttributes.externalSites_setItemAddDisplay&_webrChangeTrackingParentTransID=f46f540967b24c8c864163c3efd961bd&showOkAndAddAnother=true&rootEntity=com.webridge.entity.Entity%5BOID%5B667648EB6E036E4C9E38C9EB3B45370E%5D%5D&WizardPageOID=com.webridge.entity.Entity%5BOID%5B57EF03344D669341897CC4CA7C13B7D4%5D%5D&aldOID=com.webridge.entity.Entity%5BOID%5B6D52AB3FE31D4C4FB11A671DECD8BE85%5D%5D) 4. \* **Does the consent document need revision?** Yes  No        [Clear](http://hcapps6.huronclick.com/UHIRB/CommonAdministration/Choosers/Entity/CustomDataType/DataEntry/Form?postback=1&form=0&qualifiedAttributeName=customAttributes.externalSites&valueField=_IRBSubmission.customAttributes.externalSites_setItemAdd&typeName=_ExternalSite&entityview=com.webridge.entity.Entity%5BOID%5B0652F9BD4FBAFF47A37FE59BF2A6380C%5D%5D&displayField=_IRBSubmission.customAttributes.externalSites_setItemAddDisplay&_webrChangeTrackingParentTransID=f46f540967b24c8c864163c3efd961bd&showOkAndAddAnother=true&rootEntity=com.webridge.entity.Entity%5BOID%5B667648EB6E036E4C9E38C9EB3B45370E%5D%5D&WizardPageOID=com.webridge.entity.Entity%5BOID%5B57EF03344D669341897CC4CA7C13B7D4%5D%5D&aldOID=com.webridge.entity.Entity%5BOID%5B6D52AB3FE31D4C4FB11A671DECD8BE85%5D%5D)   If revisions are required, describe them above and submit a study modification for review. |  |
| 1. **Related studies and modifications:**      |  |  | ID | Short Title | Investigator | State | IRB Office | | --- | --- | --- | --- | --- | --- | --- | |  |  | There are no items to display | | | | | | **Related Studies and Modifications**  The modifications in the list are filtered so only modifications to studies already related to this RNI are shown.  Tip: To add a related modification when it is not available in the selection list:   1. Add the modification’s parent study. 2. Click the Save link at the top or bottom of the page.   Save link at top or bottom of SmartForm page   1. Now click Add again under Related studies and modifications.   The modification is available in the selection list. |