

Frequently Asked Questions (FAQ): Reportable New Information (RNI) versus Modification for Changes to Study Conduct Due to COVID-19

An **RNI** should be submitted to report any changes to study conduct to eliminate any immediate hazard to current participants prior to IRB approval. The PI is responsible for making the assessment that there is a need for immediate action to protect the safety and wellbeing of the participant. If there is a need, the PI may make the change without first obtaining IRB approval. Note this option is only available for changes that would impact participants already enrolled in the study. It is not appropriate to make such a change in order to enroll a new participant (for example exceptions to inclusion/exclusion criteria or changes to the consent process).

After the changes have been instituted, the RNI should be submitted to the IRB within 5 days and include sufficient detail on the temporary changes that were implemented and the harm being mitigated.

A **modification** should be submitted for any long-term study conduct changes or changes to the approved research protocols not related to eliminating an immediate hazard to current participants. The modification must receive IRB approval before the changes can be implemented.

- **Question 1:** Currently the approved protocol requires in-person administration of follow-up interviews; however, until further notice all follow-up interviews will be conducted via Zoom to mitigate the harm of possible COVID-19 infection from travel and visit to the clinic.
- **Response 1:** The PI may immediately implement this change prior to IRB approval and submit an RNI within 5 days to inform the IRB of the change to Zoom follow-up interviews to eliminate the hazard of possible COVID-19 transmission from an in-person clinic visit.
- **Question 2:** A participant completed study visit 4, which included study safety labs with their local primary care physician in Michigan instead of traveling to the study site in Chicago to mitigate harm of possible COVID-19 infection from travel and visit to the hospital.
- **Response 2:** The PI should submit an RNI within 5 days to inform the IRB of this change that was implemented and include sufficient detail about the hazard that was eliminated for the current participant.
- **Question 3:** Due to the pandemic, the informed consent process is being revised to email the consent to subjects and then a phone call with a study team member who will review the consent, answer all questions and obtain verbal consent.
- **Response 3:** A modification should be submitted to amend the protocol and consent form and obtain IRB approval prior to implementing this change. This is because this change is not removing an immediate hazard to current participants and also allows the IRB to ensure compliance with the DHHS and FDA informed consent regulations.
- **Question 4:** We would like to amend our protocol to include a new questionnaire to assess how COVID-19 is affecting our study participants.
- **Response 4:** A modification should be submitted to amend the protocol, the consent process and submit the questionnaire for IRB approval before implementing the change. This is because this change is not removing an immediate hazard to current participants.