**What should an investigator do if they want to revise an IRB approved research study?**

If investigators wish to modify an ongoing IRB-approved research study, they must submit a request to the IRB and receive IRB approval before implementing the proposed modification, unless the change is designed to eliminate an apparent immediate hazard to subjects ([45 CFR 46.103(b)(4))](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.103). If the investigators change the research in order to eliminate apparent immediate hazards to subjects without prior IRB approval, they should report those changes promptly to the IRB.

Full text can be found at <http://www.hhs.gov/ohrp/humansubjects/commonrule/index.html>

**What should an investigator do if they want to revise an IRB approved consent form?**

If investigators wish to modify an ongoing IRB an ongoing IRB approved consent form they must submit the request for modification to the IRB and receive IRB approval before starting to use the proposed modified consent form.

**What should an investigator do if they want to change their data collection method(s)?**

If investigators wish to modify their data collection method(s) in an ongoing IRB approved study they must submit the request for modification to the IRB and receive IRB approval before starting the use of the new data collection method(s). This vitally important as changes in data collection method(s) can significantly affect the risk benefit ratio and in some cases require additional oversight.

**What should an investigator do if they want to add a person to their research team that will be involved with interacting with participants?**

If investigators wish to add additional personnel that were not initially noted in the initial protocol approval they will need to ensure that the individual(s) have completed the CITI training and submit a modification application.

**What should an investigator do if they want to add a person to their research team that will only be involved with data or research materials?**

If investigators wish to add additional personnel they will need to ensure that the individual(s) complete a certificate of confidentiality and maintain this document in the research files.

**What should an investigator do if they want to add an additional data collection site(s)?**

If investigators wish to add a data collection site(s) to an ongoing IRB approved study they must submit the request for modification to the IRB and receive IRB approval before recruitment from the new site(s) is administered. A letter of support from each new site needs to be submitted.