**Do I Need to Submit a Modification Request?**

Once the VCOM IRB has reviewed and issued final approval for ANY study type, the study must be carried out exactly as originally submitted, reviewed and approved. Plans to deviate from the approved protocol (e.g. additions or deletions) must be approved by the VCOM IRB prior to the implementation of these changes, except where necessary for the safety and well-being of the participant.

Examples of some common changes made to an IRB application that require a modification request include, but are not limited to, the following:

* Changes to personnel (deleting or adding investigators)
* Changes in subject population
* Changes in recruitment plans
* Changes in research procedures
* Changes to study instruments
* Changes to consent form language
* Changes to wording/questions within a study instrument

Please remember that the PI is responsible for promptly reporting to the IRB any proposed changes in the research activity prior to being implemented. To request changes/amendments to a study, please complete and submit a Modification Request (Form G found in the forms and templates library). All revised documents should be uploaded with track changes (or changes highlighted) for IRB review. Once reviewed and approved by the VCOM IRB, a Modification approval letter will be issued.