SELF-ASSESSMENT OVERVIEW AND INSTRUCTIONS

Note: much of this information below is excerpted from the Quality Management SOP. Please refer to this SOP for further details.

Adherence to the protocol is one of the keys to protecting research participant safety and ensuring quality data.

The idea is for the research team to incorporate proactive quality control checks (called self-assessment monitoring) performed by research team members that continually assess the quality of the research conduct. These proactive measures can positively impact participant safety and the quality of the data to answer the study question. Self-assessment monitoring also helps the study team to be ready for Sponsor/Lead Team monitoring visits and audits, and can lessen findings from these activities and the related work to address the findings.

It is important and strongly recommended for any research team to develop a plan for self-assessment monitoring even if there is already a formal Quality Management Plan (QMP) from the Sponsor or Lead Team, where there is on-going monitoring of the study by outside monitors.

Self-assessment reviews can be implemented at specified time points during the study, where the study team performs a "self-audit" to applicable standards, such as the IRB-approved protocol and relevant policies of the BMC/BU Medical Campus HRPP and the IRB of Record.

The extent and nature of the self-assessment reviews should be aligned with the design of the study. In developing the plan, the PI and research team should consider factors such as risk, complexity of the study overall, complexity of certain aspects of the study, study procedures, pace of enrollment, etc.

From these considerations, the research team can decide on frequency and the level of the self-assessment reviews. For example, it may be yearly, every 6 months, quarterly, or by enrollment pace.

Whatever plan is developed for the frequency and level, if there are repeated issues of noncompliance during the assessments, the plan can be updated to widen or increase frequency. The plan can also change if the recruitment rate significantly changes from what was originally anticipated or for any other reason. All plans should be documented.

The study team should review the following categories and can use the CRRO Self-Assessment Monitoring Tools as a guide. These tools provide specific instructions for each type of self-assessment.

- Informed Consent
- Participant Eligibility
- Protocol Adherence
- Self-Assessment Review Plan

The self-assessment monitoring should be done by research staff who are trained in how to do the review. It is best to make the self-assessments as objective as possible. One way to do this is to have research team members assess study elements performed by their fellow team members that they themselves have not directly worked on. If this is not possible don't worry, self-assessments are still very effective.

The Office of Human Research Affairs (OHRA) Quality Assurance (QA) team and the CRRO team (CRRO@bu.edu) are available for consultations and to provide training on performing Self-assessments.

Documentation that self-assessment monitoring was done should be maintained. This demonstrates that the study team has performed this important quality oversight. As applicable, the research team should keep logs, completed assessment tools (showing what was reviewed), and findings/response to findings. This documentation is typically not added to the regulatory binder, but should be maintained as part of the overall study documentation.

What to do regarding findings from self-assessment monitoring:

- The research team should be familiar with the requirements of the BMC/BUMC HRPP as well as the IRB of Record in determining reporting of deviations and reportable findings.
    - Refer to Deviation Reporting SOP.
- All deviations should be recorded on a Deviation log. See the CRRO Deviation Log Template, or use a Sponsor/Lead Team provided template. The research team should assess if a deviation has potential to impact participant safety or quality of the study data.
- Deviations that meet the definition of Major Deviation or Reportable Finding (depending on the definition of the IRB of Record) or Unanticipated Problem will need to be reported to the IRB (and possibly other entities) within an expedited timeframe.
    - Refer to Deviation Reporting SOP for further guidance on reporting deviations.
- The PI should evaluate if study procedures need to be changed to prevent similar deviations. Reminder: If changes to study processes change the IRB-approved protocol then an amendment should be submitted to the IRB prior to implementing the changes.
- If corrections are made to previously collected data or documentation, the correction must be initialed, dated, and explained (if necessary to provide more information on why the correction was made). A note-to-file may be utilized.

In response to any identified issues, the study team may consider requesting a Quality Assurance (QA) review by the OHRA QA team to provide a more formal review of the study conduct and compliance with regulatory and policy standards.