Quality Management: Taking a Proactive Approach and Using Self-Assessments to Ensure High Quality Research

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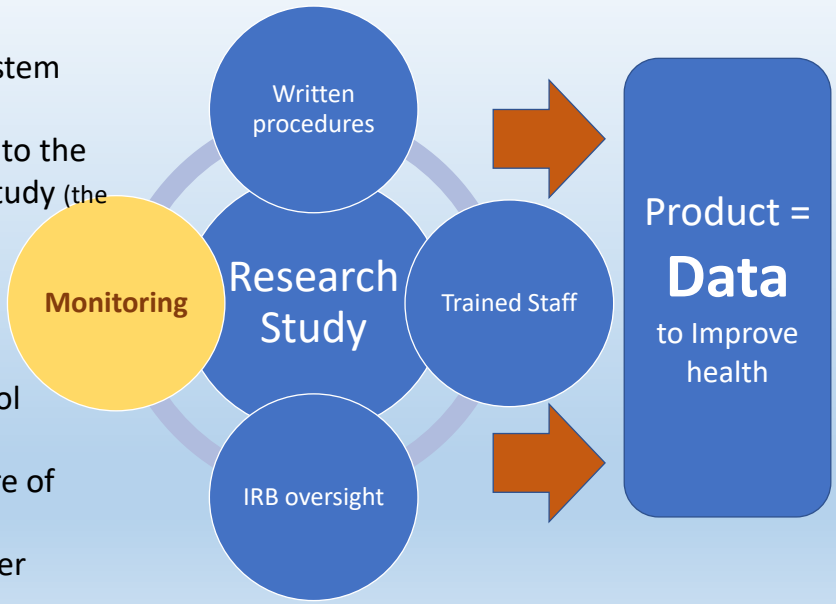
Clinical Research as a Quality System

Monitoring:

- Key element of a Quality System
- Quality control tool
- On-going systematic review to the relevant standards for the study (the IRB-approved protocol at minimum)

GOALS:

- Ensure study is conducted, recorded, reported in accordance with the protocol and applicable regulations
- Protect rights, safety, welfare of subjects
- Ensure quality data to answer the study question



What are Self-Assessments and Why Should we do them?

What

- Proactive on-going quality checks by the study team focused on adherence to the IRB approved protocol and other applicable standards (regulations, GCP, SOPs, policies, etc.)
  - "In the moment" study management checklists and workflows
  - Process of conducting "self-audits" of your study

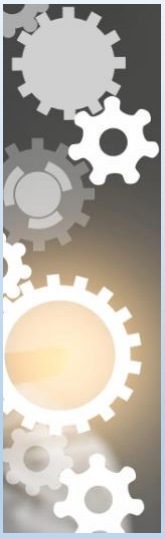
Why

- Key to protecting subjects and ensuring reliable data
- Helps to ensure the study meets necessary standards for conducting the research
- Gives study teams more control in overall quality
  - Proactive vs. reactive
  - Identification of possible non-adherence early on
  - Improves quality; ultimately saves time
  - Identifies gaps in training and competency
- Helps the study team be "audit-ready"
  - Lessens findings from audit and monitoring visits and lessens work associated with addressing findings

Monitoring:
On-going **systematic review to the relevant standards** for the study (IRB-approved protocol at minimum)

Ensure you use a Systematic approach

- Develop a plan for self-assessments
  - Even if monitoring is already being done by the sponsor/lead site
- What does a systematic approach look like…. Define your Plan:
  - What processes will you focus on in your review? (consent, eligibility, adherence, etc.)
  - How many subject records for each "category" of review (i.e. informed consent, eligibility, study procedures, etc.)
  - How often?
  - Who will do it?
  - Then in doing your self-assessment, you will review elements in a systematic way
- Make sure you know the relevant standards for your research and audit to those standards
- Utilize CRRO Tools for Self-Assessment
- Overall, you are checking:
  - Did you do what you say in your protocol you were going to do…
  - Can you show (by your documentation) that you adhered to the standard?



What are the standards that guide *your* research?

- IRB approved research plan
  - protocol(s), IRB application, supporting documents
  - All versions that have been approved
- BMC/BU Medical Campus HRPP Policies
- BMC/BU Medical Campus Standard Operating Procedures
- Regulations
  - FDA regs on drug or device research; OHRP regulations
- ICH Good Clinical Practice (GCP)
  - If protocol states it adheres to ICH GCP
  - If not specified, refer to/incorporate GCP to meet "best practice" standards
- Requirements or policies of lead site, sponsor, funder
- Guidance

Following up on Self-Assessment Findings

- Documentation, Required Reporting, Corrections, Preventive Actions
  - See next slide for Corrective and Preventive Action Plan (CAPA) resources
- Check BMC/BU Medical Campus SOP: Protocol Deviation Reporting
- Check policies for the BMC/BU Medical Campus IRB:
  - HRPP 7.4.5: Submission of Reportable Events and New Information
  - HRPP 6.6.5: Deviations
- Check policies for outside IRB if applicable

Resources for Developing a Corrective and Preventive Action Plan (CAPA)

✓CAPA Template

RPN Workshops

- Corrective And Preventive Action Plans: What they are and why you should care – (November 2022)
- Developing Effective Corrective and Preventive Action Plans (June 2019)

Clinical Research Seminar

- How to develop a Corrective and Preventative Action Plan (CAPA) that even the FDA will love (April 2018)

Clinical Research Times

- Developing a Corrective and Preventive Action Plan (May 2022)

Self-Assessment Tool Templates

- All available on CRRO Tools Website

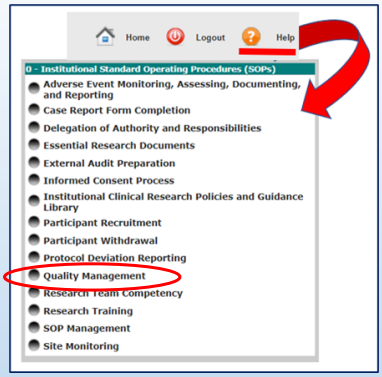
- Self-Assessment Overview Instructions
- Customizable templates for Self-Assessments
  - Review Plan
  - Informed Consent
  - Participant Eligibility
  - Protocol Adherence

Standard Operating Procedures

- Cross-institutional collaboration between Boston University Medical Campus and Boston Medical Center
- Effective January 1st, 2023
- Found within INSPIR help menu

- Set of written instructions that document routine activity followed by an organization to comply with regulations
- Form an integral part of a successful quality system as it provides individuals with the information to perform a job properly, and facilitates consistency in the quality and integrity of work performed
- Guidance on how to complete some of the daily activities of a research team and also address overarching structural activities

- The SOPs will specifically guide clinical research studies that target BMC patients, use BMC patient data, or utilize BMC facilities and/or services.
  - BMC patient: any individual with a clinical encounter generating a BMC-specific medical record
  - BMC patient data: patient data that is derived from BMC medical records and/or systems
  - BMC facilities: clinical or non-clinical space owned or operated by BMC
  - BMC services: a unit or group operated or managed primarily by BMC staff



Recommendation

- SOPs provide excellent guidance for studies that are outside of the scope and can be followed/used for any study

Standard Operating Procedures

- Highlights for Self-Assessments
  - ➢ Quality Management
- Clinical Research Seminar: November 2022
  - BMC Clinical Research Standard Operating Procedures Implementation
- Clinical Research Times
  - December 2022 Feature Article: Spotlight on SOPs - A Bright New Future
  - Monthly starting January 2023, Spotlight on SOP section

Adverse Event Monitoring, Assessing, and Reporting
Case Report Form Completion
Delegation of Authority and Responsibilities
Essential Research Documents
External Audit Preparation
Informed Consent Process
Institutional Research Policies and Guidance Documents
Participant Withdrawal
Protocol Deviation Reporting
Quality Management
Research Team Competency
Research Training
Site Monitoring Visits
SOP Management
Subject Recruitment

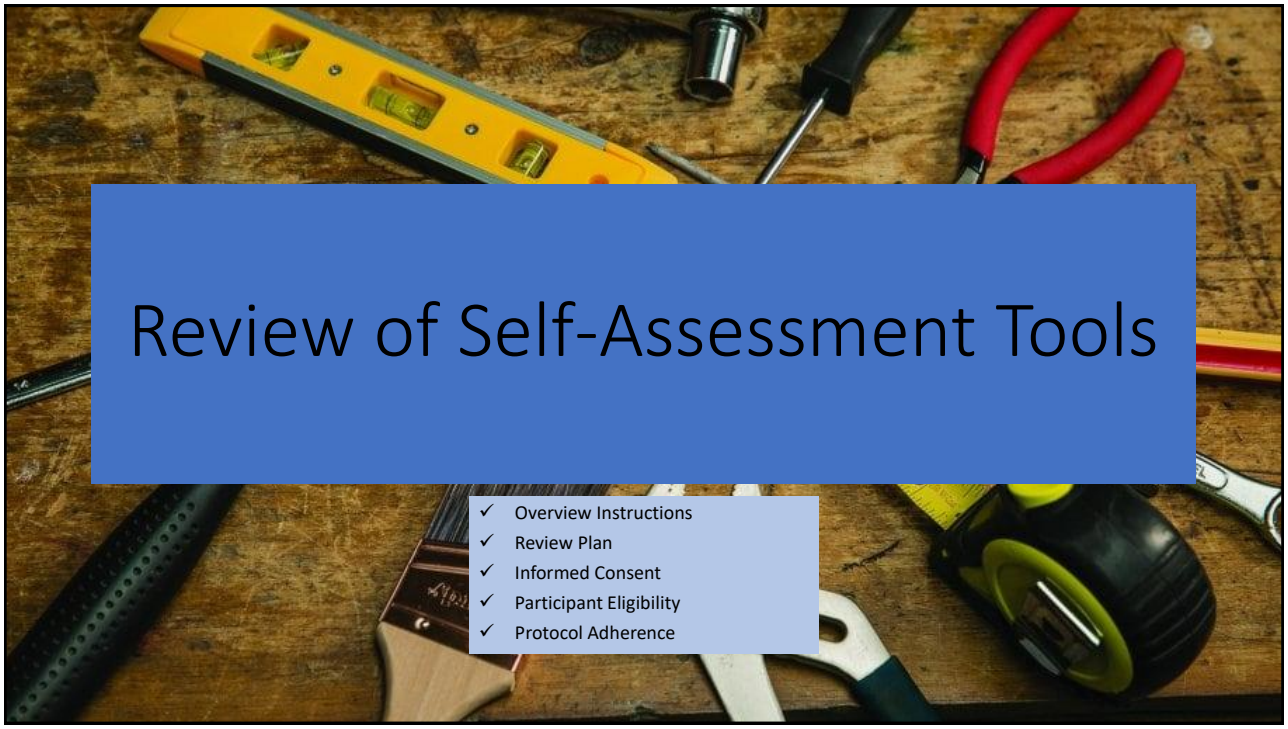
Quality Management SOP – *Overview*

Purpose

- Provides best practice recommendations for conducting self-assessment monitoring of study documentation and processes
- Ensure and support safety of research participants and quality and reliability of the data though ongoing self-assessment monitoring to verify adherence to the approved protocol and study plan, institutional policies, policies of the IRB of record, and applicable regulatory requirements

Responsibility

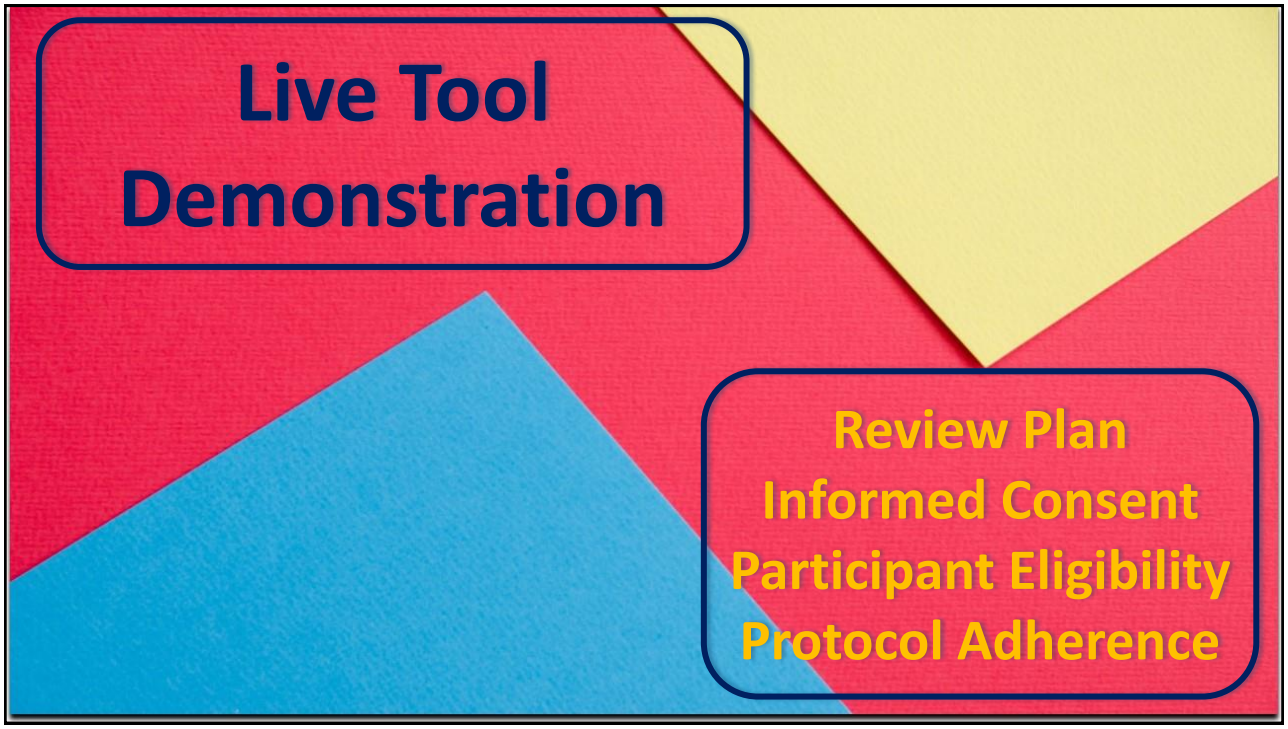
- PI is responsible for the oversight of the conduct of the study and ultimately, the quality of the study and the resulting data
- Oversight includes ongoing assurance that the research team is conducting research processes according to the IRB-approved protocol and that the study documentation is sufficient to show compliance to the IRB-approved protocol



Overview – How to use + recommendations

- Start with reading this document before using the tools
  - Contains high-level instructions
  - Contains links to additional training and resources

- Recommendations → These apply to all tools
  - Carefully review General Instructions box – don't delete until study-specific edits have been completed
  - Carefully review comments – don't delete until study-specific edits have been completed
  - Header – Copy full name of study, not just shortened or brief title
  - Footer – Don't delete version number of CRRO template or page numbering



Plan – How to use + recommendations

Self-Assessment Plan Table

- This is where you document your plan – how many "participant" you will look at for consenting, eligibility, and adherence.
  - These don't need to be the same, you can look at 100% for consents, 100% for eligibility, and only 50% for adherence.
  - *But what you say you will be doing, you should actually do*
- There are three rows for other tools to be developed and used at study team discretion – if you aren't planning to look at anything else, these rows should be deleted.
- You can change your plan, just use a new form – and keep both old and new forms!

Self-Assessment Completion Log

- This is where you document the actual assessments you complete.
- Each "type" of assessment should have its own row for the date the review is being completed.
- If more room is needed for comments, a separate memo or note-to-file can be completed.
- Rows can be added for additional assessments if needed
  - Add new row at bottom (use "tab" or just "insert row")
  - Copy information from row above → Paste – Overwrite Cells

Additional Tools for Quality Checks

- ✓ "In the moment" – Procedure or Visit Checklists
- ✓ Developing Study-Specific Self-Assessment Tools

Additional Quality Checks: *Using Procedure or Visit Checklists*

- Study dependent
- *Management* checklists and not (necessarily) source documentation
- Helps ensure adherence to protocol and study plan
- Things to include on checklists:
  - Study identifier (full title, IRB number)
  - PI Name
  - Participant identifier
  - Printed name, signature, date – for completing
  - Possibly printed name, signature, date – for somebody completing specific procedures
  - Page numbers (X of Y)
  - Version date of checklist
- CRRO templates are available

Procedure Checklists Examples

Consent
- Who present
- Who required to be present (LIP, Witness, Translation Services)
- List questions and answers
- Signed copy given to participant
- Signed and dated by participant
- Signed and dated by researcher

Biospecimen Collection
- Collected
- Space for why not collected
- Dropped off at study freezer
- Sent to sponsor
- Confirmed received by sponsor

Safety Labs
- Order placed/signed
- Tubes dropped off
- Tubes picked up
- Shipped
- Dropped off at lab
- Values checked for safety
- Entered into EDC

Visit Checklists Could Include

Procedures or tasks at each visit

List all Questionnaires or Surveys participant needs to complete

Associated tasks after the visit (data entry, specimen shipping)

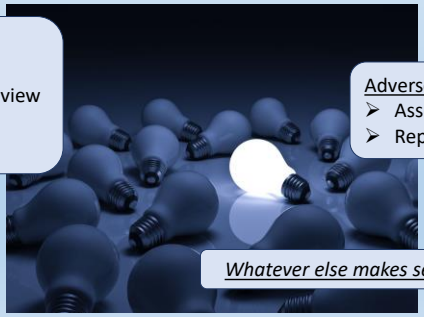
Who has to be at the visit with space for name

Additional Quality Checks: *Other Self-Assessment Tools*

- Teams can develop their own tools based on study-specific needs
- Can use CRRO-templates as a starting point or start from a blank document (contact us if you want to brainstorm about this)

Laboratory Testing
- Values
- Out of Range – PI review
- Shipped on time
- Data entry checks

Delegation or Training Logs
- Check for all staff included
- Dates are listed correctly
- PI signatures or initials



Adverse Events and Deviations
- Assessments
- Reporting

Whatever else makes sense for your study plan and procedures!

Summary and Resources

Summary – Self-Assessments

✓Self-Assessments are key to ensuring high quality research

- Reviewing study documents and adherence by doing Self-Assessments
  - Leads to quality data and participant safety
  - Leads to more successful, more efficient monitoring visits
  - Identify gaps in training to prevent future deviations

✓ Templated tools are available

- Training on how to update for study specifics and use is available by contacting CRRO

- ❑ CRRO Self-Assessment Tools
- ❑ SOP Quality Management

Located within INSPIR help tab

- ❑ Clinical Research Seminar – April 2023

Overview and Significance of Quality Assurance Process: You've been selected for a routine QA Review – Now what?

- ❑ Clinical Research Times Newsletter – March 2023

Published at the end of the month

Seminar Evaluation Survey – Look in Chat!