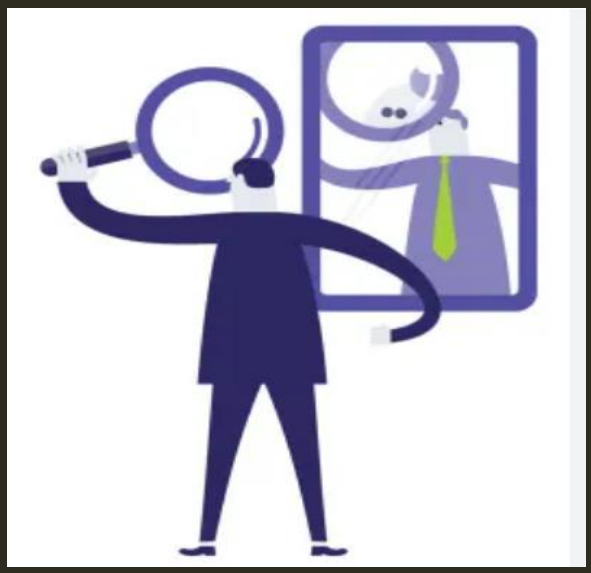
PUTTING YOUR QA HAT ON: PLANNING AND CONDUCTING SELF-ASSESSMENTS TO ENSURE HIGH QUALITY RESEARCH

Research Professionals Network Workshop
September 2024



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WORKSHOP OBJECTIVES AND FLOW

1. Introduce tools to conduct QA Reviews that can be easily adapted to your research projects
2. Review QA best practices to help you confidently carry out meaningful self-assessments
3. Use the QA tools in the context of a "real" research study and put our QA hats on to try to identify issues in study conduct and documentation that can lead to issues in safety and quality of your research studies

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LET'S DO A POLL!

Have you ever participated in conducting a Self-Assessment on your research study(ies)?

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WHY IS IT IMPORTANT TO DO SELF-ASSESSMENTS?

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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

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WHY IS IT IMPORTANT TO DO SELF-ASSESSMENTS?

Self assessments can be used to proactively discover strengths and areas for improvement during the conduct of a clinical trial

Ensures data integrity throughout the entire study duration
- Allows the study team to be accurate and consistent with their data collection
- Allows for identification of systemic problems before the end of the study

Protecting the Rights, Safety and Welfare of the Participants
- Ensures that the members of the research team are trained and are appropriately credentialed to perform delegated tasks
- Ensuring proper execution of the Informed Consent
- Ensuring participants meet eligibility criteria for enrollment (Inclusion/ Exclusion criteria)
- Ensuring adherence with the protocol as approved by the IRB

Ensures the team is following the protocol
- Allows for management of compliance with the protocol, SOPs and GCPs
- Identifying problems/ non-compliance early
- Identifies training and competency issues early

Ensure you are audit ready
- Reduces findings from monitoring visits or audits
- Less findings means less work in responding to any findings, e.g., queries, audit responses, CAPAs

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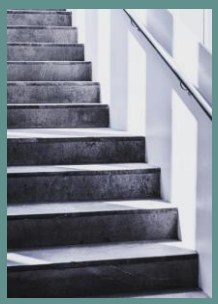
Steps of Self-Assessment



STEPS OF SELF ASSESSMENT

Planning

Conduct of the Self-Assessment

Reporting and correcting issues

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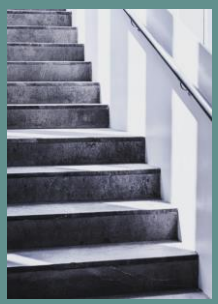
Steps of Self-Assessment



PLANNING

- What do I review? Who does the review? How often should I review?
- The extent and nature of the Self-Assessment should be in line with
  - Protocol specific such as protocol risk and complexity
  - Recruitment rate
  - Study staff experience
  - Problem issues that have occurred in the past
- Remember: It's NOT "All or Nothing" it's **"All or SOMETHING!"**
  - What's feasible considering staffing and workload
- So, it's not a one-size fits all, but here's a general plan example:
  - Review after first 3 subjects enrolled and then every 6 months
  - Review all ICFs enrolled since previous review
  - Review Eligibility and Protocol adherence for 3 subjects enrolled since previous review
  - The plan can change based on review findings!
  - Keep a record of your reviews (it's evidence you've implemented this important quality management activity.

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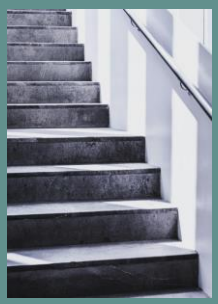
Steps of Self-Assessment



CONDUCTING YOUR SELF-ASSESSMENT

Review and understand the written plan

Make sure you know the relevant standards for your research and audit to those standards

Utilize Self-Assessment Tools

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?

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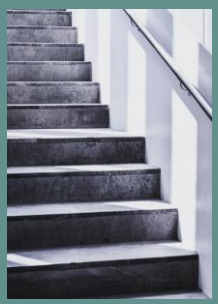
Steps of Self-Assessment



DIGGING INTO THE DETAILS

What do you need to look at?

How are you going to document what you have reviewing?

What supporting materials do you also need to look as related to the information you are reviewing?

- Regulatory materials
  - IRB approved materials, dates of approval, versions
  - Key personnel, training, delegation of authority
- Consent
  - Who conducted, is that person key personnel, appropriately trained, delegated that responsibility
  - Correct version, consent supporting documentation
  - Is the consent complete
- Eligibility
- Protocol Adherence

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WHICH STANDARDS GUIDE *YOUR* RESEARCH?

IRB approved research plan
- protocol(s), IRB application, supporting documents
- All versions that have been approved

Humans Research Protection Program Policies

Organization Standard Operating Procedures

Regulations
- FDA regulations for drug/ device research
- Office for Human Research Protections (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

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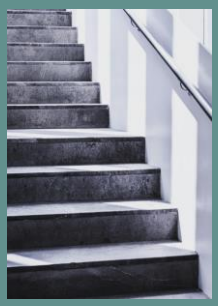
Steps of Self-Assessment



REPORTING

What do you do with self assessment review findings?
- What can you fix?
- What needs to be reported?
- When and how do you report things

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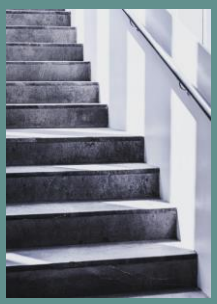
Steps of Self-Assessment



REPORTING AND CAPA [IF (NO, *WHEM*) YOU HAVE FINDINGS]:

- Reporting, to whom and what timeframe depends on:
  - IRB approved protocol requirements (usually under Safety Monitoring section
  - Institutional policies and IRB of Record's policies (i.e. definitions of Major and Minor deviations and reporting timeframe)
  - Sponsor and/or lead site policies
  - Is this an FDA regulated study where the investigator is holding the IND or IDE (and is the sponsor); then reporting to FDA may be necessary
  - Other institutional entities (i.e. Privacy Officer for issues with PHI, etc.)
  - Funder's policies may require reporting to funder in certain instances
- For Major deviations and Unanticipated Problems (UPs), reporting includes development of Corrective and Preventive Action Plan (CAPA)

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Steps of Self-Assessment

REPORTING AND CAPA [IF (NO, *WHEM*) YOU HAVE FINDINGS]:

Corrective and Preventive Action Plan

Corrective Actions/Preventive Actions

Develop, Document, and Communicate the plan to address the problem

- Correct: REACTIVE steps to correct the immediate problem
- Understand: IDENTIFY underlying cause(s) and extent of the problem(s)
- Prevent: PROACTIVE steps to prevent future recurrence of the problem(s)
- Training, Training, Training! (Usually a key reactive and proactive step; Document this training!)

Communication of the actions (assessment, approval)

- Study team, IRB, FDA, Sponsor, Funder, etc.

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SOME RESOURCES ABOUT CAPAS (LIVE LINKS)

Clinical Research Seminar:

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

RPN Workshops

Developing Effective Corrective and Preventive Action (CAPA) Plans, June 2019

Corrective and Preventive Action Plans: What they are and why you should care, November 2022

General Resource

- CR Times article – May 2022 edition

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REPORTING POLICIES & RESOURCES: UVM

IRB Policies and Procedures

- RNI Reporting
- Non-compliance

UVM OCTR SharePoint (behind a firewall):

- Regulatory Documents & Resources
- 2019 RPN Workshop Presentation

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REPORTING POLICIES: MUSC

Policy IRB HRPP 10.1 Human Research Audit
- Item K – includes broad language on what should be included in a CAPA

Policy 4.14 Protocol Deviation
- Section IV describes the submission of a CAPA to the IRB

Protocol Deviation Report Form (example)
- This form is a smart form submitted in eIRB as part of the reportable event along with other smart form pages

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REPORTING POLICIES: UF

HRP Policy 112 Reportable Events

Investigator Guidelines
- Deviation Reporting – Event Reporting – Adverse Events, Unanticipated Problems Involving Risks to Subjects of Others, Protocol Deviations, and Other Problems

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REPORTING POLICIES: BUMC/BMC

- IRB CAPA Template (directs to templates page, not actual document)
- HRPP Policy 7.4.5 Submission of Reportable Events and New Information
- HRPP Policy 6.6.5.2 Major Deviations

General Resource

- CR Times article – May 2022 edition

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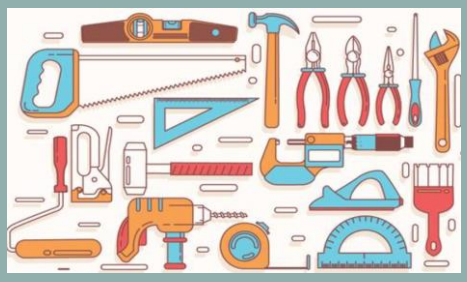
SELF-ASSESSMENT TOOLS (LIVE LINK)

- Tools available on BUMC/BMC CRRO Tools Website
- Self-Assessment Overview Instructions
- Customizable templates for Self-Assessments
  - Review Plan
  - Informed Consent
  - Participant Eligibility
  - Protocol Adherence
- Each tool has General Instructions and guidance in the margin



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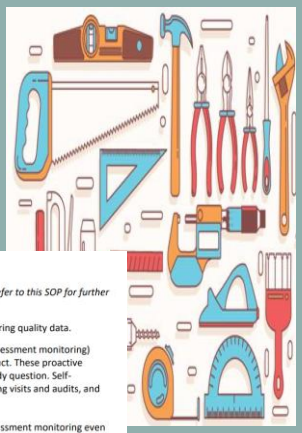
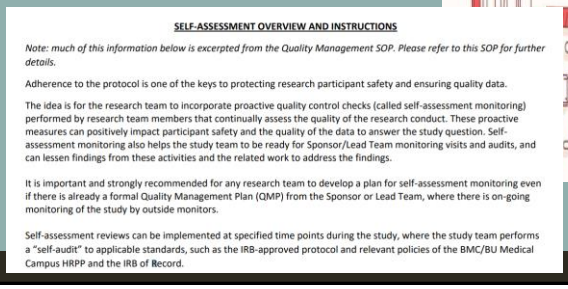
SELF-ASSESSMENT OVERVIEW INSTRUCTIONS TOOL (MT)

- General, high-level guidance on Self-Assessments
- Align with design of the study: risk, complexity, enrollment pace, etc.
- Performed by trained research staff
- What to do re: findings
- Importance of documenting/maintaining records on self-assessments
- What to do re: findings





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.

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REVIEW PLAN TOOL

- It all starts with a Plan!
- Plan the frequency of reviews, what will be reviewed, number of participant records (or percent) to be reviewed
- Template log to document review completion
- Remember, it's All or SOMETHING! ☺

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REVIEW PLAN TOOL

ASELF-ASSESSMENT REVIEW PLAN

GENERAL INSTRUCTIONS – delete this box before using.

NOTE: This form is designed to document the overall plan for self-assessments for the study as a whole. This form also functions as a log documenting completed self-assessments.

- Review the BMC SOP on Quality Management for recommendations on completing Self-Assessments.
- 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.
- 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, including this planning document. This documentation is typically not added to the regulatory binder, but should be maintained as part of the

are available for consultations and to

the OHRA QA team to provide a more

l in determining reporting of deviations

CRRO
Delete this instruction box before using.
Delete all margin comments before using.
Reply

Self-Assessment Plan

Type of Self-Assessment	Frequency	Number or Percentage of Participants to be Reviewed	Comments or Notes about Plan
Consent			☐ No comments or notes
Eligibility			☐ No comments or notes
Protocol Adherence			☐ No comments or notes

Other – at study team disc
Describe type of other revi

Self-Assessment Completion Log

Even if completed on same day, each "Type of Self-Assessment" should be documented separately. Do not combine "types" on one row.

Type of Self-Assessment	Participants Reviewed	Name Performing Self-Assessment	Date Completed	Comments or Notes about Review
☐ Consent ☐ Eligibility ☐ Protocol Adherence				☐ No comments or notes
☐ Consent ☐ Eligibility ☐ Protocol Adherence				☐ No comments or notes
☐ Consent ☐ Eligibility ☐ Protocol Adherence				☐ No comments or notes

CRRO
Rows can be added as needed.
Reply

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INFORMED CONSENT TOOL

- Record all approved versions of consent forms
- Determine what review aspects are relevant to your study
  - Limited readers, limited English proficiency speakers, children, etc.
- Use the tool to conduct a systematic review of consent forms
- Document findings to use for reporting and corrective actions

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INFORMED CONSENT TOOL

Date of Consent Self-Assessment Review:	Name Performing Consent Self-Assessment Review:

IRB approved consent form versions cross-check (list IRB-approval dates of all consent form versions that have been used in the study)		
1. 2/26/2022	4.	7.
2. 5/12/2022	5.	8.
3.	6.	9.

Consent Self-Assessment Review

A	Participant ID	OA1	OA2	OA3		
B	Consent form type					
C	Date signed by participant	4/25/22	6/1/22	6/12/2023		
D	Signed on correct, current IRB-approved version	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
E	Signed and dated by participant	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
F	Signed and dated by delegated and IRB-approved researcher	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
G	Consented signed prior to any study procedure	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
		☐ Yes	☐ Yes	☐ Yes	☐ Yes ☐ No	☐ Yes ☐ No
					☐ Yes ☐ No	☐ Yes ☐ No
					☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A

Participant ID	Notes on identified issues above – Any "No" requires further documentation. *Review HRPP Policy 6.6.3.2 and 6.6.3.4 for Reporting Requirements. Review Reporting Charts and Algorithm for more info. Studies approved by an external IRB should review those policies for all requirements.*
☐ *No identified issues on any participant reviewed as listed above. Below sections in this table may remain blank.*	
OA1	
OA2	
OA3	

CRRO
If any explanation or note requires additional space, document this as "continued on separate memo" and staple that additional documentation
Reply

CRRO
If there are no identified issues that need to be documented, check this box.
Reply

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PARTICIPANT ELIGIBILITY TOOL

- Record each inclusion and exclusion criteria (including changed criteria from protocol amendments)
- Check for source documentation that backs up eligibility for each criterion
- Check that source documentation meets ALCOA-C standard
- Place to document identified issues

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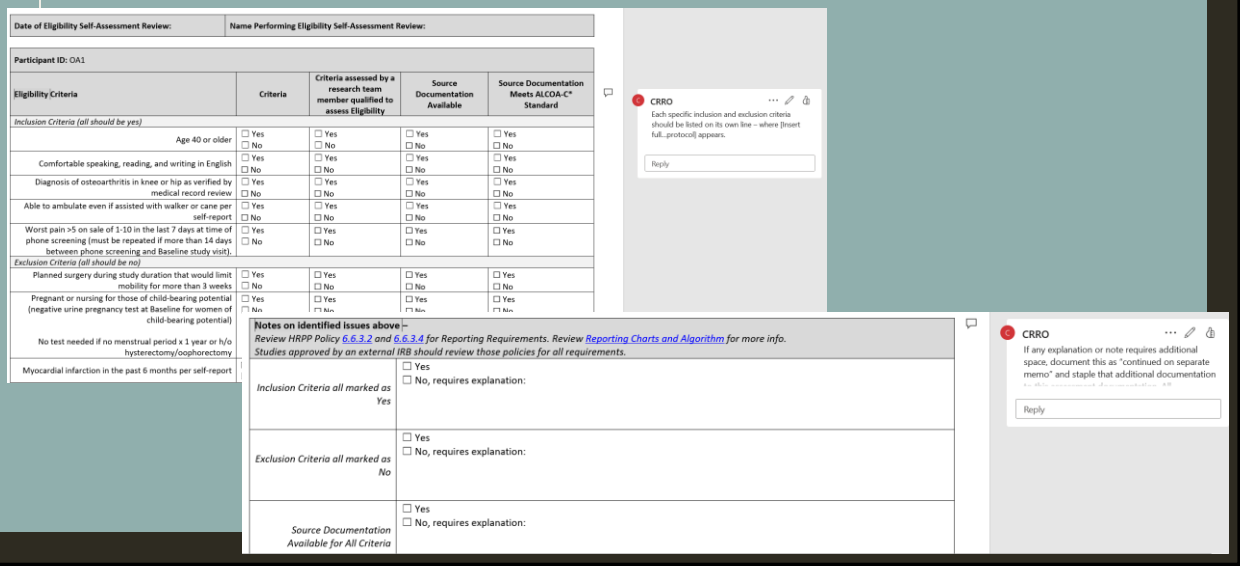
PARTICIPANT ELIGIBILITY TOOL



Date of Eligibility Self-Assessment Review:	Name Performing Eligibility Self-Assessment Review:

Participant ID: OA1

Eligibility Criteria	Criteria	Criteria assessed by a research team member qualified to assess Eligibility	Source Documentation Available	Source Documentation Meets ALCOA-C* Standard
Inclusion Criteria (all should be yes)				
Age 40 or older	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Comfortable speaking, reading, and writing in English	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Diagnosis of osteoarthritis in knee or hip as verified by medical record review	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Able to ambulate even if assisted with walker or cane per self-report	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Worst pain >5 on sale of 1-10 in the last 7 days at time of phone screening (must be repeated if more than 14 days between phone screening and Baseline study visit).	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Exclusion Criteria (all should be no)				
Planned surgery during study duration that would limit mobility for more than 3 weeks	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Pregnant or nursing for those of child-bearing potential (negative urine pregnancy test at Baseline for women of child-bearing potential) No test needed if no menstrual period x 1 year or h/o hysterectomy/oophorectomy	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Myocardial infarction in the past 6 months per self-report	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No

CRRO
Each specific inclusion and exclusion criteria should be listed on its own line – where [insert full...protocol] appears.
Reply

Notes on identified issues above –
Review HRPP Policy 6.6.3.2 and 6.6.3.4 for Reporting Requirements. Review Reporting Charts and Algorithm for more info.
Studies approved by an external IRB should review those policies for all requirements.

Inclusion Criteria all marked as Yes	☐ Yes ☐ No, requires explanation:
Exclusion Criteria all marked as No	☐ Yes ☐ No, requires explanation:
Source Documentation Available for All Criteria	☐ Yes ☐ No, requires explanation:

CRRO
If any explanation or note requires additional space, document this as "continued on separate memo" and staple that additional documentation
Reply

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PROTOCOL ADHERENCE TOOL

- Record procedures/assessments by study visit (or in between if applicable)
- Check for source documentation that backs up protocol adherence
- Check that source documentation meets ALCOA-C standard
- Place to document identified issues

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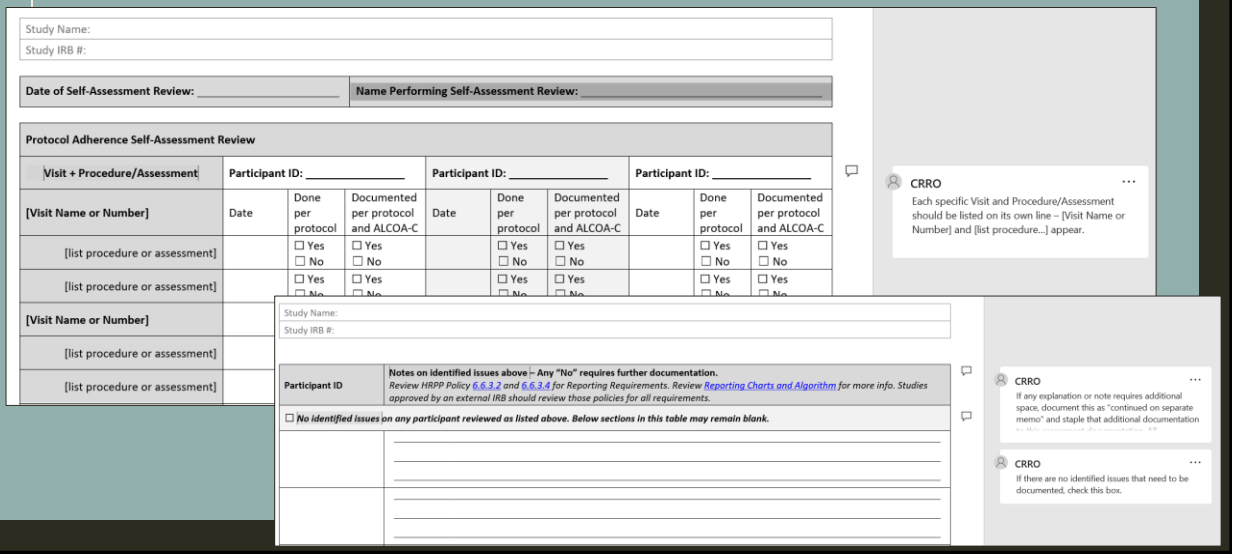
PROTOCOL ADHERENCE TOOL



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LET'S DO SOME SELF-ASSESSMENTS!

We will use the Self-Assessment template tools to assess our "real" study

You are assigned to a Breakout room that will be using either the Consent Self-Assessment tool or the Eligibility Self-Assessment Tool

(You received the documents as well as the Self-assessment tool that are assigned to your Breakout room)

Each Breakout room will be led by a facilitator who has experience in Quality Assurance and Auditing

The facilitator will orient participants to the documents to assess as well as to the Self-Assessment tool;

Facilitator will not be pointing you to findings

Everyone is encouraged to take some time at the beginning of the Breakout session to familiarize themselves with the documents for review, and work together as a "study team" in a systematic way to complete the Self-assessment review form(s)

Have Fun!! ☺

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PROTOCOL SYNOPSIS

- **Title**: Increasing Physical Activity in Older Adults with Osteoarthritis Pain in Hips or Knees
- **Purpose**: Evaluate how older adults with osteoarthritis may benefit from sessions that teach behavioral coping skills for increasing physical activity as compared to treatment as usual.
- **Subject population**: 90 adults age 40 and older who have formal diagnosis of knee or hip osteoarthritis
- **Participation**: 8 weeks

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PROTOCOL SYNOPSIS, *CONT'D.*

- **Procedures**:
  - Baseline visit
    - Physical exam
    - X-rays
    - Blood sample
    - Questionnaires on pain and physical functioning
    - Personal fitness tracker
    - Data to be collected from medical record: medical history, diagnosis of osteoarthritis, demographics, height and weight
    - Randomization to two sessions with a behavioral therapist or to continue treatment as usual
  - Subjects in counseling group will attend two 60-minute sessions 2 weeks apart
  - Six weeks after Baseline subjects fill out online questionnaires for 7 evenings in a row

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PROTOCOL IRB SUBMISSION/REVIEW HISTORY

- **Initial submission IRB approved 2/26/22**
- **There has been one amendment to increase the number of x-rays from 1 per affected joint to 2 per affected joint, approved 5/12/22**
- **New staff approved on 4/13/22**

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BREAKOUT ROOM ACTIVITY ASSIGNMENTS

Please select the breakout room to which you are assigned (by last name)

Last Name	Breakout Room	QA Review Type
Al Sarraf to Brunner-Jackson	1	Consent
Buckhannon to Damus	2	Consent
Davenport to Goodnough	3	Consent
Grant to Knight	4	Consent
Kojidi to McCaffrey	5	Eligibility
McLeod to Pratt	6	Eligibility
Raymond to Sovich	7	Eligibility
Springer to Yousuf	8	Eligibility

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RECAPPING BREAKOUT ROOM ACTIVITY

- Please share your reflections on the activity
- Please share specific examples of things you learned that you think will be particularly helpful
- Do you see yourself/your team possibly integrating a program of Self-Assessments?

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