Protocol Review & Monitoring Observership Training

January 2026

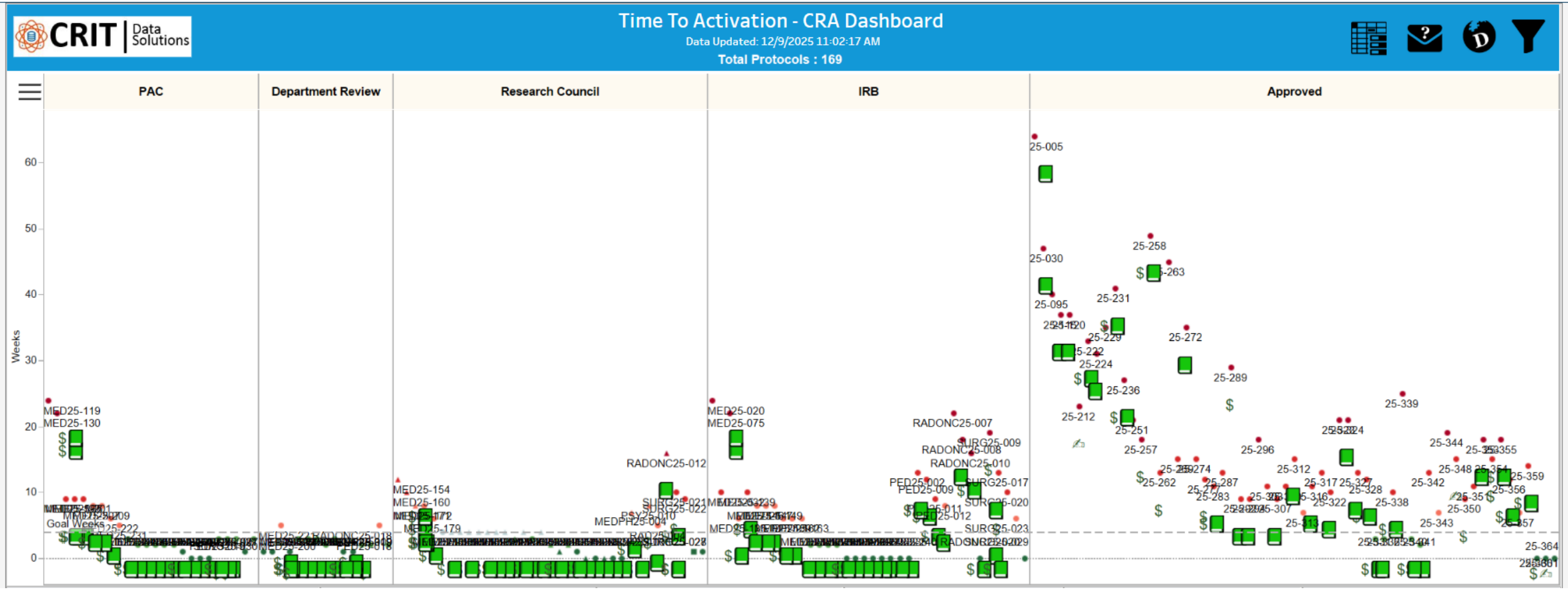
Memorial Sloan Kettering Cancer Center

Plan for Today

- Quick Overview of Review Process
- Comparison of Research Council and IRB
- Your Responsibilities as a Reviewer
- What to Expect - Plan for your upcoming observations and reviews

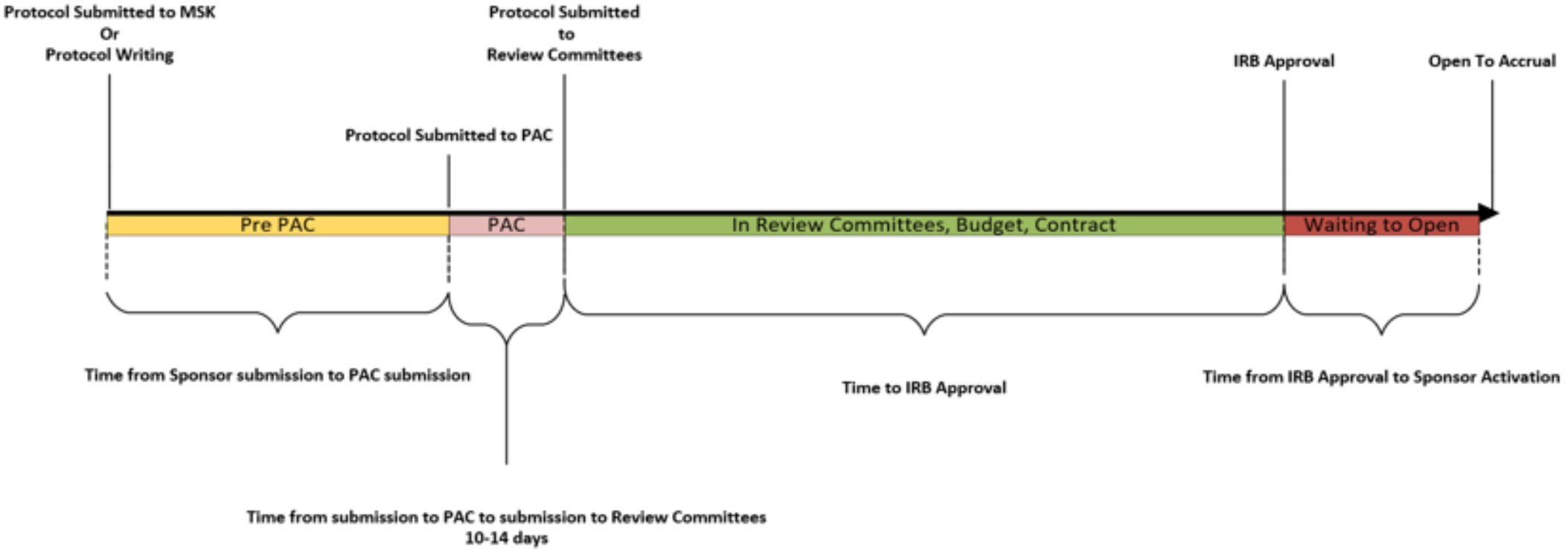
Quick Overview of Review Process

Review Process: Time to Activation Dashboard



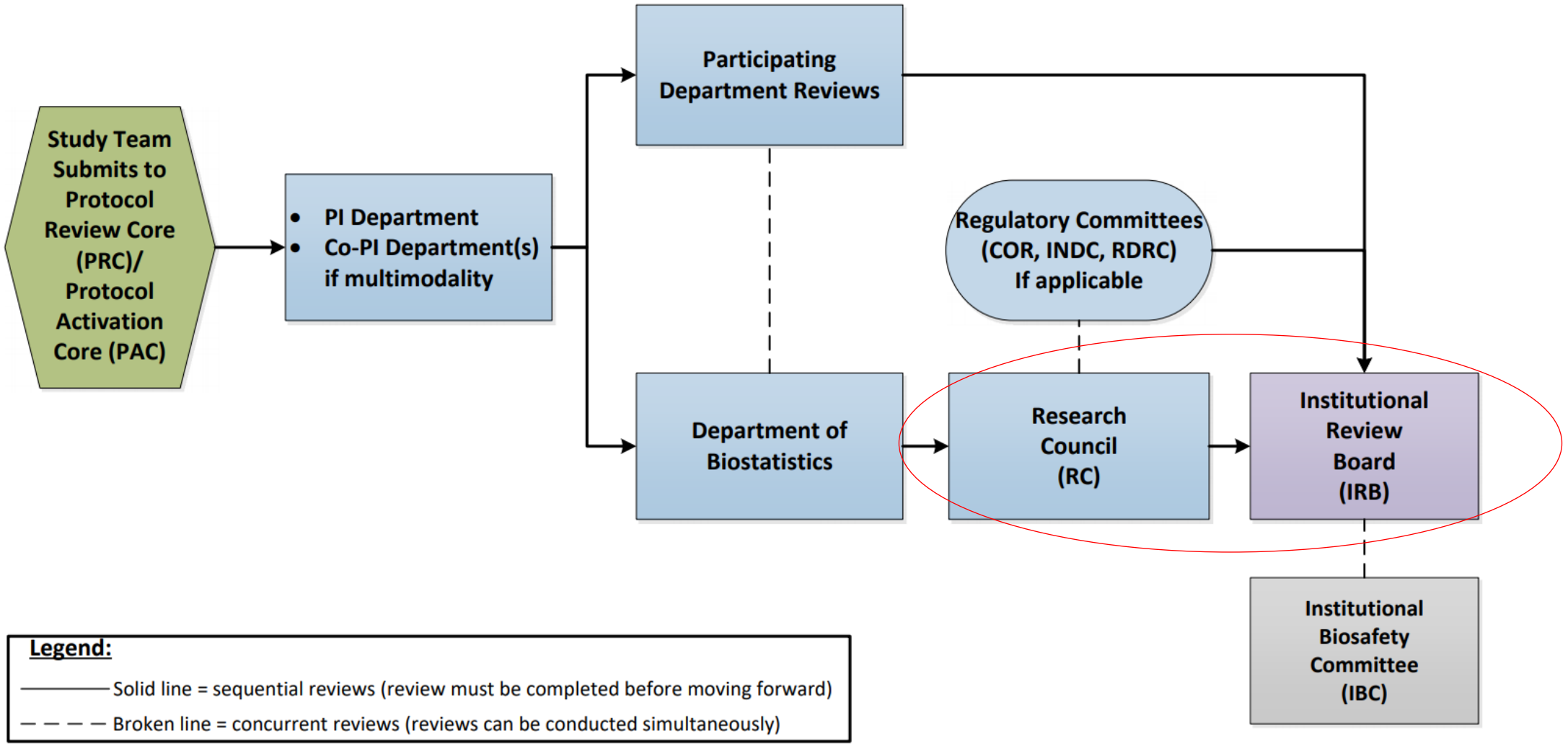
Total Protocols = 169

Review Process: Activation Timeline



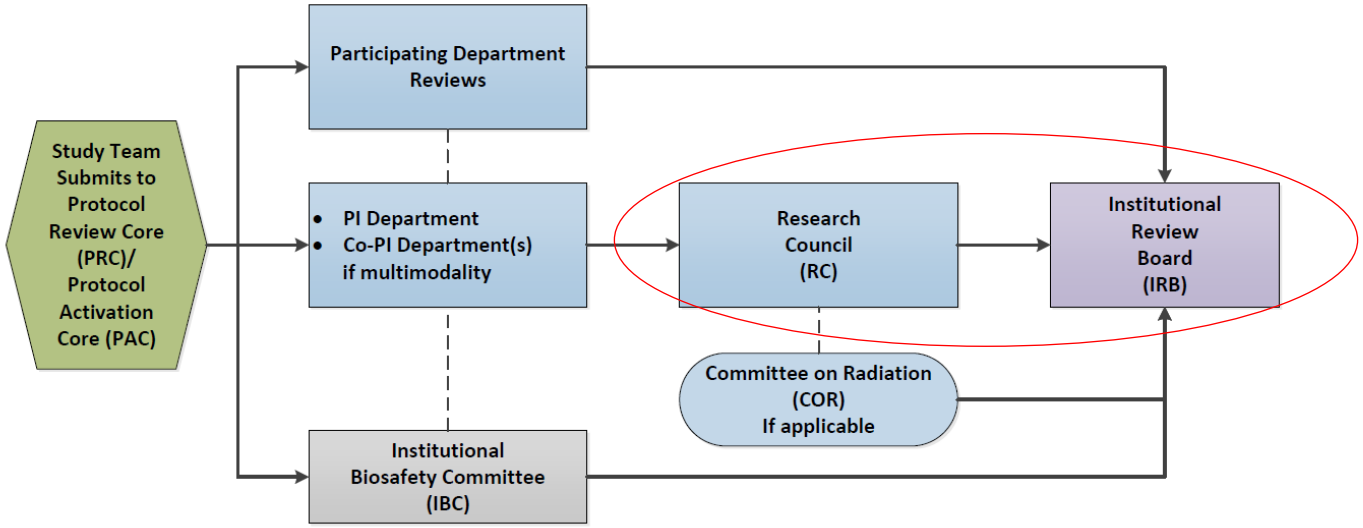
Time to Activation (TTA)
Time from Committee Submission to Open to Accrual
Goal 90 days

Review Process at MSK - Internal



Review Process at MSK - External

Current External

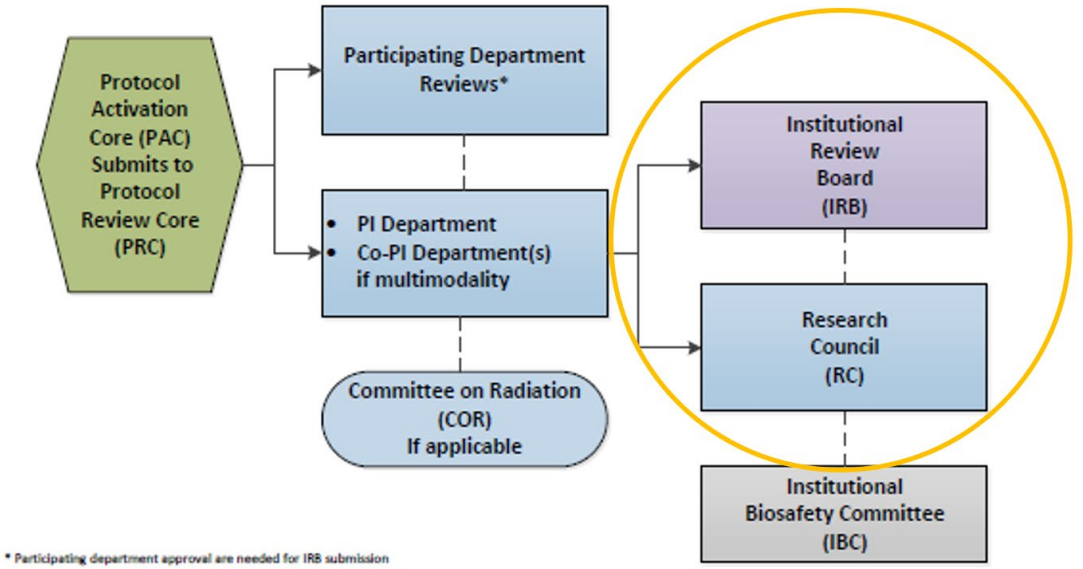


Legend:

———— Solid line = sequential reviews (review must be completed before moving forward)

– – – – Broken line = concurrent reviews (reviews can be conducted simultaneously)

Pilot: Priority 1 Industry



* Participating department approval are needed for IRB submission

Comparison of Research Council and IRB

Research Council vs IRB/PB

What's the difference, what's the same?

- Scope/Governance
- Committee Structure
- Meeting Structure/Type of Reviews

Research Council vs IRB/PB

	Research Council	IRB/PB
Scope	• Science • Priority	• Ethics • Human Subject Protection
Governance	• NCI Core Grant	• Office of Human Research Protection (OHRP) • Food and Drug Administration (FDA) • Office of Civil Rights (OCR) • Association for the Accreditation of Human Research Protection Program (AHRPP)
Reporting Structure	• MSK President	• Institutional Official (IO)

Committee Structure

Structure	Research Council	IRB/PB
# of Committees	2 (A/B) 1 meeting per week (alternates A/B)	3 (A/B/C) Each committee meets twice per month
Leadership	1 Chair 3 Co-Chairs per committee 1 Statistical Co-Chair	1 Chair per committee 2 Associate Chairs per committee
Membership	• ~70 multidisciplinary • 5 rotating statisticians	• ~86 multidisciplinary • Membership makeup is regulated by government • Community Members
Committee Management	• 1 Program Manager; 1 Protocol Review Manager per committee • Protocol Information Management System (PIMS)	• 1 IRB/PB Program Manager or Administrator per committee • PIMS

Meeting Structure/ Types of Reviews

Committee	Reviews @ Meeting	New Protocol Review Similarities	New Protocol Review Differences
Research Council	• **New Protocols** • Resubmissions • Amendments	• 3 reviewers; primary reviewer presents protocol • Discussion opened to entire committee • Formal voting required (option to abstain) • Individuals with conflicts must recuse themselves • Quorum is required	• Primary & secondary reviewers are scientific • Tertiary reviewer is statistician (externally sponsored studies only)
IRB/PB	• **New Protocols** • Resubmissions • Amendments • Continuing Reviews • Single Patient Use (SPU) • NIH genomic data certifications • COI management plans		• Primary & secondary reviewers are scientific and/or non-scientific dependent on protocol • Tertiary reviewer is CRA member • Community member (non-affiliated) feedback

Your Responsibilities as a Reviewer

Reviewer Responsibilities/ Expectations

- Materials for Review
- Scope
- Presenting to the Council/Board
- Determination Definitions

Reviewer Responsibilities: Materials for Review

- Research Proposal Submission Form (RPSF)
- Prior Committee Correspondence
- Face Sheet
- Protocol
- Appendices (if applicable)
- Investigator Brochures (if applicable)
- Manuals (if applicable)
- Informed Consent Form (IRB ONLY)

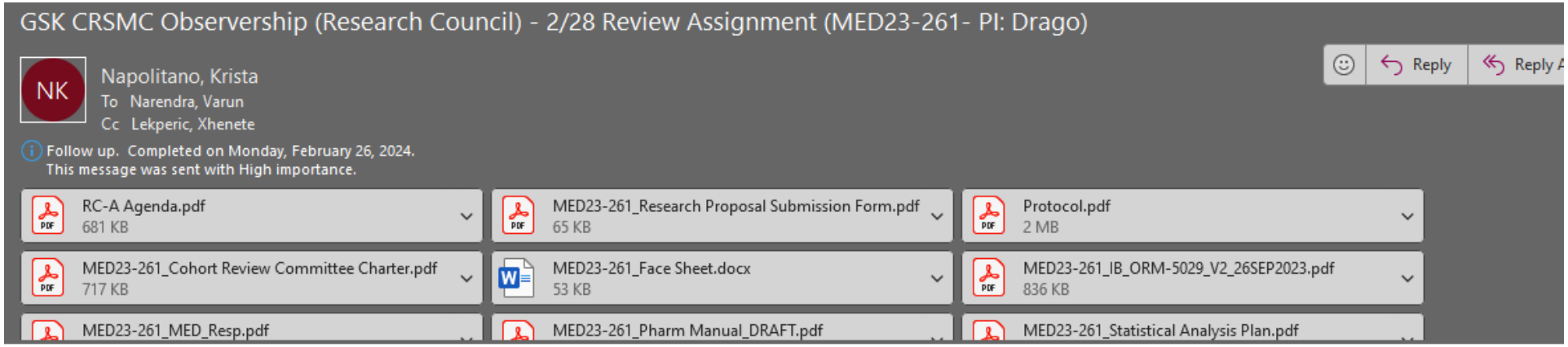
Reviewer Responsibilities: Assignment Email

Attachments:

- Agenda
- Reviewer Checklist
- Review Documents
- Policies

Reminders:

- Contacts for Questions
- Brief summary (2-4 min max)
- Closed meeting
- Set aside 2-3 hours for review



Good afternoon Dr. Narendra,

Attached are the following documents for your new protocol assignment to be reviewed at the 2/28 RC-A meeting:

- 2/28 RC-A Agenda
- RC Reviewer Form (the checklist you will complete to guide/document your review)
- Protocol documents (protocol, research proposal submission form, previous dept reviews, manuals, etc.)
- In case your assignment includes phase I expansion cohorts and/or backfill cohorts, please reference the following links from our RC portal page:
  - Dose Expansion Cohort Policy for Phase I Trials
  - Backfill Memo

Please note, per the submission form (RPSF A.7) MSK will only be participating in Part 2 (Dose Expansion) - Cohorts A and B.

Please email [redacted]me your checklist by **Tuesday at 3pm** so we may review and follow up with you or the Chair if needed before the meeting.

Reminders:

- [redacted] I are available to answer any questions you may have as you go through this process. We can have a brief discussion about the protocol before the RC meeting. Just let us know when works for you.
- As the primary reviewer for this protocol, you will present a **brief protocol summary (no more than 2-4 minutes)** including its strengths followed by any questions/concerns.
- This is a closed/confidential meeting.
- You do not have a conflict of interest (COI) with the protocols being discussed. If you have any COI concerns, please let us know.

Thank you,
Krista

Krista Napolitano (Soirefman), MA (she/her)
Program Manager, Protocol Review & Monitoring
Clinical Research Administration

Memorial Sloan Kettering Cancer Center
Main: 646-888-0958
napolitk@mskcc.org

Reviewer Responsibilities: RC Scope (checklist)

Brief Summary

- Sponsor, study question(s), importance, design, departmental reviews

Importance

- Importance of the scientific question to PI, MSK, field

Trial Design

- Scientific validity of methods, experimental design, trial endpoints
- Will the trial answer the scientific question?
- Is there adequate preclinical/clinical data?

Feasibility

- Can all tests/interventions be done?
- Do we have the patient population?
- Competing studies & effect on currently opened studies (prioritization)
- Departmental concerns addressed?

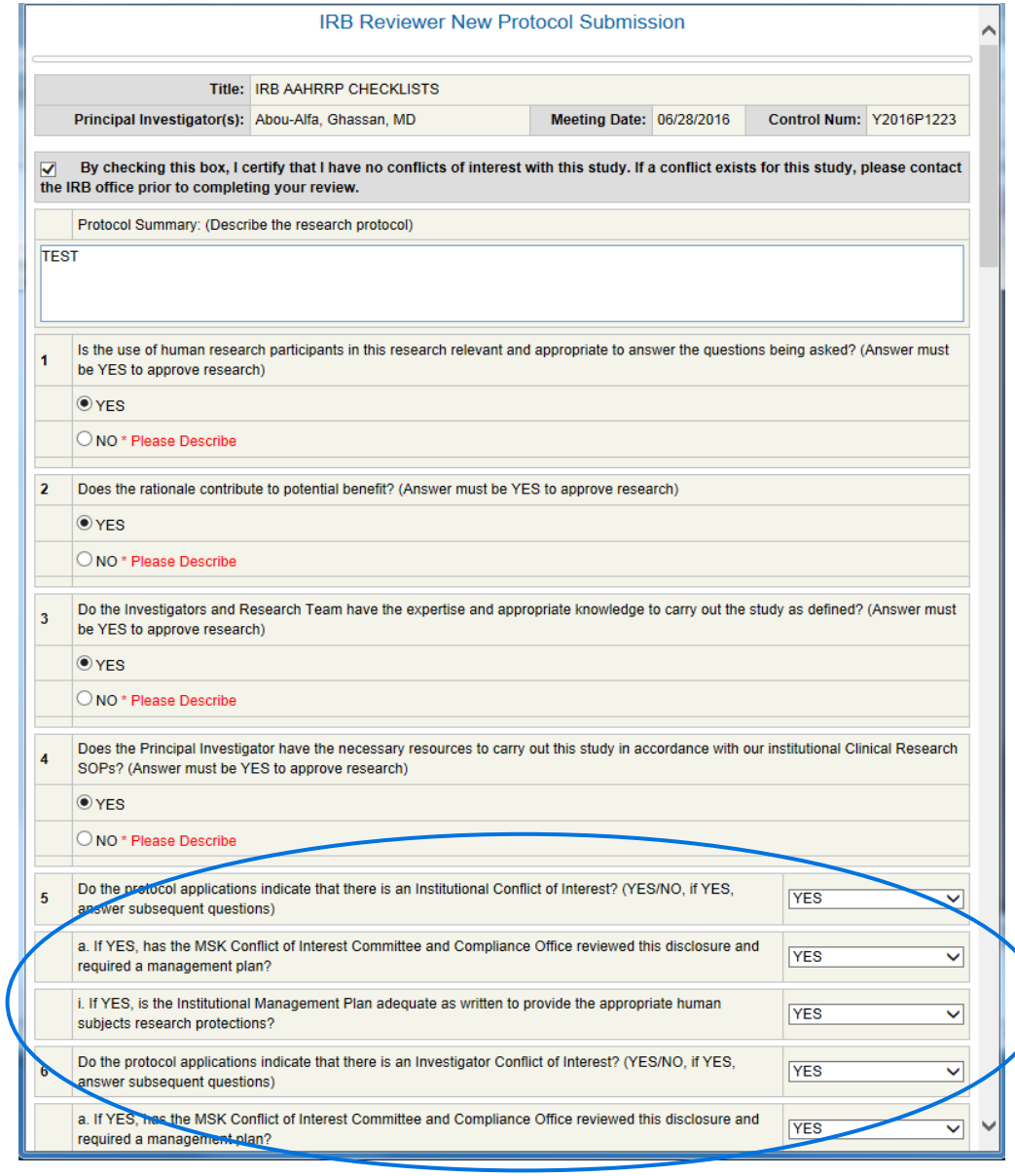
Issues for Letter to PI

- Major issues requiring RC discussion
- Minor issues (discussion not required)

Reviewer Responsibilities: IRB Scope (checklist)

111 Criteria for Approval

COI



IRB Reviewer New Protocol Submission

Title:	IRB AAHRRP CHECKLISTS
Principal Investigator(s):	Abou-Alfa, Ghassan, MD
Meeting Date:	06/28/2016
Control Num:	Y2016P1223

☑ By checking this box, I certify that I have no conflicts of interest with this study. If a conflict exists for this study, please contact the IRB office prior to completing your review.

Protocol Summary: (Describe the research protocol)

TEST

1 Is the use of human research participants in this research relevant and appropriate to answer the questions being asked? (Answer must be YES to approve research)
- ◉ YES
- ○ NO * Please Describe

2 Does the rationale contribute to potential benefit? (Answer must be YES to approve research)
- ◉ YES
- ○ NO * Please Describe

3 Do the Investigators and Research Team have the expertise and appropriate knowledge to carry out the study as defined? (Answer must be YES to approve research)
- ◉ YES
- ○ NO * Please Describe

4 Does the Principal Investigator have the necessary resources to carry out this study in accordance with our institutional Clinical Research SOPs? (Answer must be YES to approve research)
- ◉ YES
- ○ NO * Please Describe

5 Do the protocol applications indicate that there is an Institutional Conflict of Interest? (YES/NO, if YES, answer subsequent questions) — YES

a. If YES, has the MSK Conflict of Interest Committee and Compliance Office reviewed this disclosure and required a management plan? — YES

i. If YES, is the Institutional Management Plan adequate as written to provide the appropriate human subjects research protections? — YES

6 Do the protocol applications indicate that there is an Investigator Conflict of Interest? (YES/NO, if YES, answer subsequent questions) — YES

a. If YES, has the MSK Conflict of Interest Committee and Compliance Office reviewed this disclosure and required a management plan? — YES

i. If YES, is the Investigator Management Plan adequate as written to provide the appropriate human subjects research protections? — YES

7 Do the Investigators have access to the population that will allow recruitment of the necessary number of participants? (Answer must be YES or N/A to approve research)
- ◉ YES
- ○ NO * Please Describe
- ○ N/A

8 Will participant selection, as described in the recruitment plan, be equitable to all who qualify taking into account the purposes and setting of the research, any potential problems involving vulnerable populations, selection criteria and/or recruitment procedures? (Answer must be YES or N/A to approve research)
- ◉ YES
- ○ NO * Please Describe
- ○ N/A

9 Does the Recruitment Plan require access to PHI in order to screen and identify potential participants? — YES

a. If YES, is the Principal Investigator requesting a Limited Waiver of Authorization for recruitment within the protocol applications? — YES

i. If YES, have all the regulatory criteria in 45 CFR 164.512(i)(2) for a Limited Waiver for Authorization to be granted been met? — YES

10 Do you agree with the Risk Level defined by the Principal Investigator of the study? — YES

a. If not, define the risk level: — Moderate

11 Are the risks reasonable as compared to the potential benefits? (Answer must be YES to approve research)
- ◉ YES
- ○ NO * Please Describe
- ○ N/A

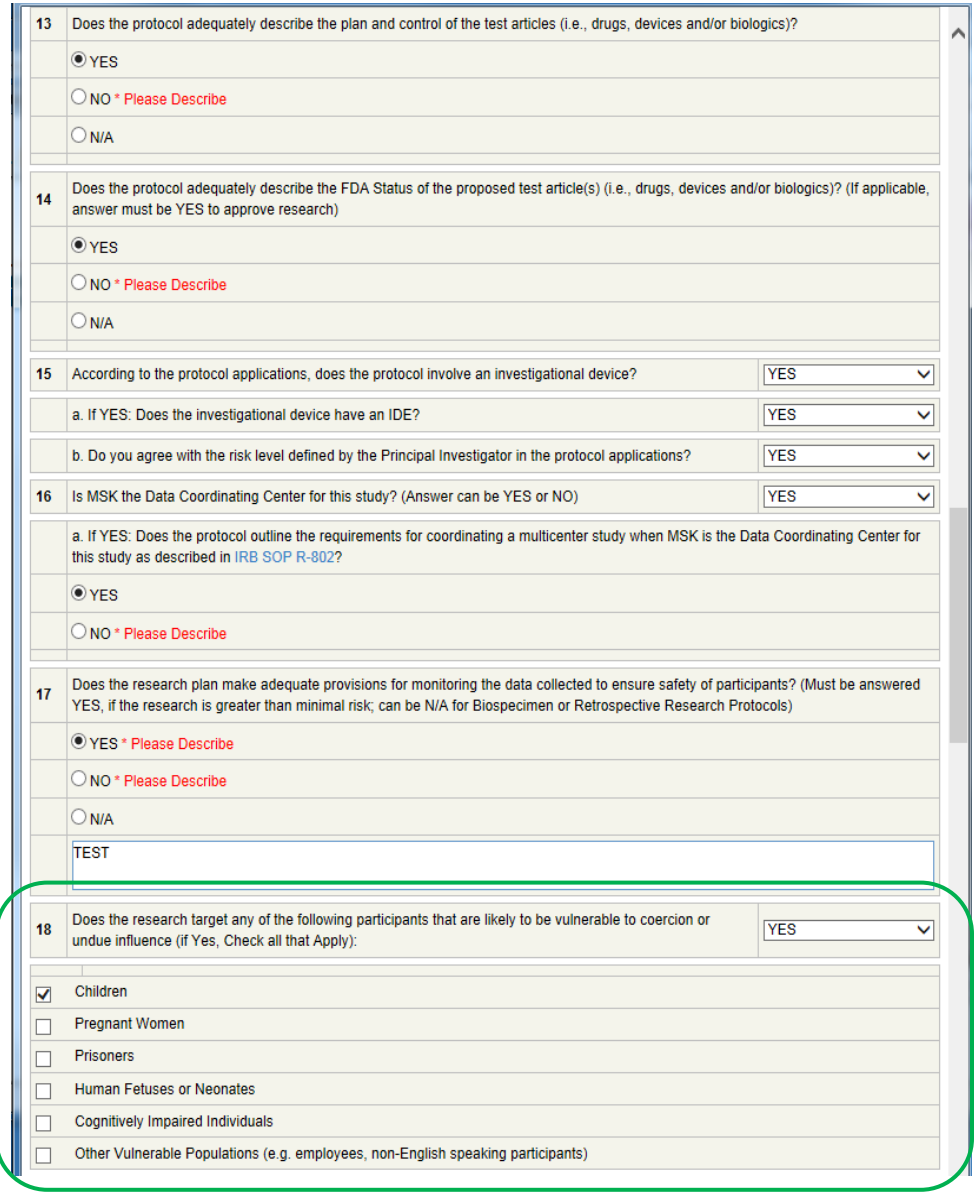
12 Are the risks to participants minimized by using tests/evaluations/procedures that are consistent with sound research design, may already be performed on the participant for diagnostic or treatment purposes, and do not pose any unnecessary risk? (Answer must be YES to approve research; can be N/A for Biospecimen or Retrospective Research Protocols)
- ◉ YES * Please Describe
- ○ NO * Please Describe
- ○ N/A

TEST

Reviewer Responsibilities: IRB Scope (checklist)

111 Criteria for Approval

Vulnerable Populations



13 Does the protocol adequately describe the plan and control of the test articles (i.e., drugs, devices and/or biologics)?
- (•) YES
- ( ) NO * Please Describe
- ( ) N/A

14 Does the protocol adequately describe the FDA Status of the proposed test article(s) (i.e., drugs, devices and/or biologics)? (If applicable, answer must be YES to approve research)
- (•) YES
- ( ) NO * Please Describe
- ( ) N/A

15 According to the protocol applications, does the protocol involve an investigational device? YES

a. If YES: Does the investigational device have an IDE? YES

b. Do you agree with the risk level defined by the Principal Investigator in the protocol applications? YES

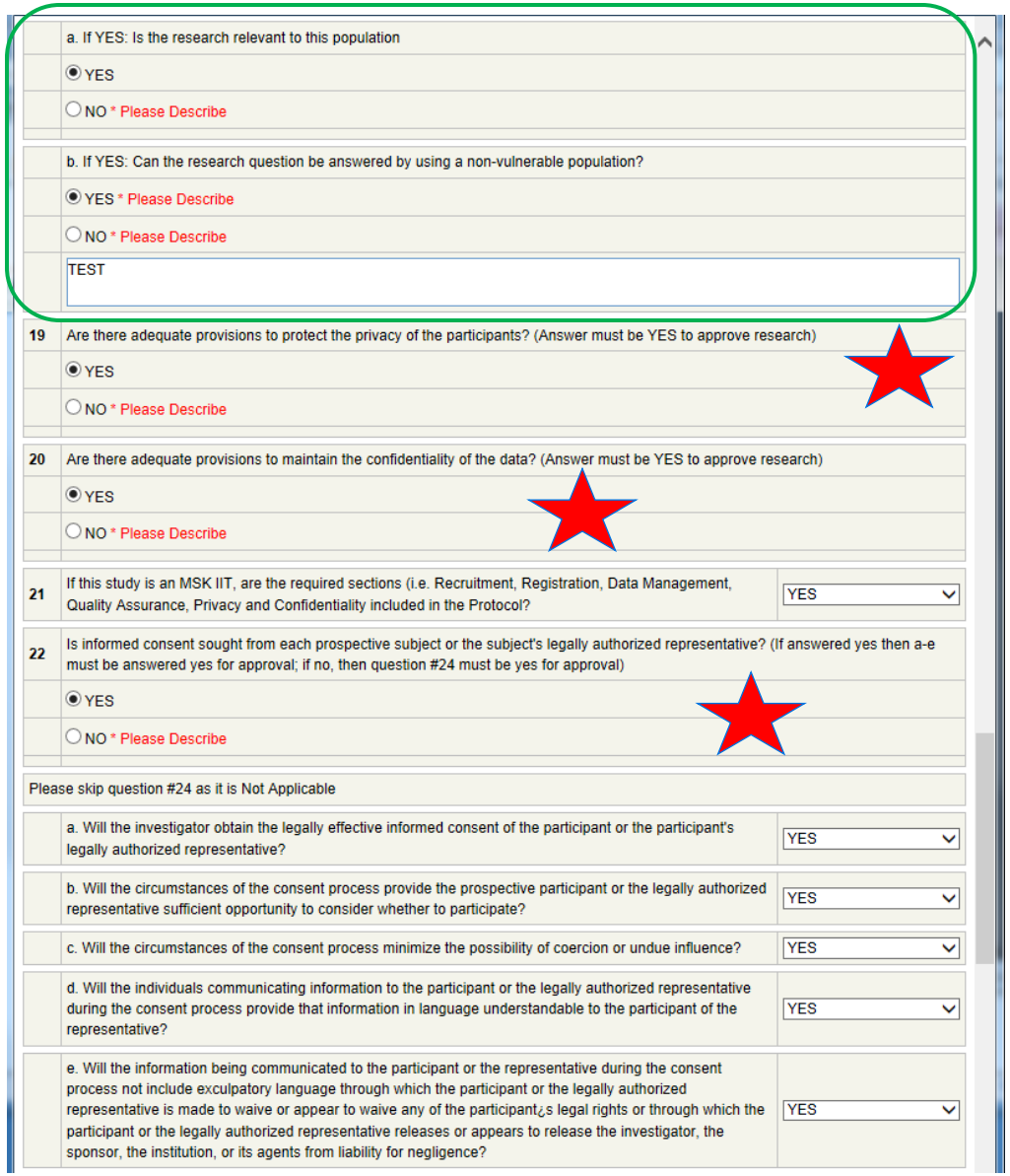
16 Is MSK the Data Coordinating Center for this study? (Answer can be YES or NO) YES

a. If YES: Does the protocol outline the requirements for coordinating a multicenter study when MSK is the Data Coordinating Center for this study as described in IRB SOP R-802?
- (•) YES
- ( ) NO * Please Describe

17 Does the research plan make adequate provisions for monitoring the data collected to ensure safety of participants? (Must be answered YES, if the research is greater than minimal risk; can be N/A for Biospecimen or Retrospective Research Protocols)
- (•) YES * Please Describe
- ( ) NO * Please Describe
- ( ) N/A

TEST

18 Does the research target any of the following participants that are likely to be vulnerable to coercion or undue influence (if Yes, Check all that Apply): YES
- [x] Children
- [ ] Pregnant Women
- [ ] Prisoners
- [ ] Human Fetuses or Neonates
- [ ] Cognitively Impaired Individuals
- [ ] Other Vulnerable Populations (e.g. employees, non-English speaking participants)



a. If YES: Is the research relevant to this population
- (•) YES
- ( ) NO * Please Describe

b. If YES: Can the research question be answered by using a non-vulnerable population?
- (•) YES * Please Describe
- ( ) NO * Please Describe

TEST

19 Are there adequate provisions to protect the privacy of the participants? (Answer must be YES to approve research)
- (•) YES
- ( ) NO * Please Describe

20 Are there adequate provisions to maintain the confidentiality of the data? (Answer must be YES to approve research)
- (•) YES
- ( ) NO * Please Describe

21 If this study is an MSK IIT, are the required sections (i.e. Recruitment, Registration, Data Management, Quality Assurance, Privacy and Confidentiality included in the Protocol? YES

22 Is informed consent sought from each prospective subject or the subject's legally authorized representative? (If answered yes then a-e must be answered yes for approval; if no, then question #24 must be yes for approval)
- (•) YES
- ( ) NO * Please Describe

Please skip question #24 as it is Not Applicable

a. Will the investigator obtain the legally effective informed consent of the participant or the participant's legally authorized representative? YES

b. Will the circumstances of the consent process provide the prospective participant or the legally authorized representative sufficient opportunity to consider whether to participate? YES

c. Will the circumstances of the consent process minimize the possibility of coercion or undue influence? YES

d. Will the individuals communicating information to the participant or the legally authorized representative during the consent process provide that information in language understandable to the participant of the representative? YES

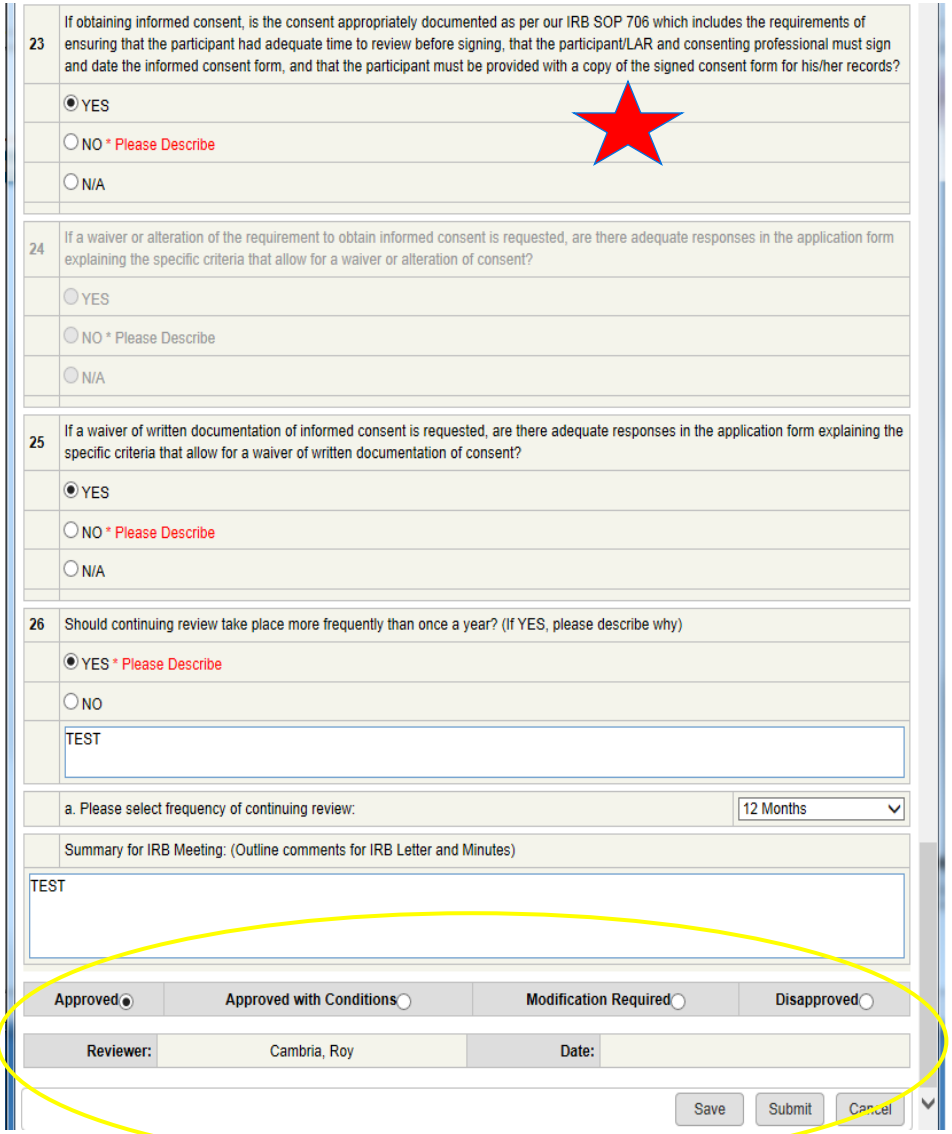
e. Will the information being communicated to the participant or the representative during the consent process not include exculpatory language through which the participant or the legally authorized representative is made to waive or appear to waive any of the participant¿s legal rights or through which the participant or the legally authorized representative releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence? YES

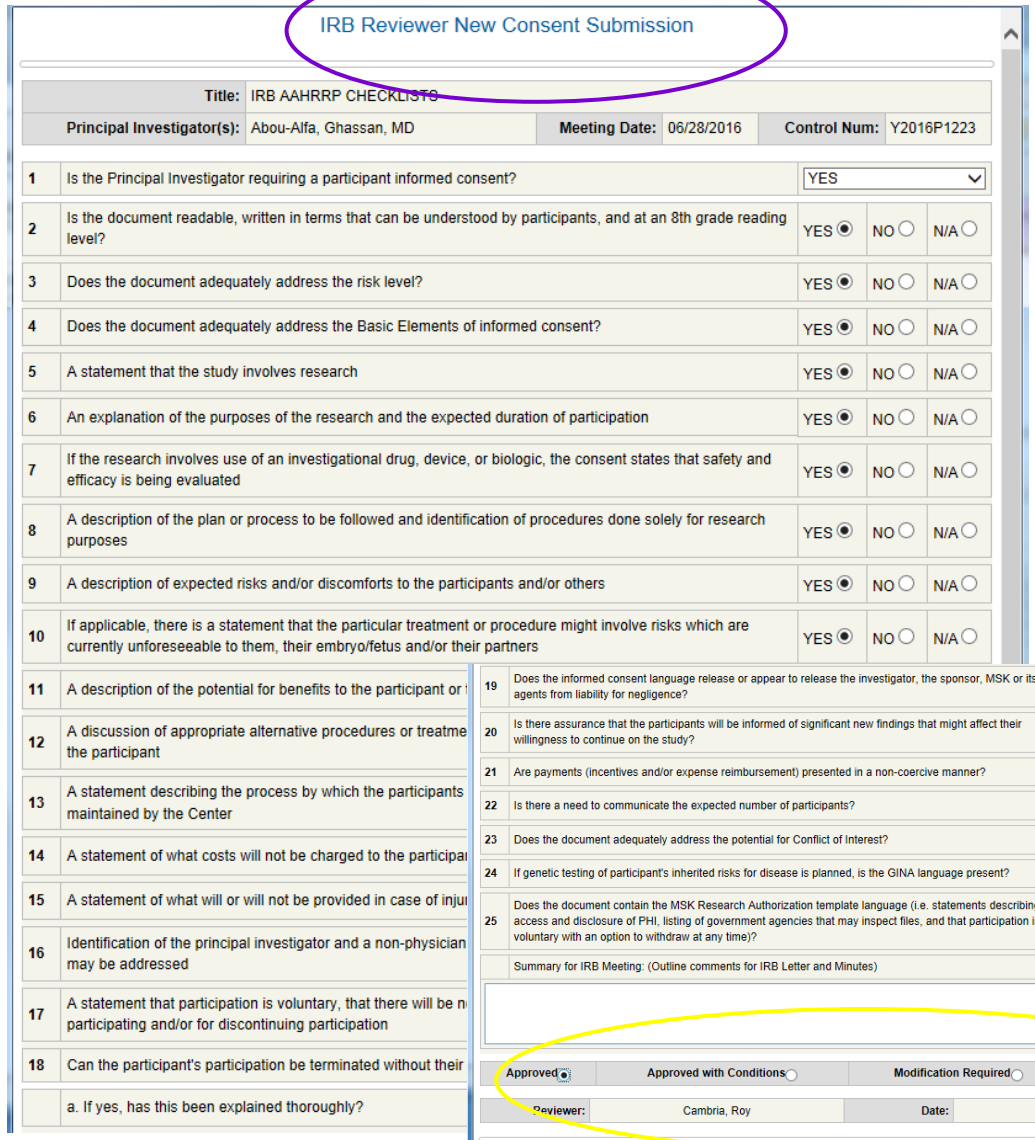
Reviewer Responsibilities: IRB Scope (checklist)

111 Criteria for Approval

Consent Checklist w/ required elements

IRB Determinations





IRB Meeting Guidance Document

Suggested Presentation Format for the Primary Reviewer

Presentation of brief protocol summary:

- Introduction *(2-4 sentences)*:
  - Type of study (phase/randomized/observational/psychosocial)
  - Background
  - Rationale (i.e. sufficient pre-clinical/clinical data)
- Investigational agent (if pertinent): *no more than 2 sentences about drug/device.*
- Experimental Design *(no more than 3-4 sentences):*
  - Objectives
  - Patient population
  - Pertinent eligibility
  - Treatment scheme
- Biostats: if relevant to safety/human subjects protection
- Consent process and comments (2-3 sentences)

Four Major 111 Topic Areas for Consideration After Presentations by the Reviewers:

Potential study design discussion topics

- Highlight areas of concern related to Criteria 1-3 of 45 CFR 46.111/21 CFR 56.111.
  - Criteria 1: Risks to subjects are minimized
  - Criteria 2: Risks to subjects are reasonable in relation to anticipated benefits
  - Criteria 3: Selection of subjects is equitable

Potential informed consent process and documentation

- Highlight areas of concern related to Criteria 4-5 of 45 CFR 46.111/21 CFR 56.111.
  - Criteria 4: Informed consent will be sought from each prospective subject
  - Criteria 5: Informed consent will be appropriately documented (or appropriately waived)

Potential data collection and data monitoring issues

- Highlight areas of concern related to Criteria 6 of 45 CFR 46.111/21 CFR 56.111.
  - Criteria 6: Adequate provisions for monitoring the data collected to ensure the safety of subjects

Potential privacy protections and data confidentiality issues

- Highlight areas of concern related to Criteria 7 of 45 CFR 46.111/21 CFR 56.111.
  - Criteria 7: Adequate provisions to protect the privacy of subjects and maintain the confidentiality of data

Reviewer Responsibilities: Presenting at Meeting

Reviewer	RC	IRB/PB
Primary	• Brief summary of study (no more than 2-4 minutes) • Comments/questions documented in reviewer checklist • Recommended Determination	• Brief summary of study with focus on objectives and 111 criteria (no more than 2-4 minutes) • Comments/questions for both protocol and consent documented in checklist • Recommended Determination, risk level, and frequency of continuing review
Secondary	• Comments/ concerns/ questions documented in reviewer checklist • Recommended Determination	• Note anything pertinent primary may have left out • Comments/ concerns/ questions for both protocol and consent documented in checklist • Recommended Determination, risk level, and frequency of continuing review
Tertiary	Statistician (external only): • Comments/questions regarding study design / statistical analysis documented in reviewer checklist • Recommended Determination	CRA: • Note anything pertinent primary may have left out • Comments/ concerns/ questions for both protocol and consent documented in checklist • Recommended Determination, risk level, and frequency of continuing review

Reviewer Responsibilities: Determination Definitions

Research Council (RC)	Institutional Review Board (IRB)	Definition	Criteria
Approve/ Approve with comments	Approve	Protocol can move forward in the review & activation process	No comments/minor/brief comments can be included at RC
Interim Approve	Approve with Conditions	Response is required and will be reviewed outside of a meeting	RC: Questions to PI regarding feasibility, prioritization, clarification of study design IRB: stipulations, no open-ended questions and 111 criteria must be met
Defer	Modifications Required	Response is required and will be reviewed at full committee meeting	RC: Significant design and/or feasibility issues identified IRB: Does not meet 111; open-ended?
Reject	Disapproved	Protocol cannot move forward in the review & activation process	Significant design, feasibility, safety issues that cannot be changed

What to Expect: Plan for your upcoming observations and reviews

What to Expect

Observership Session: Observe 1 RC & 1 IRB meeting

Assigned Review Session: Attend 1 RC & 1 IRB meeting

- Assigned protocol to review
- Paired with CRA administrator/manager – we will meet prior to your review
- Complete Reviewer Checklist
  - Present summary of protocol
  - Identify strengths and weaknesses

RC & IRB are closed meetings. Please keep discussions confidential.

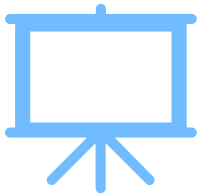
Reviewer Best Practices/Reminders

Your Review

Set aside enough time for the review (2-3 hours - MANY documents)

Review all documents, including previous committee letters and responses

Email your comments the day before the meeting



Presentation

2-4 minutes max

Questions

If you have questions – please ask!

Additional Committee Information

Contacts:
RC: Krista Napolitano
IRB: Carly Clemons

Research Council (RC) Portal Page (includes RC SOPs)

Institutional Review Board/Privacy Board (IRB/PB) Portal Page

IRB/PB SOPs

Informed Consent Toolkit (includes consent template and instructions documents)

IRB Risk Category Definitions

Questions?