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IMPLEMENTATION OF KUALI CHECKLISTS

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Outline

- Why are we implementing checklists?
  - IRB Member interest
  - Enhanced Documentation
  - SOP changes
- How will checklists work in the Kuali system?
- Questions

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Why are we implementing checklists?

- IRB Member interest
  - Many members from various committees have expressed a desire to have checklists again
- Enhanced Documentation
  - The checklists allow for more documentation of decision-making by the IRB
- SOP changes
  - The new system of SOPs OIA is using relies on checklists for documentation of certain determinations
    - Children, prisoners, pregnant subjects, cognitively impaired subjects, NSR vs. SR device, etc.

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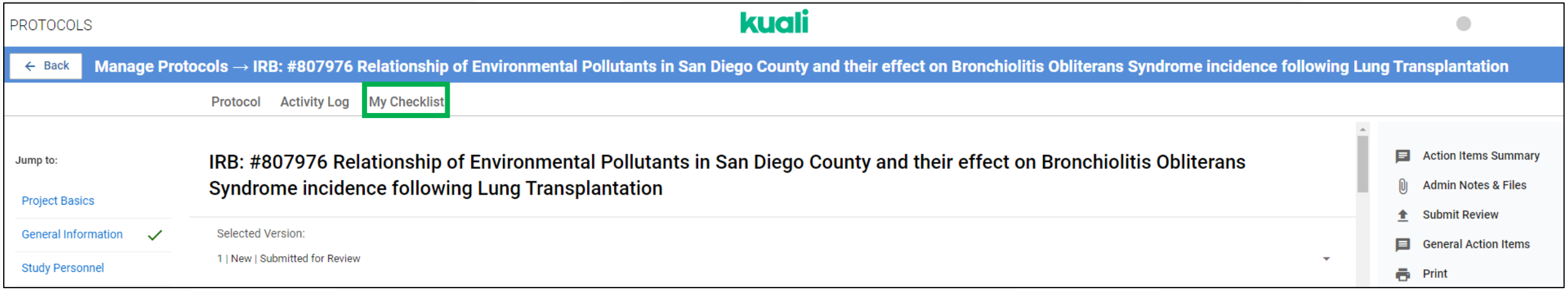
How will checklists work in the Kuali system?

- When an IRB member is assigned to review, they will get a new tab called “My Checklist” across the top of the page.



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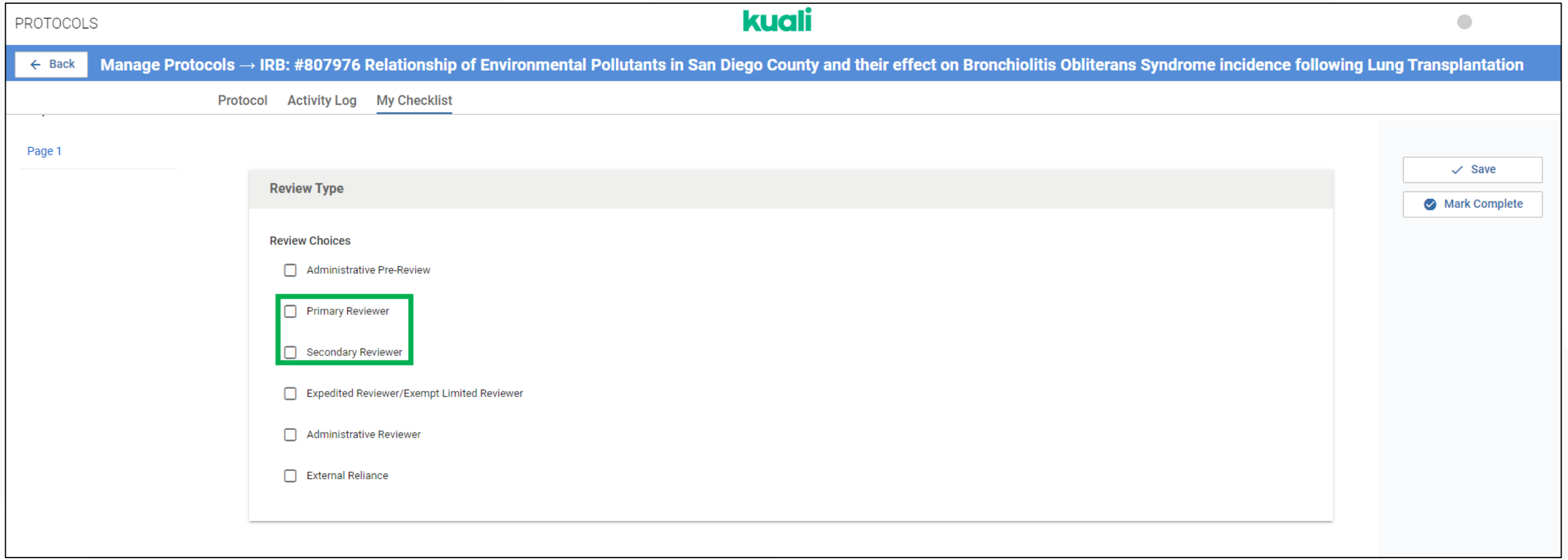
How will checklists work in the Kuali system?

- Clicking the “My Checklist” tab will open the checklist.
- Based on your assignment, select either Primary or Secondary Reviewer.
  - Assignments can be found in the General Action Item left by your committee analyst.



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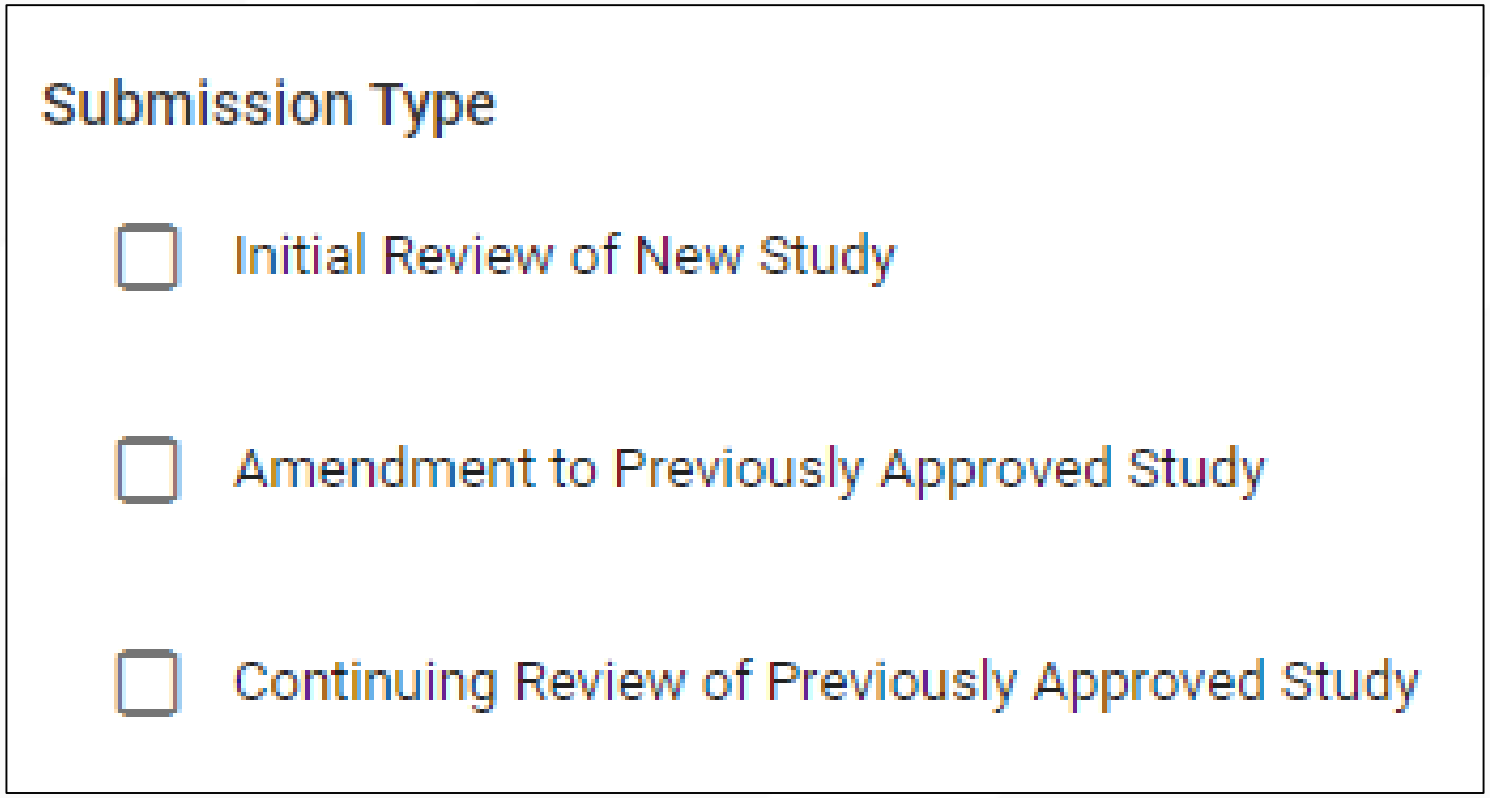
How will checklists work in the Kuali system?

- Checking either the “Primary Reviewer” or “Secondary Reviewer” box will result in another question about the submission type.
- Answer based on the type of submission you’re reviewing.



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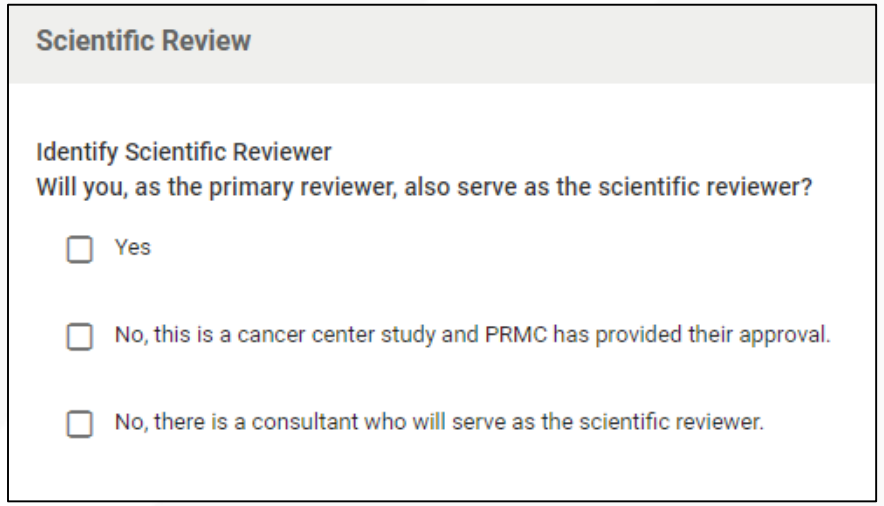
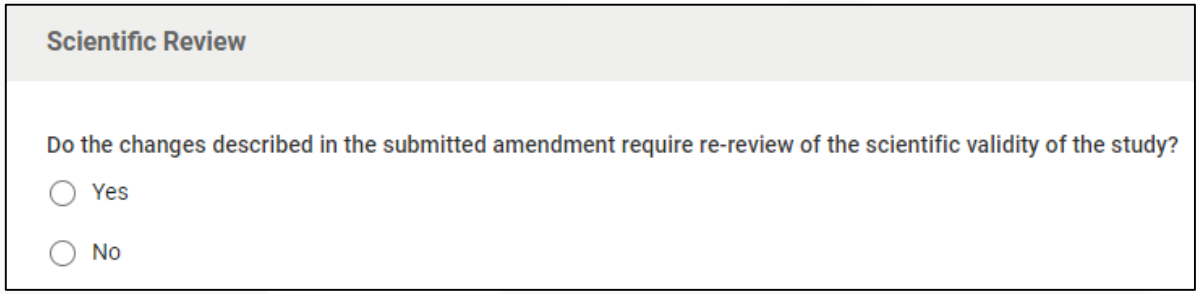
How will checklists work in the Kuali system?

- Primary reviewers will be asked questions about whether Scientific Review is necessary depending on whether this is an initial or amendment submission.

Initial Review



Amendment Review



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How will checklists work in the Kuali system?

- Answering “Yes” that you will serve as the scientific reviewer will open the five Scientific Review questions.

Does the protocol accurately describe the research in a clear, detailed protocol in terms of:

- Objectives
- Background
- Setting
- Procedures
- Data and safety monitoring plan (as applicable)
- Risks
- Potential benefits
- Alternatives to participation

◯ Yes

◯ No

Does the study propose the least risky procedures to answer the hypothesis?

◯ Yes

◯ No

Does the study include sufficient procedures to assess subject safety (e.g. lab tests, imaging, clinical/psychological questionnaires, etc.)?

◯ Yes

◯ No

If carried out as proposed, is the study likely to provide an answer to its overall hypothesis thus providing benefit to at least society if not the subjects?

◯ Yes

◯ No

Are the stated benefits, whether to society or individual subjects, realistic?

◯ Yes

◯ No

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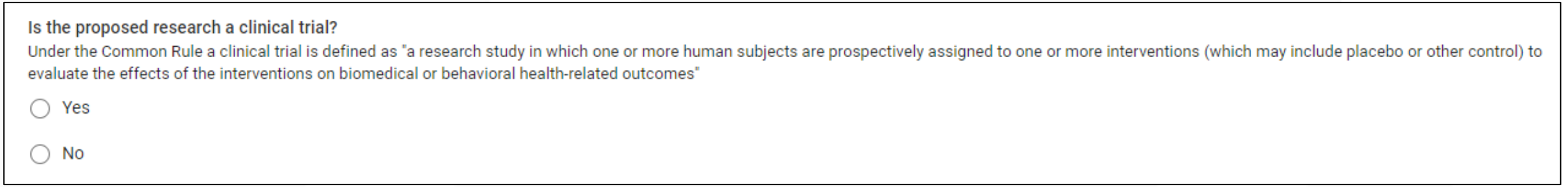
How will checklists work in the Kuali system?

- If completing the Scientific Review questions, reviewers will also be asked if the study is a clinical trial.



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How will checklists work in the Kuali system?

- Answering that the study is a clinical trial will open the three additional Clinical Trial questions.

Is there sufficient information regarding the investigational product to determine whether the risk/benefit ratio is appropriate to justify the study?

NOTE: In Phase 1 (First in Human) studies, this may be limited to pre-clinical data.

- ◯ Yes
- ◯ No
- ◯ N/A - Behavioral Intervention Only

Has the investigator demonstrated (e.g. based on retrospective data) a potential for recruiting the required number of suitable subjects within the agreed recruitment period?

- ◯ Yes
- ◯ No

Is there adequate expertise from the study personnel to safely conduct the study (e.g. a study of medical device or treatment includes a physician with expertise in condition of study)?

- ◯ Yes
- ◯ No
- ◯ N/A - No medical decision-making required

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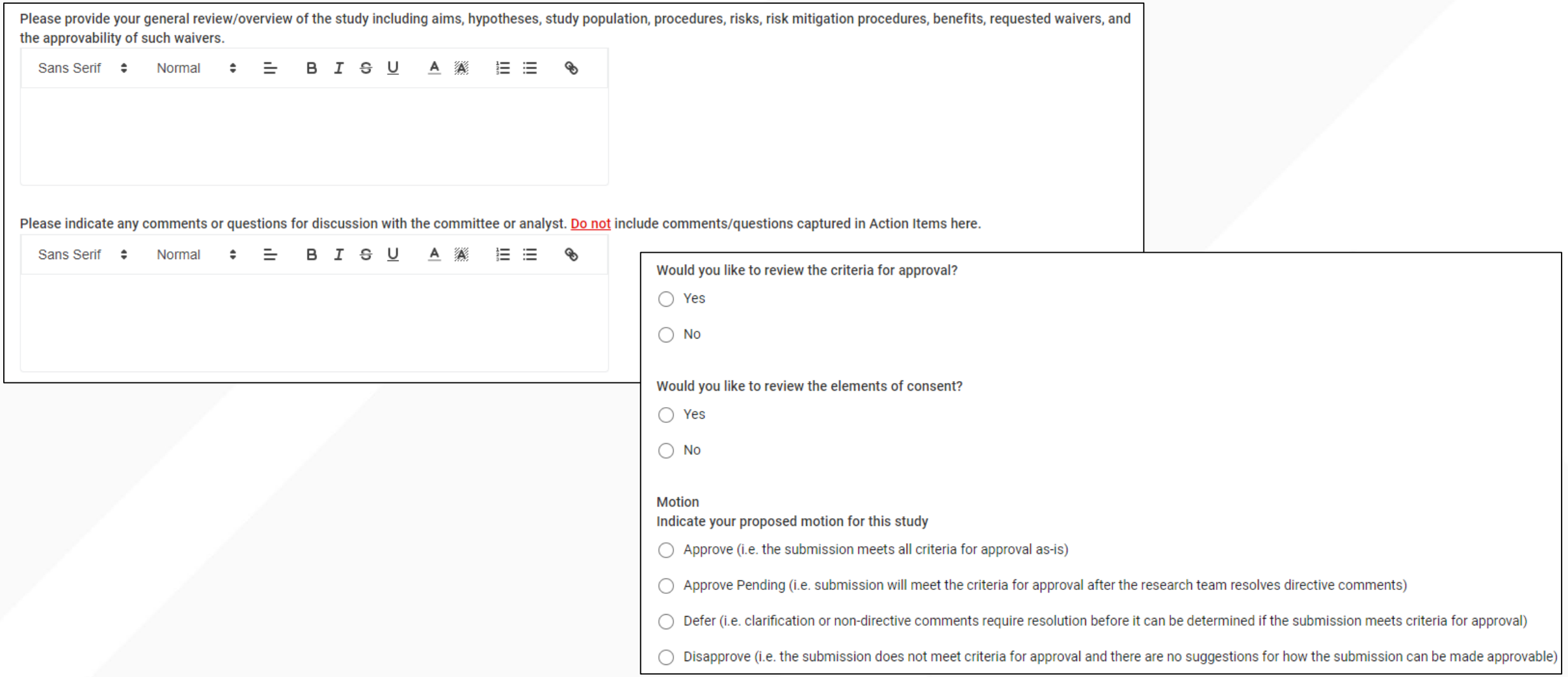
How will checklists work in the Kuali system?

- All reviewers will then have a “Committee Reviewer” section



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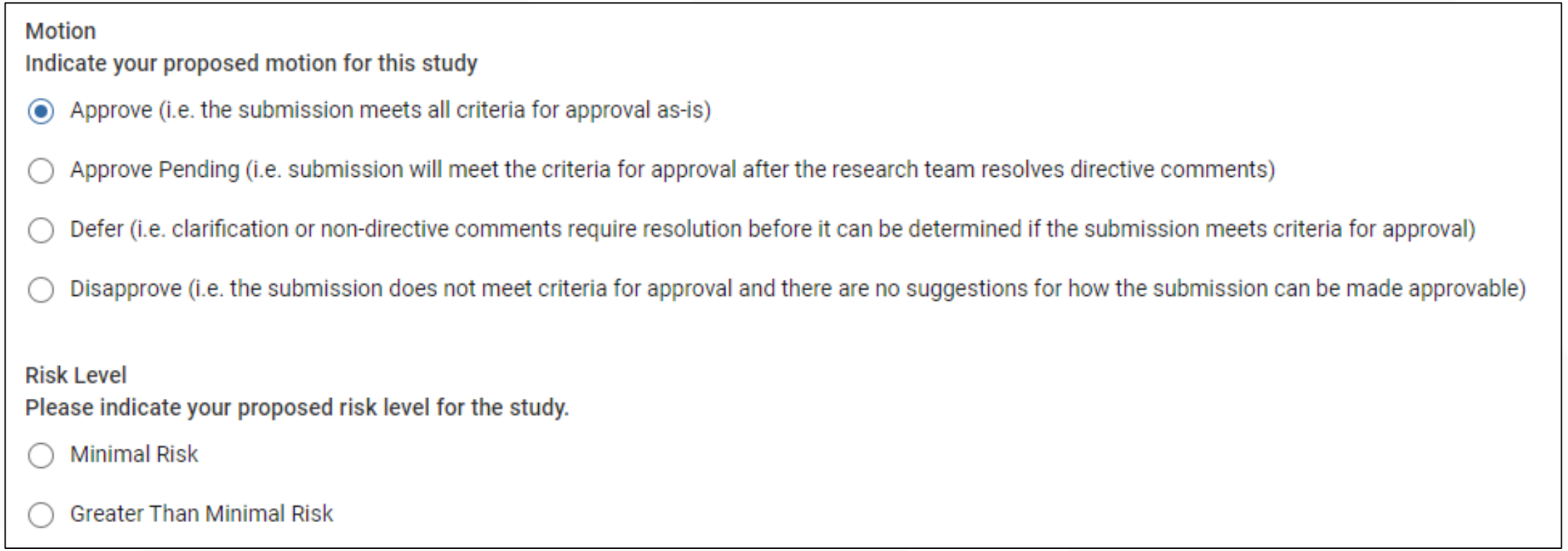
How will checklists work in the Kuali system?

- Reviewers who indicate a motion of “Approve” or “Approve Pending” will be prompted to provide a risk level for the study.



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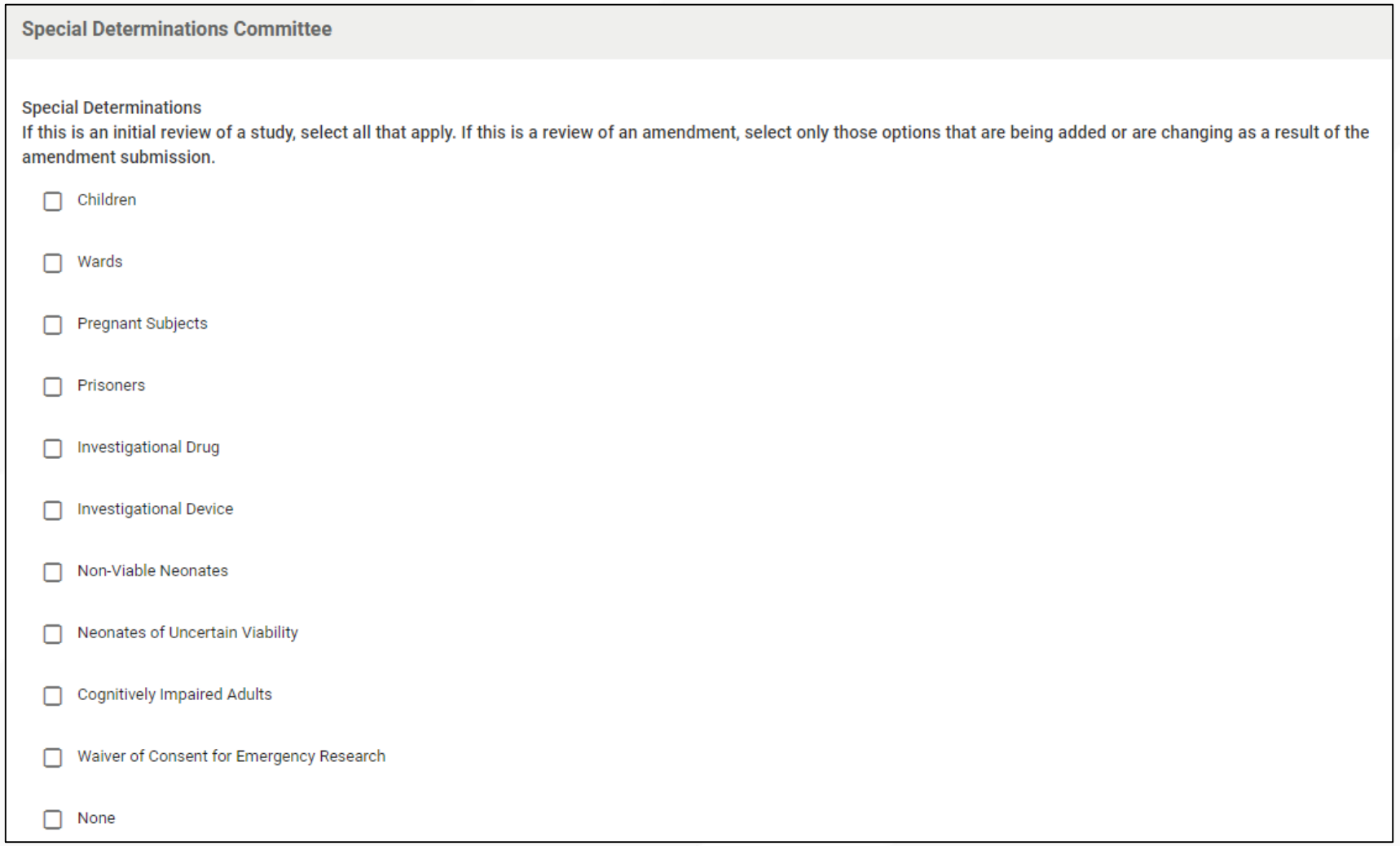
How will checklists work in the Kuali system?

- All reviewers will then have a “Special Determinations” section



Special Determinations Committee

Special Determinations
If this is an initial review of a study, select all that apply. If this is a review of an amendment, select only those options that are being added or are changing as a result of the amendment submission.

- [ ] Children
- [ ] Wards
- [ ] Pregnant Subjects
- [ ] Prisoners
- [ ] Investigational Drug
- [ ] Investigational Device
- [ ] Non-Viable Neonates
- [ ] Neonates of Uncertain Viability
- [ ] Cognitively Impaired Adults
- [ ] Waiver of Consent for Emergency Research
- [ ] None

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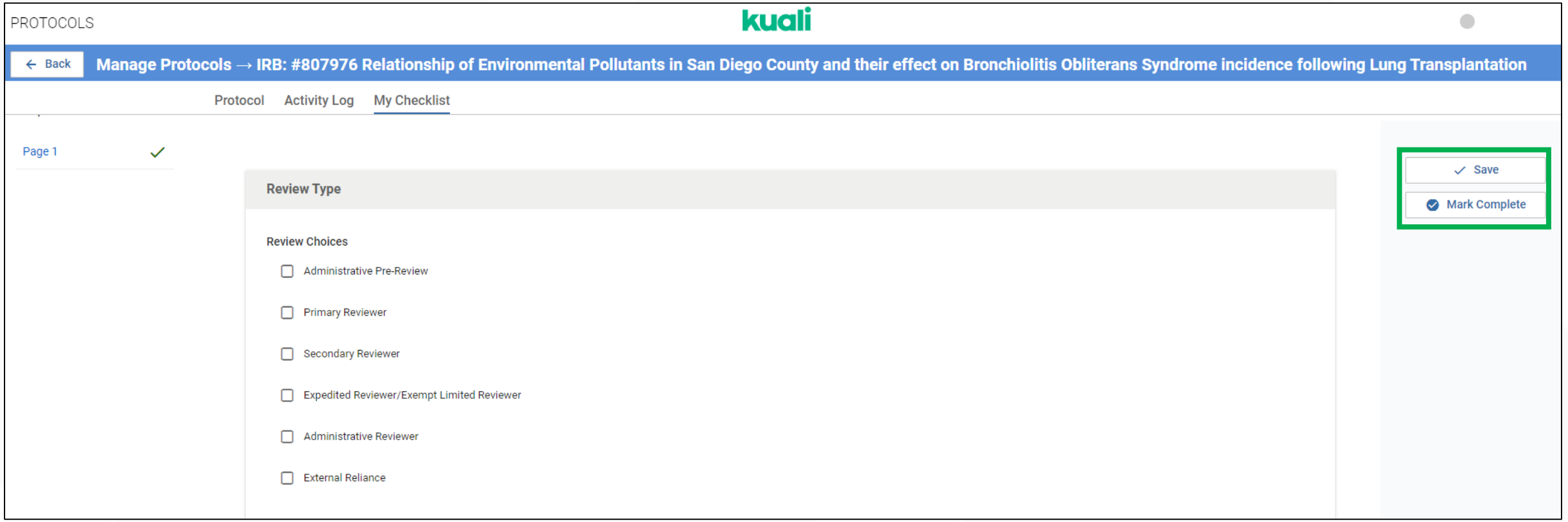
How will checklists work in the Kuali system?

- As you complete sections of the checklist, be sure to click “Save” periodically to save your work.
- Do not click “Mark Complete” until you’ve completed your checklist and the motion at the meeting is “Approve” or “Approve Pending”



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QUESTIONS?