

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 Quali system?
- Questions

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.

How will checklists work in the Kualo system?

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

The screenshot displays the Kualo system interface. At the top left, the word "PROTOCOLS" is visible. The Kualo logo is centered at the top. A blue navigation bar contains a "Back" button and the text "Manage Protocols → IRB: #807976 Relationship of Environmental Pollutants in San Diego County and their effect on Bronchiolitis Obliterans Syndrome incidence following Lung Transplantation". Below this, a tabbed interface shows "Protocol", "Activity Log", and "My Checklist" (which is highlighted with a green border). On the left, a "Jump to:" section lists "Project Basics", "General Information" (with a green checkmark), and "Study Personnel". The main content area shows the IRB title and "Selected Version: 1 | New | Submitted for Review". On the right, a vertical menu includes "Action Items Summary", "Admin Notes & Files", "Submit Review", "General Action Items", and "Print".

How will checklists work in the Kualo 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.

The screenshot displays the Kualo system interface. At the top, the 'PROTOCOLS' header is visible on the left, and the 'kualo' logo is centered. A blue navigation bar contains a 'Back' button and the protocol title: 'Manage Protocols → IRB: #807976 Relationship of Environmental Pollutants in San Diego County and their effect on Bronchiolitis Obliterans Syndrome incidence following Lung Transplantation'. Below this, a tabbed interface shows 'Protocol', 'Activity Log', and 'My Checklist' (which is active). The main content area shows 'Page 1' and a 'Review Type' section. Under 'Review Choices', several options are listed with checkboxes: 'Administrative Pre-Review', 'Primary Reviewer' (highlighted with a green box), 'Secondary Reviewer', 'Expedited Reviewer/Exempt Limited Reviewer', 'Administrative Reviewer', and 'External Reliance'. On the right side, there are two buttons: 'Save' and 'Mark Complete'.

How will checklists work in the Kualu 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.

Submission Type

- Initial Review of New Study
- Amendment to Previously Approved Study
- Continuing Review of Previously Approved Study

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

Scientific Review

Identify Scientific Reviewer
Will you, as the primary reviewer, also serve as the scientific reviewer?

Yes

No, this is a cancer center study and PRMC has provided their approval.

No, there is a consultant who will serve as the scientific reviewer.

Amendment Review

Scientific Review

Do the changes described in the submitted amendment require re-review of the scientific validity of the study?

Yes

No

How will checklists work in the Kualu 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

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.

Is the proposed research a clinical trial?

Under the Common Rule a clinical trial is defined as "a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes"

Yes

No

How will checklists work in the Kualu 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

How will checklists work in the Kuali system?

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

Please provide your general review/overview of the study including aims, hypotheses, study population, procedures, risks, risk mitigation procedures, benefits, requested waivers, and the approvability of such waivers.

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Please indicate any comments or questions for discussion with the committee or analyst. **Do not** include comments/questions captured in Action Items here.

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Would you like to review the criteria for approval?

- Yes
- No

Would you like to review the elements of consent?

- Yes
- No

Motion

Indicate your proposed motion for this study

- Approve (i.e. the submission meets all criteria for approval as-is)
- Approve Pending (i.e. submission will meet the criteria for approval after the research team resolves directive comments)
- Defer (i.e. clarification or non-directive comments require resolution before it can be determined if the submission meets criteria for approval)
- Disapprove (i.e. the submission does not meet criteria for approval and there are no suggestions for how the submission can be made approvable)

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.

Motion

Indicate your proposed motion for this study

- Approve (i.e. the submission meets all criteria for approval as-is)
- Approve Pending (i.e. submission will meet the criteria for approval after the research team resolves directive comments)
- Defer (i.e. clarification or non-directive comments require resolution before it can be determined if the submission meets criteria for approval)
- Disapprove (i.e. the submission does not meet criteria for approval and there are no suggestions for how the submission can be made approvable)

Risk Level

Please indicate your proposed risk level for the study.

- Minimal Risk
- Greater Than Minimal Risk

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

How will checklists work in the Kualu 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”

PROTOCOLS kuali

← Back Manage Protocols → IRB: #807976 Relationship of Environmental Pollutants in San Diego County and their effect on Bronchiolitis Obliterans Syndrome incidence following Lung Transplantation

Protocol Activity Log My Checklist

Page 1 ✓

Review Type

Review Choices

- Administrative Pre-Review
- Primary Reviewer
- Secondary Reviewer
- Expedited Reviewer/Exempt Limited Reviewer
- Administrative Reviewer
- External Reliance

✓ Save

🔍 Mark Complete

QUESTIONS?