

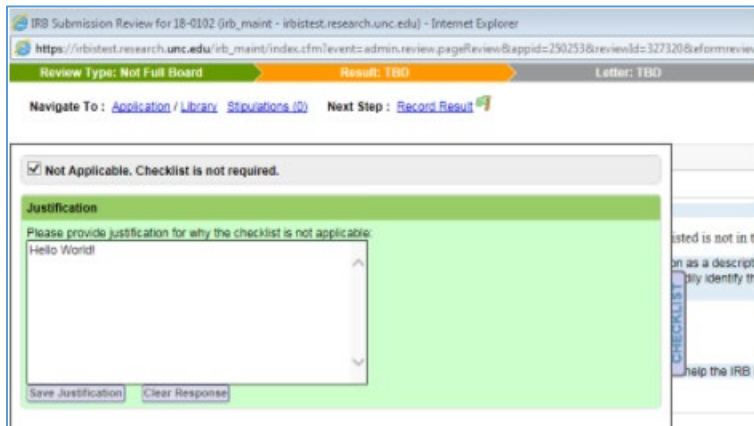
IRBIS changes, effective 9:30 AM, March 13, 2018

IRBIS 5.09.06.02 Update:

The Expedited Checklist will apply to all applications designated as Not Full Board. It will be accessible from the left hand menu of the Application review window, just below the Item List.

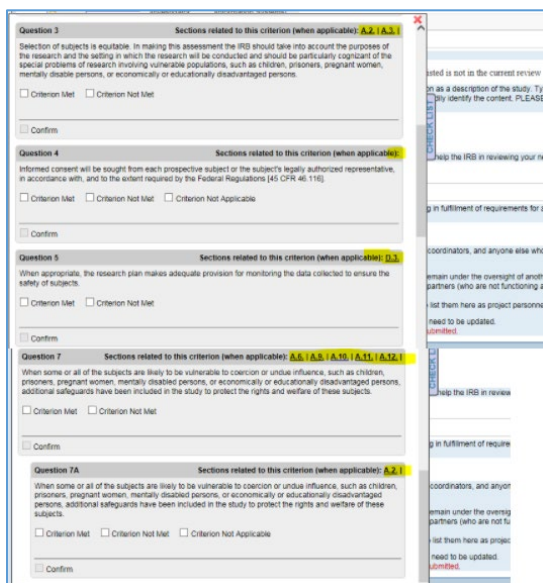
NHSRs, HUDs, Exempts, Rely Ons, Closures, and Full Board submissions do not have access to the Checklist tab on the Applications screen.

During the transition from the old checklist to the new, some studies may want to bypass this requirement. A Justification text area has been added for when the N/A option is checked.

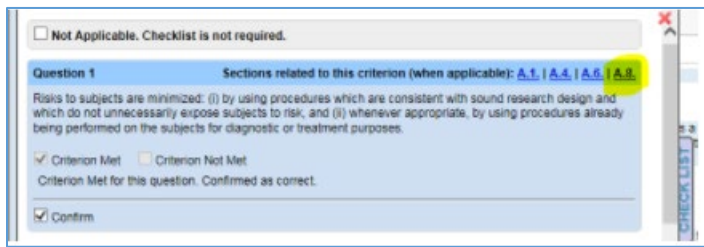


This should only be used if the old checklist has been filed out, or if the study is not subject to the policy.

From within the Checklist, hyperlinks to the relevant section(s) will now take the user to that area within the application and will close the checklist once IRBIS has navigated to the section selected. To return to the checklist, click the tab to reopen.



We do not show specific sections related to the criteria if the section listed is not in the current review. Each criterion must be noted as Met, Not Met, or not applicable (n/a only available for certain criteria)



Not Applicable. Checklist is not required.

Question 1 Sections related to this criterion (when applicable): [A.1](#) | [A.4](#) | [A.6](#) | [A.8](#)

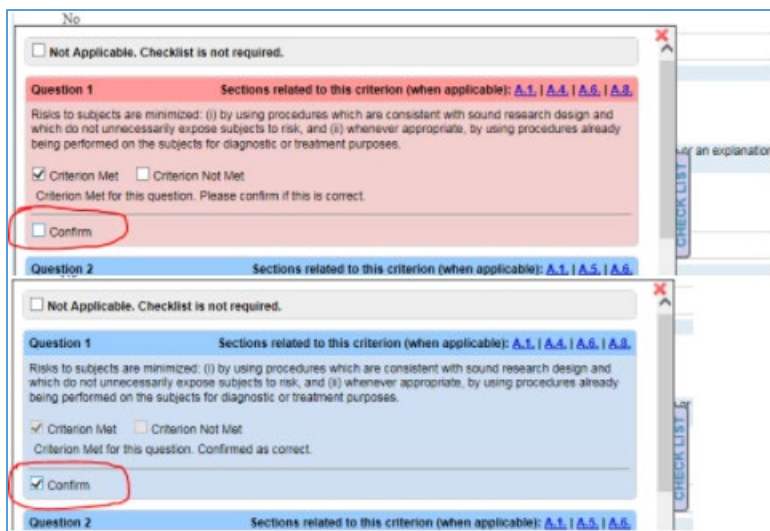
Risks to subjects are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

Criterion Met Criterion Not Met

Criterion Met for this question. Confirmed as correct.

Confirm

A checklist confirmation has been implemented. It's very similar to the PI Response confirmations. You select criterion met/criterion not met and a confirm is required before the submission can be finalized. Just as responses to stipulations, the person (Analyst or Chair) who is finalizing the review is the one who should confirm the checklist is correct.



No

Not Applicable. Checklist is not required.

Question 1 Sections related to this criterion (when applicable): [A.1](#) | [A.4](#) | [A.6](#) | [A.8](#)

Risks to subjects are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

Criterion Met Criterion Not Met

Criterion Met for this question. Please confirm if this is correct.

Confirm

Question 2 Sections related to this criterion (when applicable): [A.1](#) | [A.5](#) | [A.6](#)

Not Applicable. Checklist is not required.

Question 1 Sections related to this criterion (when applicable): [A.1](#) | [A.4](#) | [A.6](#) | [A.8](#)

Risks to subjects are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

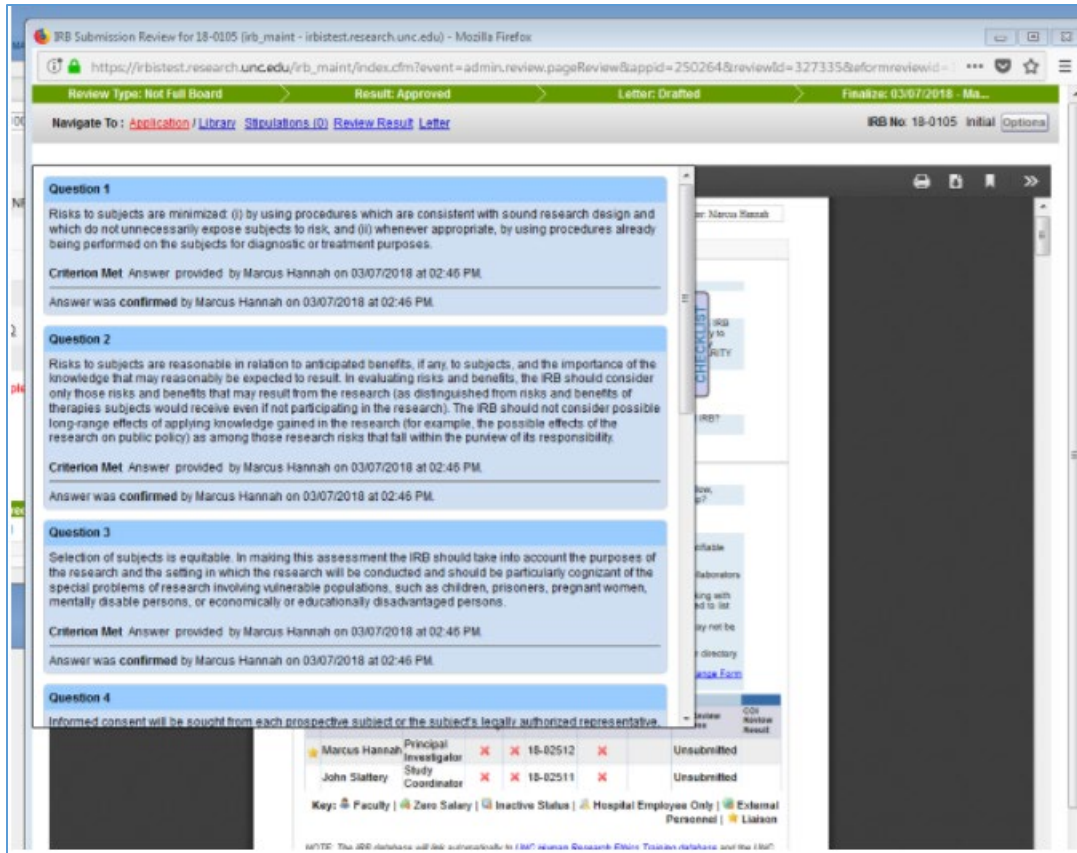
Criterion Met Criterion Not Met

Criterion Met for this question. Confirmed as correct.

Confirm

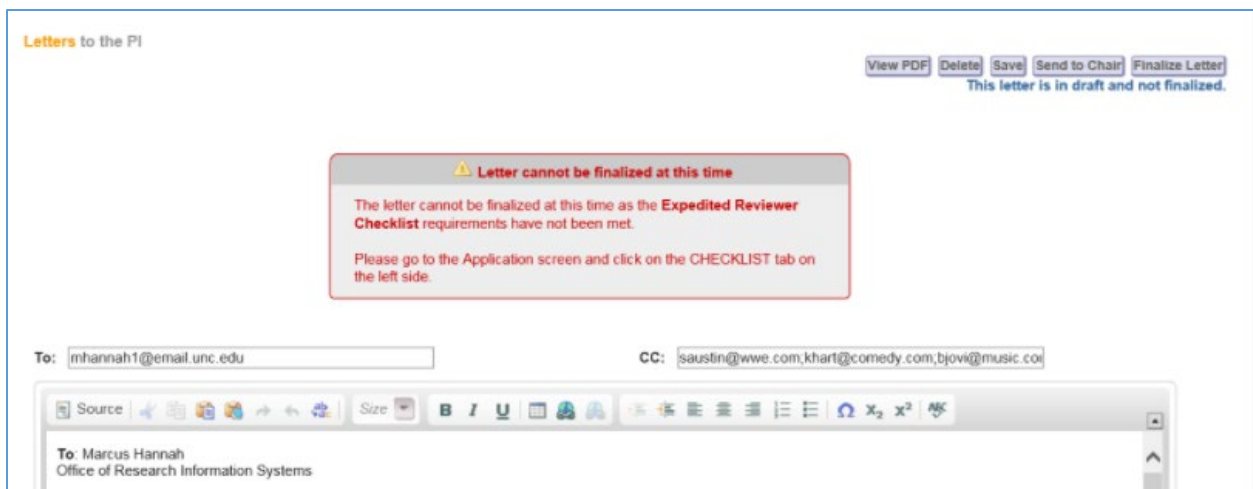
Question 2 Sections related to this criterion (when applicable): [A.1](#) | [A.5](#) | [A.6](#)

At the bottom of the checklist there is a Confirm All option.



All criteria must be noted as Met, Not Met, or N/A and confirmed in order to proceed with finalizing a letter. Each new review (i.e. swim lane) will carry over the selections made in the checklist during the previous review, but may be changed as needed.

The new hard stop will be displayed in the event any criteria have not had a selection confirmed which will keep you from finalizing the letter:



Once a submission is approved, a PDF is created and stored automatically in OHRE attachments that is a read only display of the Checklist for each review. This is useful when reviewing timestamps for auditing purposes.

View OHRE Attachments
✕

Document Management for IRB NO: 18-0036

Attachment Type: Select Attachment Type

Click Browse to select a file: Browse... No file selected.

Upload

OHRE Attachments: These are OHRE Only Attachments View All Attachments

File Name	Document Type	Submission	Date	
18-0036_Initial_REF_169141.pdf <small>Uploaded by Marcus Hannah on 03/08/2018</small>	Reviewer Checklist	Initial	03/08/2018	Delete

View 1 - 1 of 1 Page 1 of 1

IRB Reviewer Checklist Initial Application

IRB #: 18-0036 Review Result: Approved

PI Name: Marcus Hannah Date Completed: 03/08/2018

Question 1

Risks to subjects are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

Criterion Met Answer provided by Marcus Hannah on 03/08/2018 at 12:13 PM.

Answer was **confirmed** by John Slattery on 03/08/2018 at 12:39 PM.

Question 2

Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

Criterion Met Answer provided by John Slattery on 03/08/2018 at 12:39 PM.

Answer was **confirmed** by John Slattery on 03/08/2018 at 12:39 PM.

Question 3