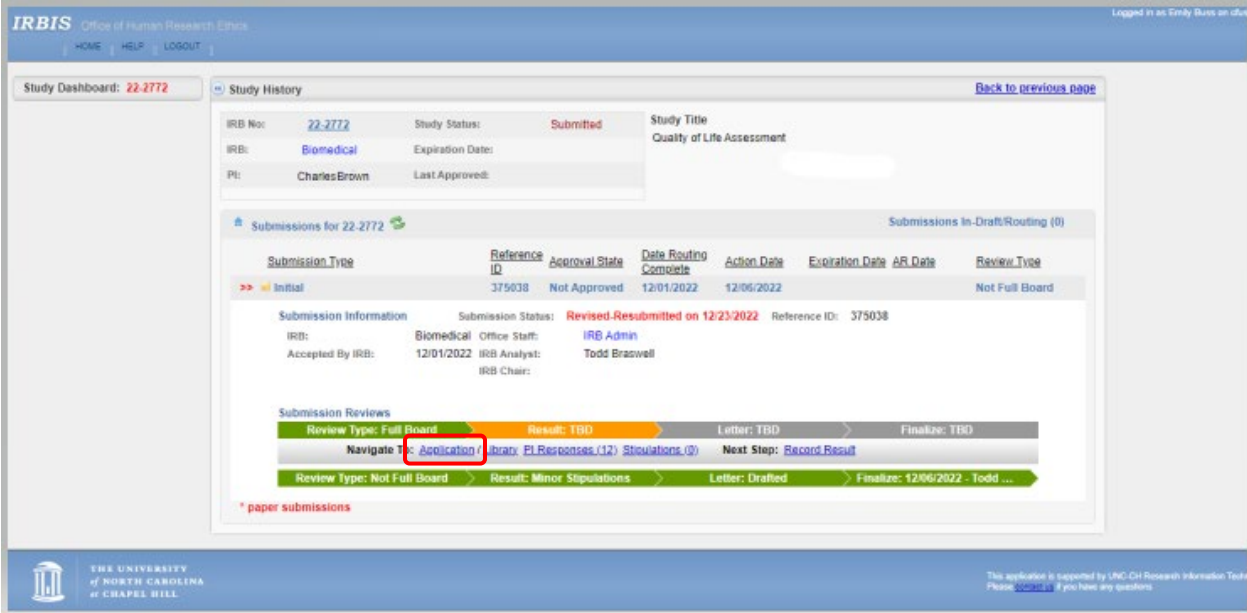


# IRBIS changes, effective August 29, 2023

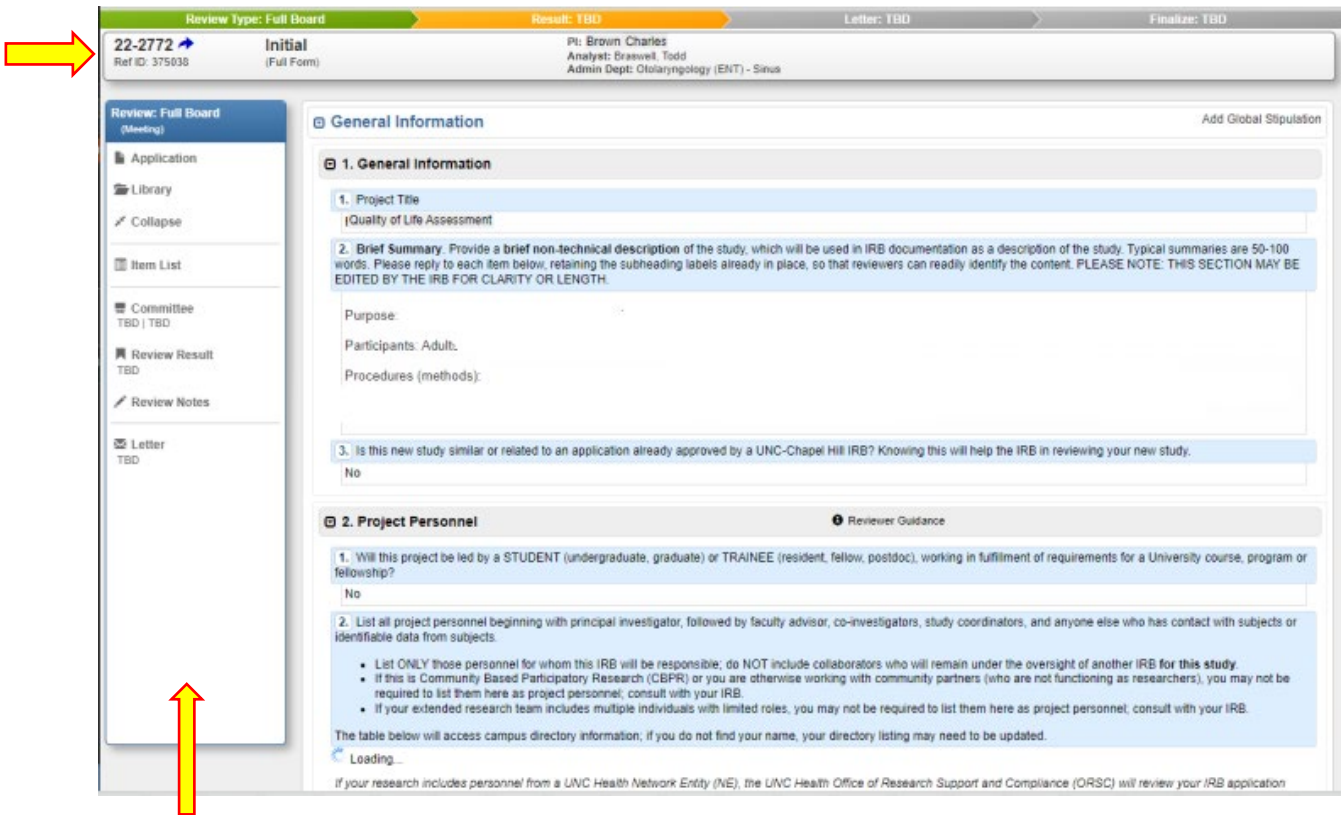
Summary of Changes	
Screen Menu .....	2
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Library .....	3
Collapse / Expand.....	3
Checklist .....	5
PI Responses .....	6
Item List .....	6
Committee .....	7
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A new application pop-up screen will be turned on Tuesday evening, August 29, 2023. With the improved program languages now available, the screen will have quicker response, additional functionality and provide for more automated functions in the future.

The Study History screen will remain unchanged. Accessing the application remains the same as well.



The screen display will continue to show the swim lane at the top of the window. Additional submission information is included in the block below.



The left hand menu provides faster navigation between the various screens and incorporates the Options links.

---

## Screen Menu

**Application**: Displays the full, expanded application.

**Library**: Scrolls down to the document library.

**Collapse/Expand**: Just as it says! It collapses or expands the application sections.

**Item List**: A list of all sections and sub-sections of the application.

**Committee**:

**Checklist**: The 111 checklist.

**Review Result**: Selection of your review determination.

**Review Notes**: Study Findings, Submission Findings, link to the Meeting Notes.

**Letter**: Select letter template and draft the review letter.

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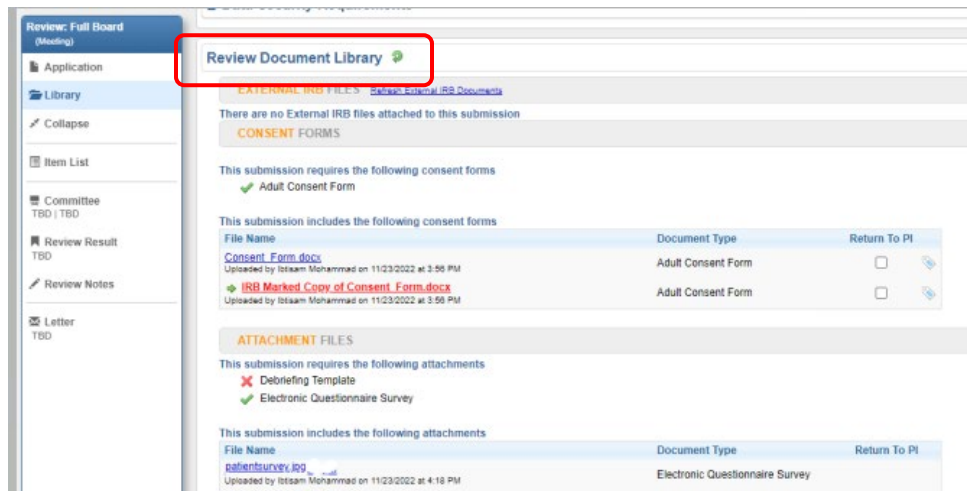
## Application

The application opens with all sections and subsections displayed.

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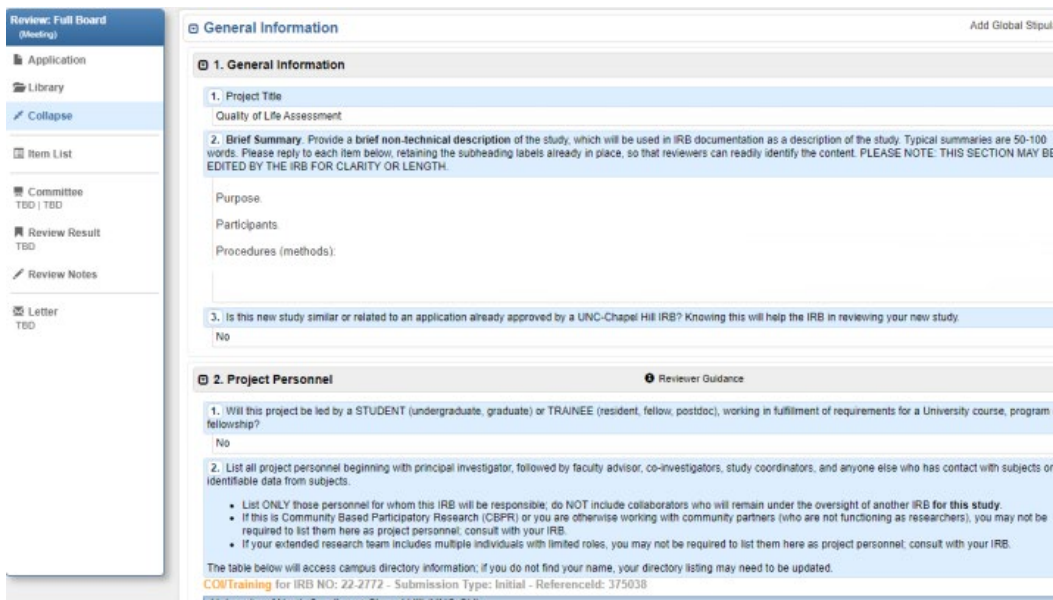
# Library

The Library link has the same function as the existing Library hyperlink at the top of the screen:



# Collapse / Expand

The Collapse function will collapse the application so that you only see the sections and sub-sections of the application.



Click #1:

Review: Not Full Board  
(Expedited, Exempt, N-HSR, other)

Review Conditions: ●  
Next Step: Record Result

Application  
Library  
Stipulations (1)  
Collapse Again

Item List  
Checklist  
Options  
Review Result  
TBD  
Review Notes  
Letter  
TBD

Post Approval Submissions Add Global Stipulation

General Information

1. General Information

2. Project Personnel Reviewer Guidance

3. Funding Sources Reviewer Guidance

4. Screening Questions

Location Reviewer Guidance

Scientific Review

Scientific Review

Part A. Questions Common to All Studies

A.1. Background and Rationale Reviewer Guidance

A.2. Subjects Reviewer Guidance

Click #2:

Review: Not Full Board  
(Expedited, Exempt, N-HSR, other)

Review Conditions: ●  
Next Step: Record Result

Application  
Library  
Stipulations (1)  
Expand All

Item List  
Checklist  
Options  
Review Result  
TBD  
Review Notes  
Letter

General Information

Scientific Review

Part A. Questions Common to All Studies

Part B. Direct Interaction

Part C. Existing Data, Records, Specimens

Part D. The Consent Process

Data Security Requirements

Review Document Library Refresh External IRB Documents

EXTERNAL IRB FILES Refresh External IRB Documents

There are no External IRB files attached to this submission

CONSENT FORMS Add Global Stipulation

This submission requires the following consent forms

- Adult Consent Form
- Text for the Online Consent Form

This submission includes the following consent forms

Expand all will expand the application fully to show all questions.

Application  
Library  
Stipulations (1)  
Expand All

Review: Full Board  
(Meeting)

Application  
Library  
Collapse

Item List  
Committee  
TED | TBD  
Review Result  
TBD  
Review Notes  
Letter  
TBD

General Information Add Global Stipulation

1. General Information

1. Project Title  
Quality of Life Assessment

2. Brief Summary Provide a brief non-technical description of the study, which will be used in IRB documentation as a description of the study. Typical summaries are 50-100 words. Please reply to each item below, retaining the subheading labels already in place, so that reviewers can readily identify the content. PLEASE NOTE: THIS SECTION MAY BE EDITED BY THE IRB FOR CLARITY OR LENGTH.

Purpose:  
Participants:  
Procedures (methods):

3. Is this new study similar or related to an application already approved by a UNC-Chapel Hill IRB? Knowing this will help the IRB in reviewing your new study.

No

2. Project Personnel Reviewer Guidance

1. Will this project be led by a STUDENT (undergraduate, graduate) or TRAINEE (resident, fellow, postdoc), working in fulfillment of requirements for a University course, program or fellowship?

No

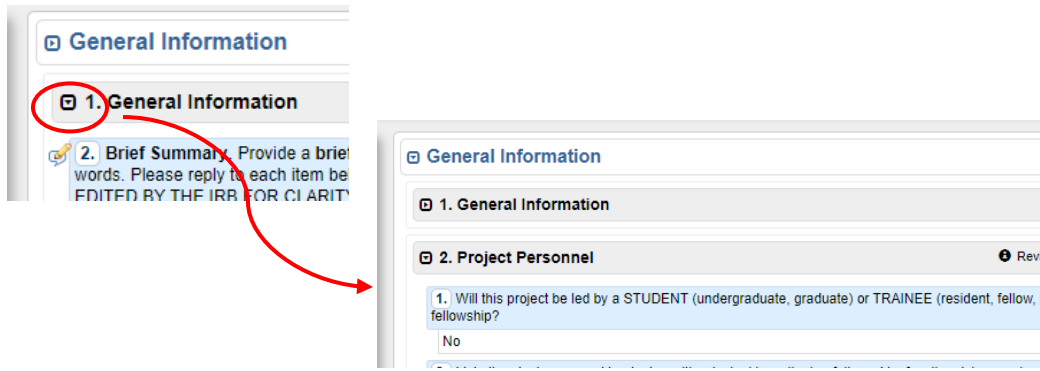
2. List all project personnel beginning with principal investigator, followed by faculty advisor, co-investigators, study coordinators, and anyone else who has contact with subjects or identifiable data from subjects.

- List ONLY those personnel for whom this IRB will be responsible; do NOT include collaborators who will remain under the oversight of another IRB for this study.
- If this is Community Based Participatory Research (CBPR) or you are otherwise working with community partners (who are not functioning as researchers), you may not be required to list them here as project personnel, consult with your IRB.
- If your extended research team includes multiple individuals with limited roles, you may not be required to list them here as project personnel, consult with your IRB.

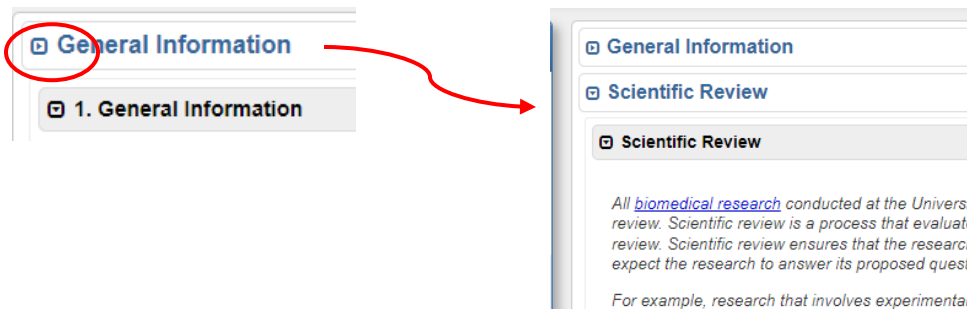
The table below will access campus directory information; if you do not find your name, your directory listing may need to be updated.

COMTraining for IRB NO: 22-2772 - Submission Type: Initial - ReferenceID: 375036  
University of North Carolina at Chapel Hill (UNC-CH)

If you wish to collapse the General Information sub-section, click on the down arrow.

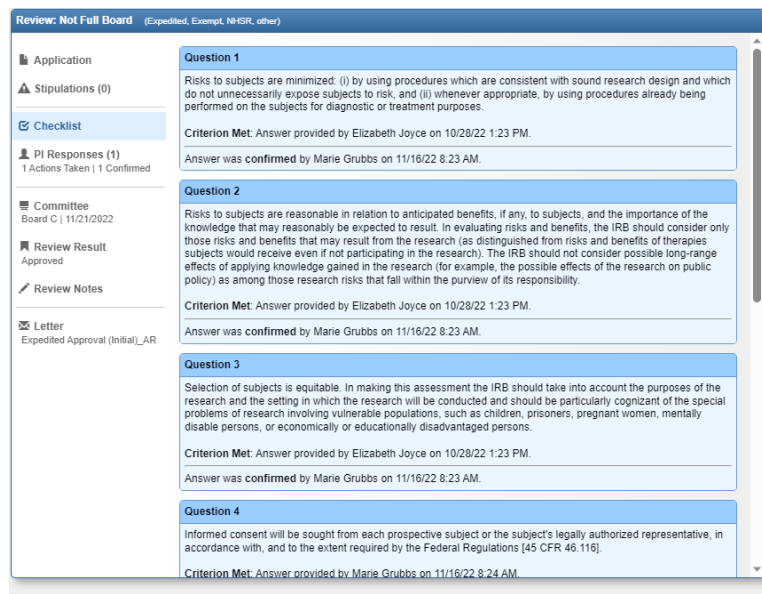


If you wish to collapse the entire General Information section, click on the right arrow.



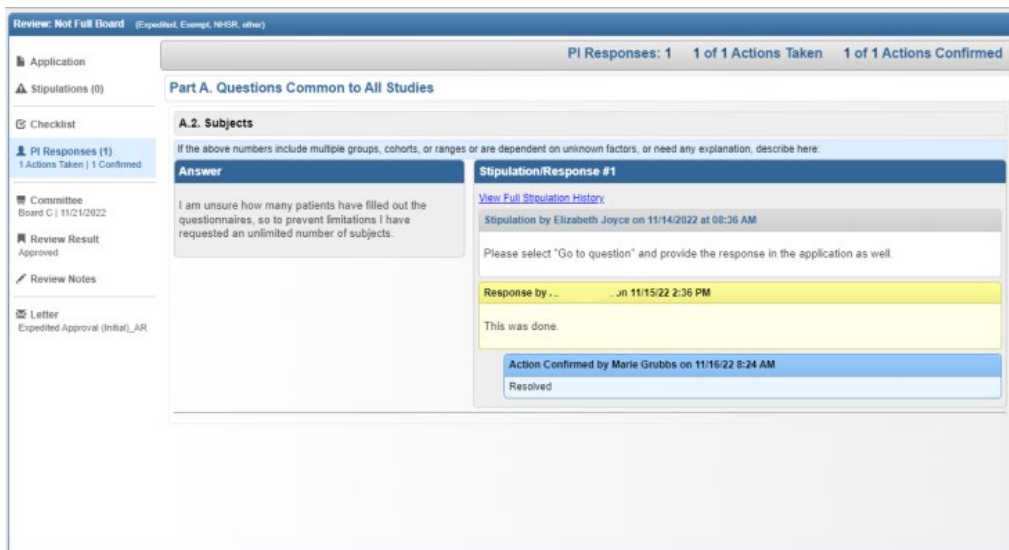
## Checklist

Once the submission is approved, you can view the 111 criteria for approval checklist.



## PI Responses

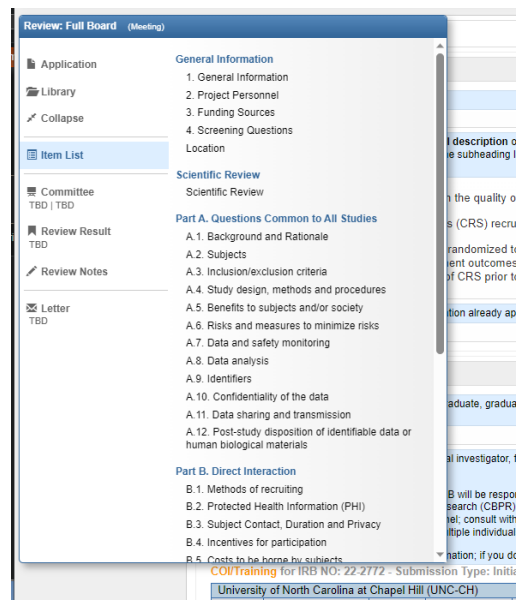
Once the submission is approved, you will be able to see the study team's responses to last set of stipulations.



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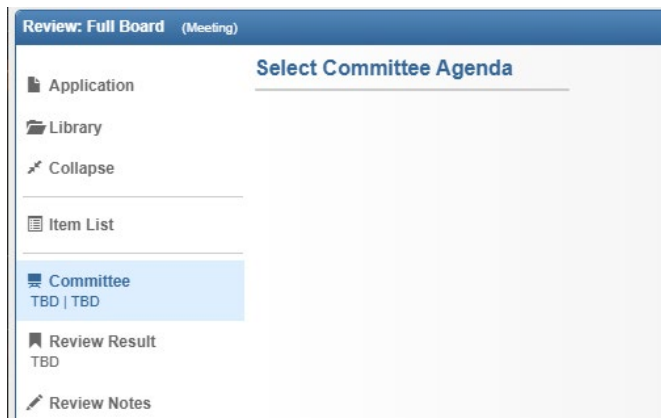
## Item List

The item list remains unchanged. A list of all sections and sub-sections of the application are displayed with the option to navigate to any section.

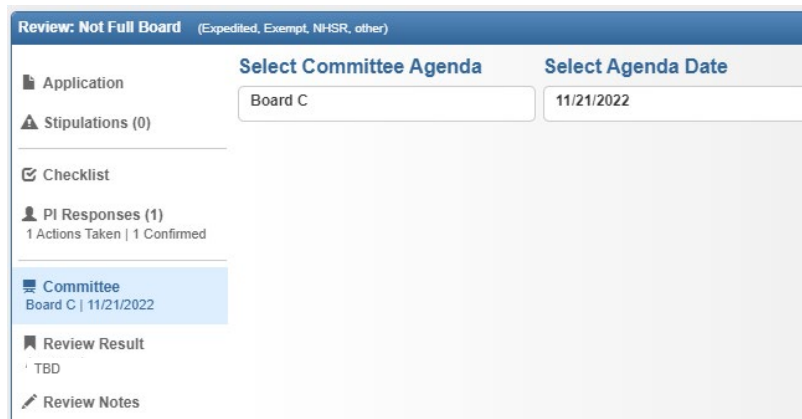


## Committee

The Committee screen will reflect the committee to which the submission is assigned. If it is blank, then a committee assignment has not been made.



Once a Full Board study has been assigned to an agenda, you will see the committee and the agenda date.

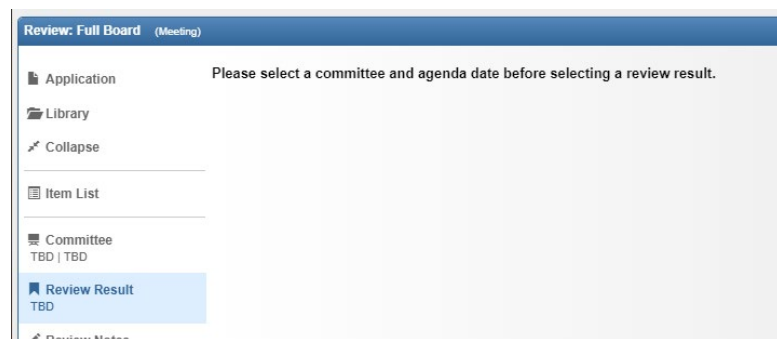


For studies that are reviewed via expedited procedures, the committee date will be assigned on the final approval.

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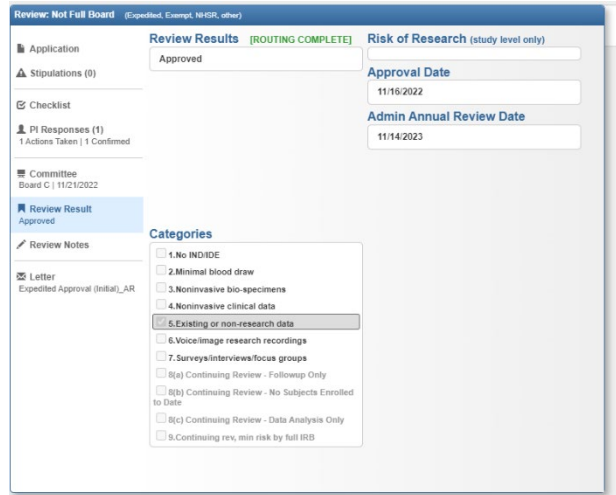
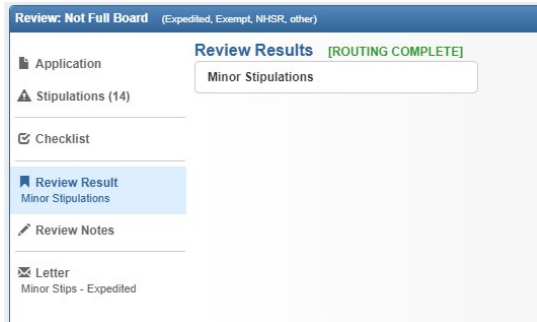
## Review Result

Until a review is finalized, you will not see anything on the Review Result screen.



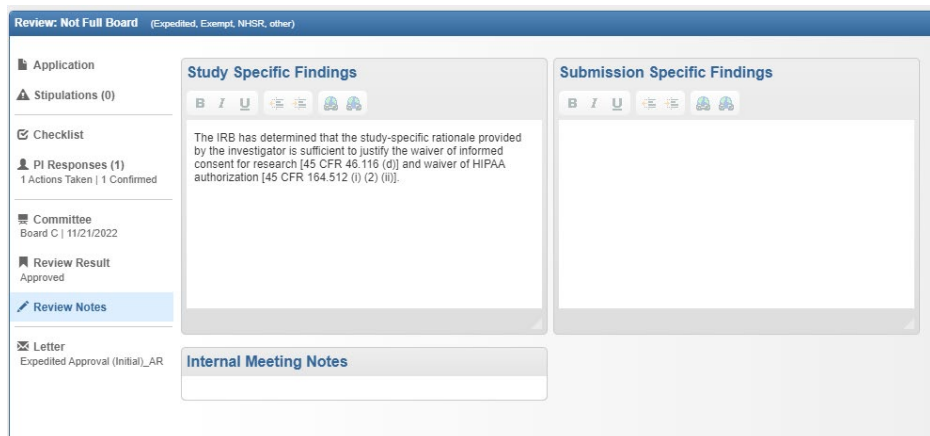
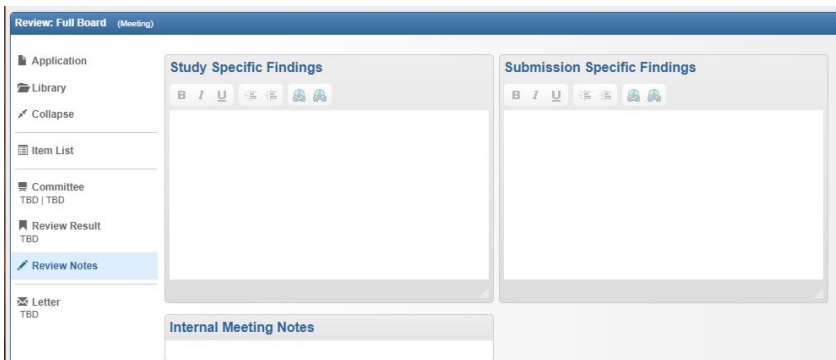


Once a review is finalized, you will see the result.



## Review Notes

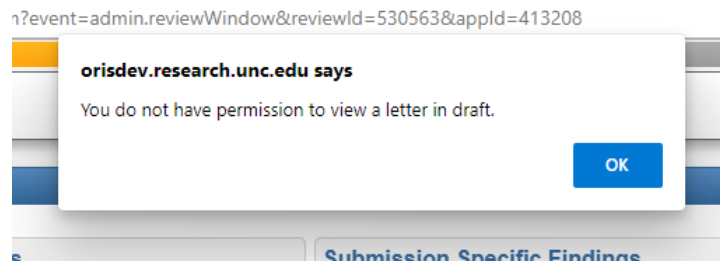
Similarly, the Review Notes screen will be blank until the submission is approved.





## Letter

If you click on the Letter tab before the review is final, you will receive a notice that you do not have permission to view the letters.



Once a review is final, you can view the letter that has been sent to the study team.

