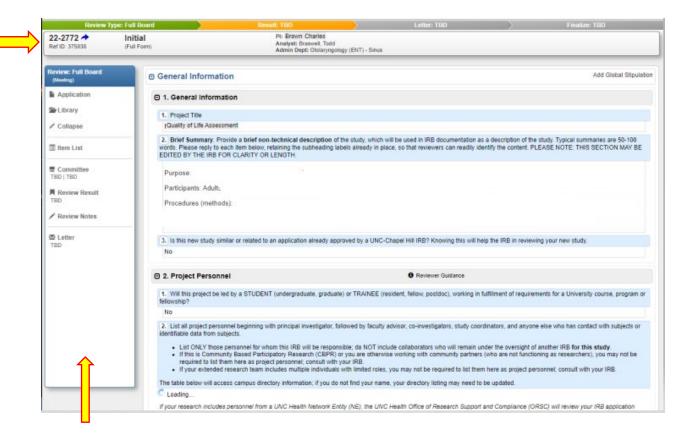
Summary of Changes
Screen Menu 2
Application 2
Library 3
Collapse / Expand
Checklist
PI Responses
Item List6
Committee
Review Result7
Review Notes
Letter

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.

Study Dashboard: 22-2772 Back to previous page Study History Submitted Study Title IRB No: 22-2772 Study Status: Quality of Life Assessment Biomedical Expiration Date: IRB: CharlesBrown Last Approved: issions In-Draft/Routing (0) Submissions for 22-2772 South Statement Sta Reference Approval State Date Routing Action Date Expiration Date AR Date Submission Type Review Type 375038 Not Approved 12/01/2022 12/06/2022 initial : Not Full Board Submission Information Submission Status: Revised-Resubmitted on 12/23/2022 Reference ID: 375038 IRB Admin Biomedical Office Staff: IRB: 12/01/2022 IRB Analyst: IRB Chair: Accepted By IRB: Todd Braswell **Review Type: Full E** and Letter: TBD Navigate Tr: Application (Jorany PLResponses (12) Sticulations (0) Next Step: Record Result Review Type: Not Full Bo Letter: Drat > Fit * paper submissions 1.1 This application is supported by UNC I Please <u>commit is</u> if you have any que

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.

Application

The application opens with all sections and subsections displayed.

Library

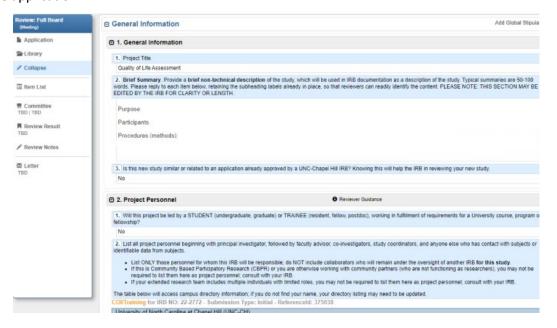
The Library link has the same function as the existing Library hyperlink at the top of the screen:

.....

Review Type: Not I	ull Board	Application	
vigate To: <u>Applicatior</u>	Library tipulations (0)	Library	
Review: Full B (Meeting)			
Application	Review Document Library 🦻		
Elbrary	EATERNAL IND TILES Befresh External IRB Documenta		
⊀ Collapse	There are no External IRB files attached to this submission CONSENT FORMS		
🗏 Item List	This submission requires the following consent forms		
Committee TBD TBD	Aduit Consent Form This submission includes the following consent forms		
Review Re	File Name	Document Type	Return To PI
TBD	Consent Form docx Uploaded by Iblisam Mohammed on 11/23/2022 at 3:55 PM	Adult Consent Form	0
I Review No		Adult Consent Form	0
TBD	ATTACHMENT FILES		
	This submission requires the following attachments X Debriefing Template		
	Jelectronic Questionnaire Survey		
	This submission includes the following attachments		
	File Name	Document Type	Return To PI
	patientsurvey.jog		

Collapse / Expand

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

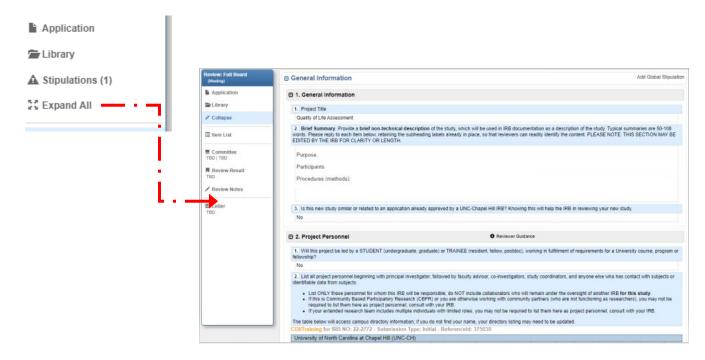


	Review: Not Full Board	Post Approval Submissions		Add Global Stipulation
	(Expedited, Exempt, NHSR, other)	General Information		
	Review Conditions: 🥮 Next Step: Record Result	1. General Information		
Click #1:	Application	2. Project Personnel	Reviewer Guidance	
	🖆 Library	3. Funding Sources	Reviewer Guidance	
	A Stipulations (1)	4. Screening Questions		
	✓ Collapse Again			
	Item List	Location	Reviewer Guidance	
	Checklist	Scientific Review		
	Options	Scientific Review		
	Review Result	Part A. Questions Common to All Studies		
	X Review Notes	A.1. Background and Rationale	Reviewer Guidance	
	₩ Letter TBD	• A.2. Subjects	Reviewer Guidance	



Review: Not Full Board	General Information	
(Expedited, Exempt, NHSR, other)	Scientific Review	
Review Conditions: 🥮	Part A. Questions Common to All Studies	
Next Step: Record Result	Part B. Direct Interaction	
Application	Part C. Existing Data, Records, Specimens	
🖀 Library	Part D. The Consent Process	
A Stipulations (1)	Data Security Requirements	
SS Expand All		
Item List	Review Document Library 🦻	
Checklist	EXTERNAL IRB FILES Refresh External IRB Documents	
=	There are no External IRB files attached to this submission	
	CONSENT FORMS	
Options 0		
Review Result	This submission requires the following consent forms	
Review Result		

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



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

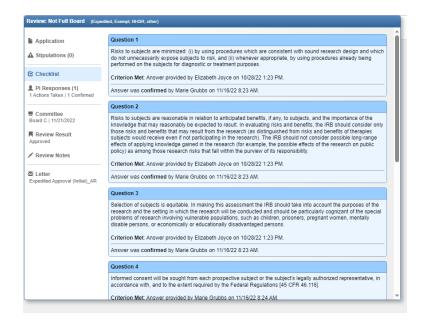
General Information	
1. General Information	
2. Brief Summary, Provide a brief words. Please reply to each item be	General Information
EDITED BY THE IRB FOR CLARITY	1. General Information
	🖸 2. Project Personnel 🔒 R
-	1. Will this project be led by a STUDENT (undergraduate, graduate) or TRAINEE (resident, fello fellowship?
	No

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

General Information	General Information
1. General Information	Scientific Review
	Scientific Review
	All <u>biomedical research</u> conducted at the Universit review. Scientific review is a process that evaluate review. Scientific review ensures that the research expect the research to answer its proposed questi
	For example, research that involves experimental

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.

Application		PI Responses: 1 1 of 1 Actions Taken 1 of 1 Actions Confirmed
Stipulations (0)	Part A. Questions Common to All Studies	
S Checklist	A.2. Subjects	
PI Responses (1)	If the above numbers include multiple groups, cohorts, or ran	ges or are dependent on unknown factors, or need any explanation, describe here:
1 Actions Taken 1 Confirmed	Answer	Stipulation/Response #1
Committee	I am unsure how many patients have filled out the	View Full Stipulation History
Board C 11/21/2022	questionnaires, so to prevent limitations I have	Stipulation by Elizabeth Joyce on 11/14/2022 at 08:36 AM
Review Result Approved	requested an unlimited number of subjects.	Please select "Go to question" and provide the response in the application as well.
Review Notes		Response by
₩ Letter Expedited Approval (Initial)_AR		This was done.
		Action Confirmed by Marie Grubbs on 11/16/22 8:24 AM
		Resolved

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.

Application	Select Committee Agenda
Library	
* Collapse	
Item List	
Committee BD TBD	
Review Result	

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

Application	Select Committee Agenda	Select Agenda Date
	Board C	11/21/2022
Stipulations (0)		
🗹 Checklist		
PI Responses (1)		
1 Actions Taken 1 Confirmed		
E Committee		
Board C 11/21/2022		
Review Result		
TBD		
Review Notes		

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

Review Result

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

Review: Full Board (Me	eting)
Application	Please select a committee and agenda date before selecting a review result.
🚔 Library	
✓ Collapse	
🔳 Item List	
E Committee	
Review Result	
Review Notes	

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

Stipulations (14)	Minor Stipulations	Application	Review Results [ROUTING COMPLETE]	Risk of Research (study level only
		▲ Stipulations (0)	Approva	Approval Date
Checklist		Checklist		11/16/2022
				Admin Annual Review Date
Review Result inor Stipulations		PI Responses (1) 1 Actions Taken 1 Confirmed		11/14/2023
Review Notes		Ecommittee Board C 11/21/2022		
		Review Result Approved		
Letter Ainor Stips - Expedited		✓ Review Notes	Categories	
initial cupo Exposition			2.Minimal blood draw	
		Expedited Approval (Initial)_AR	3.Noninvasive bio-specimens	
			4.Noninvasive clinical data	
			5.Existing or non-research data	
			6.Voice/image research recordings	
			7. Surveys/interviews/focus groups	
			8(a) Continuing Review - Followup Only	
			8(b) Continuing Review - No Subjects Enrolled to Date	
			🗍 8(c) Continuing Review - Data Analysis Only	
			9.Continuing rev, min risk by full IRB	

Review Notes

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

BIU (# # 8) (%

Application	Study Specific Findings	Submission Specific Findings
Stipulations (0)	B Z U (# # 🙈 🙈	B Z U 😤 😤 🙈
Checklist Presponses (1) Actions Taken 1 Confirmed Committee Board C 11/21/2022 Review Result Approved	The IRB has determined that the study-specific rationale provided by the investigator is sufficient to justify the waiver of informed consent for research [45 CFR 46.116 (d)] and waiver of HIPAA authorization [45 CFR 164.512 (i) (2) (ii)].	
Review Notes		
Expedited Approval (Initial)_AR	Internal Meeting Notes	

<u>Letter</u>

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.

n?even	nt=admin.reviewWindow&reviewId=530563&appId=413208	
	orisdev.research.unc.edu says	
	You do not have permission to view a letter in draft.	
	ОК	
e	Submission Specific Findings	

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

