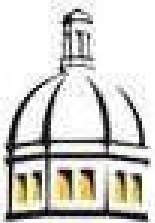


InfoEd

Reviewing a Submission: Quick Guide for IRB Members



THE UNIVERSITY OF
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Logging Into InfoEd

LOG IN at <https://usm.infoedglobal.com> using your USM (SOAR) credentials. Must use w!

You cannot log into InfoEd unless you are first registered in USM's InfoEd system. Most faculty members and graduate students are pre-loaded, but if you are having trouble logging in, most likely you need to be added to the system.

To be added, fill out the form at https://usmforms.formstack.com/forms/infoed_new_user_registration.



InfoEd Dashboard Summary

Home My Profile Locate My Records Locate Records Calendar Messages Assignments Quick Find

Human Protocol
SPIN

Messages ← Shows all messages regarding your protocols

Inbox New Mail Switch Recipients You Select Delete

Submission to IRB Office	Sysadmin, InfoEd	Tue 27-Jul-2021 08:50 AM	<input type="checkbox"/>
Protocol Number: 21-059	CoInvestigator, Jane	Fri 23-Jul-2021 09:33 AM	<input type="checkbox"/>
Protocol Number: 21-054 - Coordinator	DeptHead, Jim	Tue 13-Jul-2021 11:39 AM	<input type="checkbox"/>
Protocol Number: 21-046 - Coordinator	Bruton, Samuel	Fri 09-Jul-2021 13:06 PM	<input type="checkbox"/>

Assignments ← Shows all tasks needing your attention

Open Your action items

Drag a column header and drop it here to group by that column

<input type="checkbox"/>	Module	Record Number	Record Owner	Object	Record Status	Subject	Assigned
▶	Human Subjects	21-054	Investigator, Suzy	Initial Application	Coordinator	Coordinator	13-Jul-2021 11:39:44 AM
▶	Human Subjects	21-083	Bruton, Samuel	Initial Application	In Review	Your action is required	10-Aug-2021 3:11:11 PM



Reviewing the Submission

Under 'Assignments' you will find a listing of submissions awaiting your review.

Assignments Open ▾ Your action items ▾

Drag a column header and drop it here to group by that column

<input type="checkbox"/>	Module ▾	Record Number ▾	Record Owner ▾	Object ▾	Record Status ▾	Subject ▾	Assigned ▾
▶	Human Subjects	21-054	Investigator, Suzy	Initial Application	Coordinator	Coordinator	13-Jul-2021 11:39:44 AM
▶	Human Subjects	21-083	Bruton, Samuel	Initial Application	In Review	Your action is required	0-Aug-2021 6:11:11 PM

To begin reviewing the submission, click on the protocol number.



Reviewing the Submission (continued)

The full application will be shown after you click the link. You will need to thoroughly review the study by clicking through all of the pages. Click on the pencil icon to leave comments.



Check to Submit

Validate

Submit

Save

INVESTIGATOR INFORMATION

USM AFFILIATED INVESTIGATORS


NON-USM AFFILIATED INVESTIGATORS


RESEARCH PROCEDURES

RISKS AND BENEFITS

REVIEW

RESEARCH PROCEDURES

RP1. Briefly describe the project and its goal(s) in two to three paragraphs.  Fame and fortune.

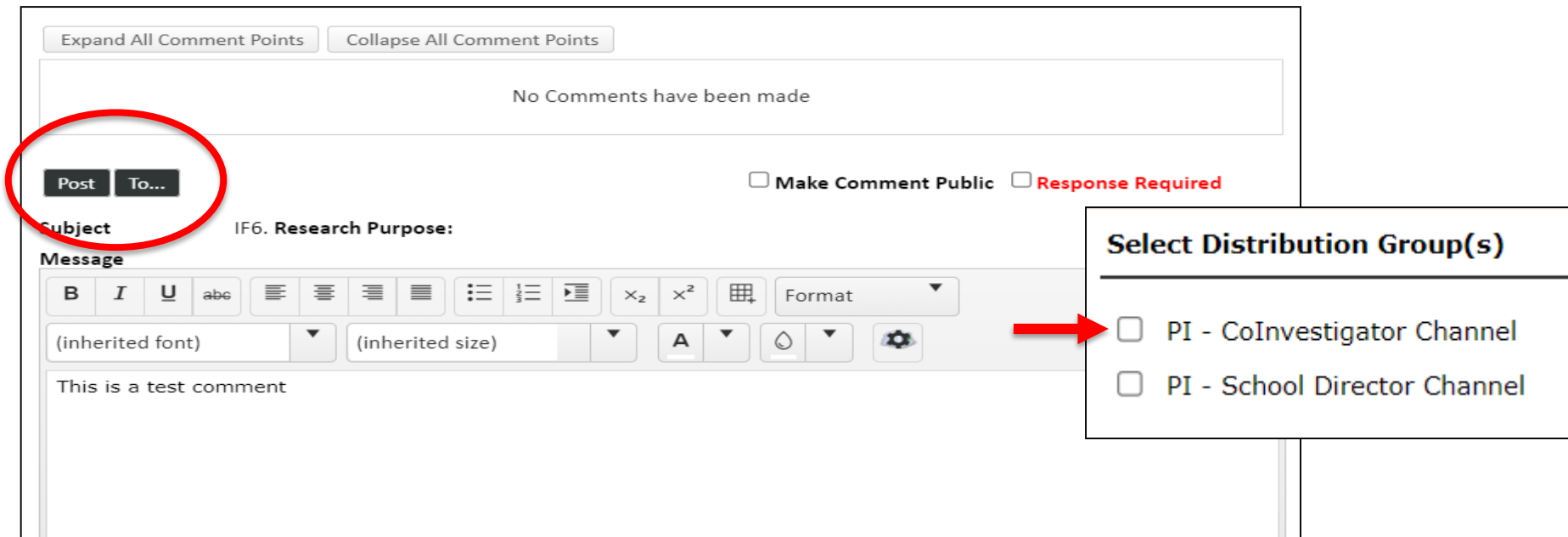
RP2. Are any of the subjects under 18 years of age? 
 Yes No

RP3. Indicate all potentially vulnerable subjects involved in the study.

- Children
- Nursing home patients
- Prisoners
- Not applicable
- Mentally ill patients
- Pregnant females
- HIV positive individuals
- Other

Reviewing the Submission (continued)

Type your comment in the textbox and select 'To' then check the 'PI – CoInvestigator Channel' to ensure all comments can be seen by the PI(s). If you want your comment to require a response, check 'Response Required'. You may disregard the 'Make Comment Public' button as all comments will be visible. Click 'Post' to complete the comment. Once a comment is posted, it will be saved to the application, so you may start a review and return back to it.



The screenshot shows a comment submission form. At the top, there are two buttons: "Expand All Comment Points" and "Collapse All Comment Points". Below these is a large text area containing the message "No Comments have been made".

Below the text area, there are two buttons: "Post" and "To...". These two buttons are circled in red. To the right of these buttons are two checkboxes: "Make Comment Public" and "Response Required".

Below the buttons, the "Subject" is "IF6. Research Purpose:". Below the subject is a "Message" field with a rich text editor toolbar. The toolbar includes buttons for Bold (B), Italic (I), Underline (U), text color (abc), background color, bulleted list, numbered list, link, unlink, subscript (x₂), superscript (x²), table, and a "Format" dropdown. Below the toolbar are two dropdown menus for font and size, and a text color dropdown. The message text is "This is a test comment".

To the right of the message field, there is a red arrow pointing to a "Select Distribution Group(s)" dialog box. This dialog box has a title bar and two checkboxes: "PI - CoInvestigator Channel" and "PI - School Director Channel".



Reviewing the Submission (continued)

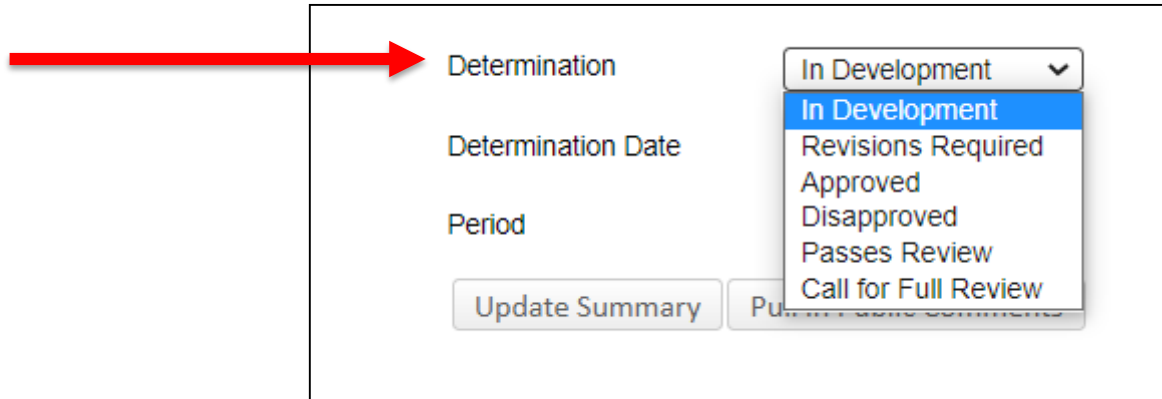
After reviewing each item and leaving any necessary comments, you will go to the 'Assignment' section at the top of the application and select your review decision in the dropdown box next to each upload.

ASSIGNMENT

Form/Document	Document Type	Submitted		Review Status	Comments
authorization_for_hipaa_phi_3-5-14-INBRE.doc	Application	04-Oct-2021 4:07:37 PM	VIEW	Not Applicable ▾	
Cayuse IRB Records	Application	04-Oct-2021 4:13:33 PM	VIEW	Not Applicable ▾	
Data Collection Instruments.pdf	Application	04-Oct-2021 4:06:15 PM	VIEW	Not Applicable ▾	
Data Collection Summary.pdf	Application	04-Oct-2021 4:06:41 PM	VIEW	Not Applicable ▾	
FlyerSample2020.pdf	Application	04-Oct-2021 4:03:46 PM	VIEW	Not Applicable ▾	
Human Subjects Research Application	Application	04-Oct-2021 4:23:13 PM	PDF	Un-Reviewed ▾ Un-Reviewed OK As Is Action Required Acknowledged	
Intervention Flow.pdf	Application	04-Oct-2021 4:07:03 PM	VIEW	Not Applicable ▾	
ME2L New Flyer(Finalized)_JL.pdf	Application	04-Oct-2021 4:16:57 PM	VIEW	Not Applicable ▾	

Reviewing the Submission (continued)

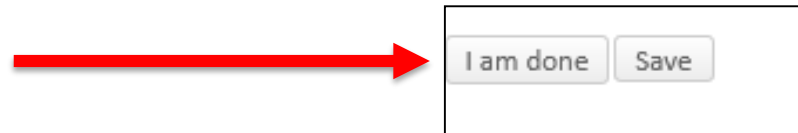
After you have indicated a review status for each document, you then will indicate your reviewer determination using the dropdown box. Here is where you will select your review decision. After this, you will then click 'I am Done' at the bottom of the 'Assignment' section.



A screenshot of a web form for reviewing a submission. A red arrow points to the 'Determination' dropdown menu, which is open and showing several options. The 'Determination' label is highlighted. Below the dropdown are fields for 'Determination Date' and 'Period'. At the bottom of the form are two buttons: 'Update Summary' and 'Publish Comments'.

Determination	In Development ▼
Determination Date	In Development
Period	Revisions Required
	Approved
	Disapproved
	Passes Review
	Call for Full Review

Update Summary Publish Comments

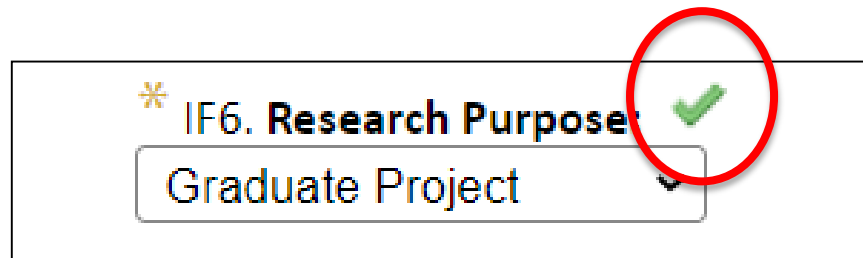


A screenshot of two buttons: 'I am done' and 'Save'. A red arrow points to the 'I am done' button.

I am done Save

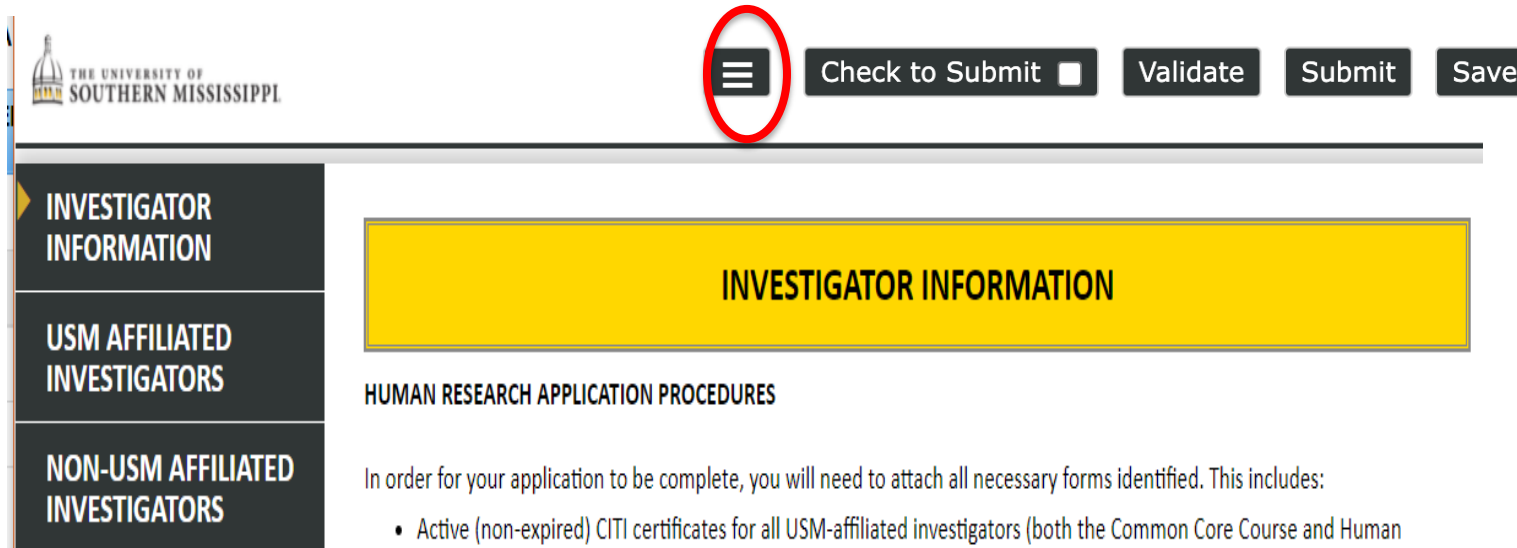
Reviewing a Revised Submission

Once a PI makes requested changes and the study is returned back to you, you can see how the PI addressed any comments made by opening the submission and clicking on any comments made. Green checkmarks indicate that a response-required comment has been addressed. Once you review the revisions made, you will return to the reviewer dashboard page to either approve the study or request additional revisions be made.



Reviewing a Revised Submission or Modification

If a PI submits a revised submission or modification for a previously approved protocol, you can see what changes have been made. To compare the previous submission with the new one, click the button with three lines and then “form history”.



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☰ Check to Submit Validate Submit Save

INVESTIGATOR INFORMATION

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INVESTIGATOR INFORMATION

HUMAN RESEARCH APPLICATION PROCEDURES

In order for your application to be complete, you will need to attach all necessary forms identified. This includes:

- Active (non-expired) CITI certificates for all USM-affiliated investigators (both the Common Core Course and Human



Reviewing a Revised Submission or Modification (continued)




To compare the current application to a previous version, select the versions to be compared and select 'go'. This will allow you to easily identify requested revisions.

Human Subjects Research Application					
COMPLETED ON	COMPLETED BY	SUBMISSION NUMBER	SIGNATURE – SUBMISSION TYPE	VIEW	COMPARE FROM TO
27-Aug-2021 09:58:40 AM	Suzy Investigator	21-091-21	Electronically Signed: 27-Aug-2021 10:01:09 AM - by Suzy Investigator, Cell & Molecular Biology - Modification		<input type="radio"/> <input type="radio"/>
27-Aug-2021 09:57:28 AM	Suzy Investigator	21-091-21	- Modification		<input checked="" type="radio"/> <input type="radio"/>
16-Aug-2021 10:10:14 AM	Suzy Investigator	21-091-01	Electronically Signed: 16-Aug-2021 10:10:58 AM - by Suzy Investigator, Cell & Molecular Biology - Initial Application		<input type="radio"/> <input checked="" type="radio"/>
				<input type="button" value="Go"/>	



Reviewing a Revised Submission or Modification (continued)

Changes to the application will be highlighted throughout the submission in a side-by-side comparison. After reviewing the revisions, return to the approved or revisions required screen to make a decision.

Updated by: Suzy Investigator @ 27-Aug-2021 09:57:28 AM	Updated by: Suzy Investigator @ 16-Aug-2021 10:10:14 AM
INVESTIGATOR INFORMATION	INVESTIGATOR INFORMATION
HUMAN RESEARCH APPLICATION PROCEDURES	HUMAN RESEARCH APPLICATION PROCEDURES
In order for your application to be complete, you will need to attach all necessary forms identified. This includes: <ul style="list-style-type: none"> Active (non-expired) CITI certificates for all USM-affiliated investigators (both the Common Core Course and Human Subjects Research Course), consent form(s) or scripts, additional required documents, such as research instruments, recruitment materials, and external permission letters (if applicable). For more information on the IRB process and requirements, please refer to the Office of Research Integrity's website. 	In order for your application to be complete, you will need to attach all necessary forms identified. This includes: <ul style="list-style-type: none"> Active (non-expired) CITI certificates for all USM-affiliated investigators (both the Common Core Course and Human Subjects Research Course), consent form(s) or scripts, additional required documents, such as research instruments, recruitment materials, and external permission letters (if applicable). For more information on the IRB process and requirements, please refer to the Office of Research Integrity's website.
<p>IF1. Protocol Number  21-091</p> <p>IF3. Formal project title:  TESTING - 8/16/21</p>	<p>IF1. Protocol Number 21-091</p> <p>IF3. Formal project title: TESTING - 8/16/21</p>
<p>IF2. Submission Number  21-091-24</p>	<p>IF2. Submission Number 21-091-01</p>



Reviewing a Revised Submission or Modification (continued)

If the submission is satisfactory, select Approved. If significant changes are required, select 'Revisions Required' to have the submission returned to the PI for edits.

The screenshot shows a review interface for a Human Subject Protocol - Initial Application. On the left, there is a vertical navigation bar with buttons for REVIEW, HELP, and PROFILE. The main content area displays the application details: Number: 21-085, Title: Tuesday Demo, Sponsor, and Submitted: 10-Aug-2021 12:02:02 PM. Below this is a table with columns for Form/Document, Document Type, and Submitted. The table contains one row: Human Subjects Research Application, Application, 10-Aug-2021 12:02:02 PM, and a PDF icon. Below the table is an 'Add Comments' section with a text area and a rich text editor toolbar. To the right of the text area is a 'Select a decision:' section with two buttons: 'Approved' and 'Revisions Required'. A red oval highlights these two buttons. In the top right corner, there is a 'Close' button and a 'Comments I can see...' section that states 'No Comments have been recorded'.

****NOTE: Your browser must have pop-up blockers turned off in order for the review to process.**



Questions?

[www.usm.edu/research/
office-research-integrity](http://www.usm.edu/research/office-research-integrity)

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