

Tips when responding to stipulations/ pre-review comments and revising existing documents:

- The instructions and screen shots below provide guidance to assist investigators with their response to stipulations. When possible, the HRPP office recommends that you use two browsers (e.g. Chrome and Firefox) when responding to stipulations/ pre-review comments. This will allow you to use one browser to view and respond to your stipulations/ pre-review comments, and the other to revise and upload study documents. Note – you will need to save the page and hit refresh to update the screen in the browser you are viewing and responding to stipulations/ pre-review comments if you choose to use two browsers.

Processes that are specific to the use of a single browser and to the use of two browsers are identified in the instructions where applicable.

Contents

Navigating to the pre-review comments/stipulations page.....	2
Responding to Stipulations/ Pre-Review Comments.....	3
Revising the application/protocol that is linked from a specific stipulation	5
Revising an existing study document that is linked from a specific stipulation.....	8
Revising the application/protocol that was not originally attached to the submission (Submission Types other than Initial Submissions).....	11
Adding a new document.....	13
Submitting the response back to the HRPP	15

Navigating to the pre-review comments/stipulations page

- Log in to iRIS
- Scroll to your tasks
- Click to open the task called either 'Submission Correction' or 'Submission Response'. Note other paths may give you a read-only version of the application, so we recommend accessing the submission using this method.

The screenshot shows the 'All Tasks' interface. At the top, there are tabs for 'Outstanding' and 'Completed'. Below this, there are buttons for 'All Tasks' and 'Study Tasks'. A 'Task List' dropdown menu is set to 'All'. A message indicates '22 result(s) found...'. A table lists tasks with columns: 'Click to open', 'Task Type', 'Received', and 'Description'. The first row shows a 'Submission Correction' task received on '02/04/2021 09:03:07 AM PST' with the description 'IRB returned the submission for corrections'. A red box highlights the 'Click to open' icon for this task.

- Once you have opened the task, you will be able to view all the stipulations/ pre-review comments associated with the review from the 'Stipulations and Comments' page. If you have opted to use two browsers to respond, you will need to begin from this page in each browser.

The screenshot shows the 'Notification of Pre-Review Comments' page. It includes sections for '1.1 Instructions', '1.2 Principal Investigator' (Tiffany Andrews), '1.3 Study Title' (Test), and '1.4 Study Number' (IRB-2021-0708). Section '1.5 Pre-review comments' contains 'Stipulations that must be addressed:'. A specific stipulation is shown with a description: 'Please revise this section to include all OSU study team members.' Below this is a table for 'Stipulation Type' with columns: 'Operation', 'Action Status', 'Component Name', and 'Action'. The table shows an action 'Modify Existing Attachment' with a status of 'Action Not Complete' for the component 'HRPP and IRB Application and Protocol (Version 1.0)'. A 'Revise Existing' button is visible. At the bottom, there is a question 'Do you accept this Stipulation?' with radio buttons for 'N/A', 'Yes', and 'No', and a rich text editor toolbar.

Responding to Stipulations/ Pre-Review Comments

- Each stipulation/ pre-review comment requires the investigator to address the following in their response:
 - Indicate if you accept the stipulation
 - Complete the text field to indicate how you have addressed the item, or provide justification for rejecting the item
 - Change the action to 'Complete Action' (this option will be available after you have revised the document)

Stipulation Type: (Stipulation must be addressed)

Links to Components	Operation	Action Status	Component Name	Action
(These are the items that are linked to this stipulation)	Modify Existing Attachment	Action Not Complete	HRPP and IRB Application and Protocol (Version 1.1) HRPP and IRB Application and Protocol (Version 1.0) Section: Study Overview Question: Provide details of where data will be collected:	Compare Application Version <input type="radio"/> Complete Action <input checked="" type="radio"/> Incomplete Action

Do you accept this Stipulation? N/A Yes No

Provide an explanation on how you addressed this Stipulation:

I revised the applicable section of the application to indicate where data will be collected.

- You will need to click 'save section' at the top of the screen to capture your responses to stipulations/pre-review comments. If you are using a single browser to respond to stipulations/ pre-review items we recommend you complete this action after responding to each stipulation to avoid losing information.

- **Two Browsers:** As a reminder, you will need to click 'save section' and refresh your browser to update the screen in the browser you are viewing to respond to stipulations/ pre-review comments.

My Workspaces | IRB Number: **IRB-2019-0064** | PI: Coleman, Jillian M | Study Assistant | **Pre-Review Correction Form - IRB - (Version 2.0)** | Back

Print Friendly | Refresh Constant Fields | **Save Section** | Save and Continue to Next Section

Section view of the Form | Entire view of the Form

1.0 Notification of Pre-Review Comments
2.0 **Stipulations and Comments**

2.0 Stipulations and Comments

Stipulations that must be addressed:

Stipulation 1 out of 1:

Description:
revise document

Stipulation Type: (Stipulation must be addressed)

Operation	Action Status	Component Name	Action
Modify Existing Attachment	Action Not Complete	Study Consent Template 2 Consent form for minimal risk studies 09202018 (Version 1.2)	Compare Consent Version <input type="radio"/> Complete Action <input checked="" type="radio"/> Incomplete Action
		Study Consent Template 2 Consent form for minimal risk studies 09202018 (Version 1.1)	

Links to Components
(These are the items that are linked to this stipulation)

Do you accept this Stipulation? N/A Yes No

Provide an explanation on how you addressed this Stipulation:

Revising the application/protocol that is linked from a specific stipulation

- When applicable, the stipulation/ pre-review comment will be linked to the HRPP Application and Protocol, and identify the section and question requiring revision.
- Click 'Revise Existing' next to the linked HRPP application and protocol

Stipulation 1 out of 2:

Description:
Please revise question 2 to in the 'Study Overview' section to provide an answer

Stipulation Type: (Stipulation must be addressed)

Links to Components (These are the items that are linked to this stipulation)	Operation	Action Status	Component Name	Action
	Modify Existing Attachment	Action Not Complete	 HRPP and IRB Application and Protocol (Version 1.0) Section: Study Overview Question: Provide details of where data will be collected:	

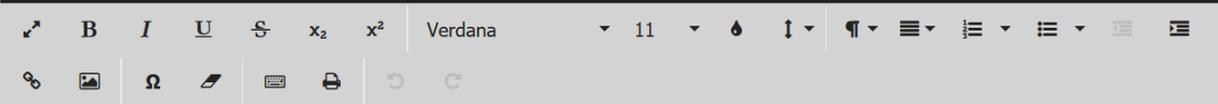
- The system will take you directly to the section of the application the stipulation/ pre-review comment is linked to so you can make the applicable revisions. Make sure to click 'save section' before leaving the section to avoid losing information.

Print Friendly  Save and Continue to Next Section

Entire view of the Application

13.2 Provide details of where data will be collected:

Modifications Required:
 Please revise question 2 to in the 'Study Overview' section to provide an answer

- **Single Browser:** Once you are finished making the revisions, click 'back'. This will take you back to the stipulations page so you can provide your response (i.e. accept/reject the stipulation/ pre-review comment, address the text field, and complete the action).

IRB Number: **IRB-2021-0711** Study Assistant **HRPP and IRB Application and Protocol (Version 1.1)** ← Back

PI: Andrews, Tiffany

Print Friendly Save Section Save and Continue to Next Section

Entire view of the Application

13.2 Provide details of where data will be collected:

Modifications Required:

Please revise question 2 to in the 'Study Overview' section to provide an answer

I edited this section as you have requested

- Note – if there are more stipulations requiring edits to the application/protocol, going forward you will now click on the new version of the document in order to make the edits, rather than 'revise existing'. The rest of the instructions remain the same as previously noted.

Stipulation 2 out of 2:

Description:
Please provide an to question 1 in the 'Methods and Procedures' section.

Stipulation Type: (Stipulation must be addressed)

Operation	Action Status	Component Name	Action
Modify Existing Attachment	Action Not Complete	HRPP and IRB Application and Protocol (Version 1.1)	Compare Application Version
		HRPP and IRB Application and Protocol (Version 1.0) Section: Methods and Procedures Question: Provide a description of the methods and procedures to be followed during this research project:	<input type="radio"/> Complete Action <input checked="" type="radio"/> Incomplete Action

Links to Components
(These are the items that are linked to this stipulation)

- **Two browsers:** Once you have generated a new version of the application in one browser, you will use the application section menu on the left side of the screen to navigate to other sections in order to complete all the revisions rather than clicking 'back'. Make sure to click 'save section' or 'save and continue' before leaving the section to avoid losing information. Use the other browser screen to view and respond to each stipulation/preview comment as previously noted.

Print Friendly Save Section Save and Continue to Next Section

Section view of Application

- 1.0 General Information
- 2.0 Setup Department(s) Access
- 3.0 Grant Key Personnel access to the study
- 4.0 Help Text
- 5.0 Submission Type
- 6.0 Study Summary
- 7.0 Determination of Whether the Project Requires IRB Review
- 8.0 Extent of the Review Required by OSU
- 9.0 OSU will be the RESPONSIBLE Institution but Review External ...
- 10.0 Regulatory Flexibility
- 11.0 Conflicts of Interest and Competing Relationships
- 12.0 Sources of Funding and Support for this Project
- 13.0 Study Overview
- 14.0 Target Enrollment
- 15.0 Participant Demographics
- 16.0 Identification and Recruitment of Participants

Entire view of the Application

3.0 Study Team
Setup Study Personnel

Modifications Required:

Please revise this section to include all OSU study team members.

3.1 * Name of Principal Investigator (FAQ: Who can be a Principal Investigator (PI):

Tiffany Andrews

3.2 Additional Study Team Members:

Additional investigators:
(Do not list individuals who will receive IRB approval at their own external institution or whose institution has determined that they are not engaged.)

To remove a study team member prior to submitting the application, check the box next to their name and click the "remove" button.

3.3 * Please add a Study Contact:

Andrews, Tiffany

Revising an existing study document that is linked from a specific stipulation

- When applicable, the stipulation/pre-review item will be linked to the study document(s)
- Click 'revise existing' next to the document you wish to revise, then click 'check-out unapproved document'

My Workspaces | IRB Number: **IRB-2019-0064** | System Administration | Pre-Review Correction Form - IRB - (Version 2.0) | Back

Print Friendly | Refresh Constant Fields | Save Section | Save and Continue to Next Section

Section view of the Form | Entire view of the Form

1.0 Notification of Pre-Review Comments
2.0 Stipulations and Comments

2.0 Stipulations and Comments

Stipulations that must be addressed:

⚠ Stipulation 1 out of 1:

Description:
revise document

Stipulation Type: (Stipulation must be addressed)

Operation	Action Status	Component Name	Action
Modify Existing Attachment	Action Not Complete	Study Consent Template 2 Consent form for minimal risk studies 09202018 (Version 1.1)	Revise Existing

Links to Components (These are the items that are linked to this stipulation)

Do you accept this Stipulation? N/A Yes No

Create a new version | Save Changes

Consent Review | Consent CheckList

View the Unapproved Consent | View the Approved Consent

* Title:

Version Date: 07/05/2019

Category: Consent

Version Number: 1.2

Outcome: --none--

Language: English

Description:

Comments:

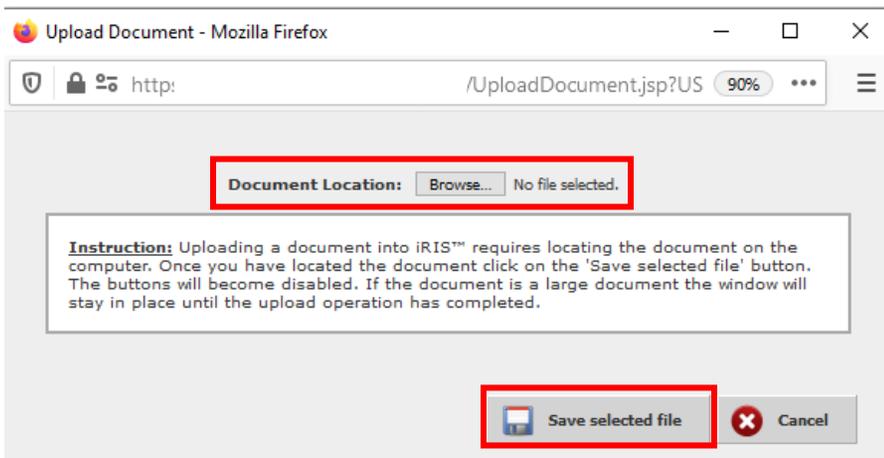
Check-out the Unapproved Document to your machine for editing:

- The document will download and be visible at the bottom of the screen in a few moments. You can ignore the downloaded document if you already have a copy on your computer that you have edited. The downloaded document is available only in the event you do not have existing access to the file. If you need to use it, open it, and save it to your computer so you can make the requested revisions.

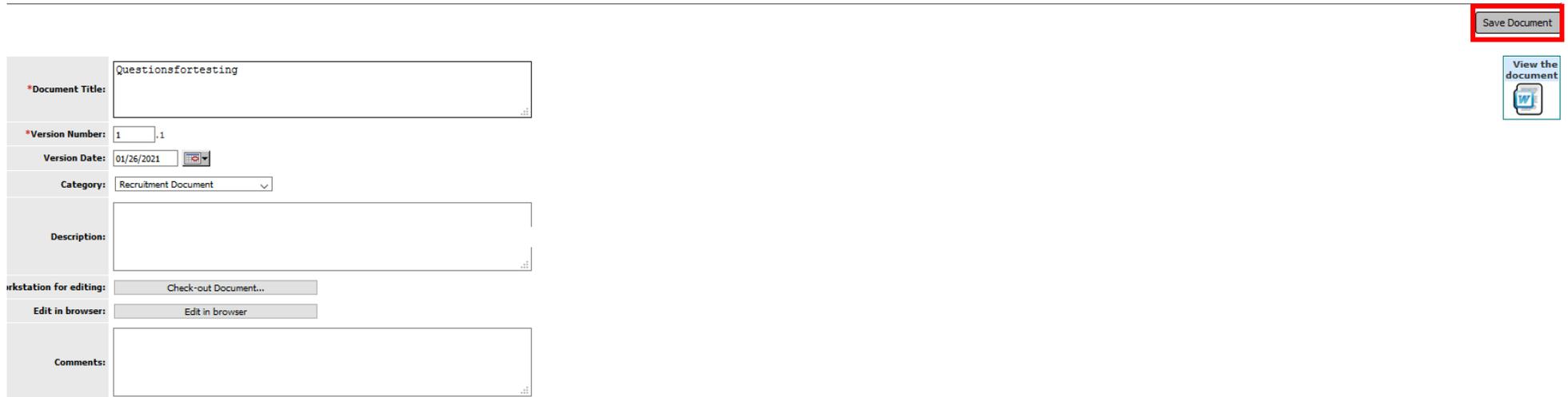
- When you are ready to upload the newly revised version of the document click 'check-in document'

*Document Title:	Recruitmentfortesting
*Version Number:	1 .1
Version Date:	01/26/2021
Category:	Recruitment Document
Description:	
This document is currently checked out by: Tiffany Andrews at 03/16/2021	
Check-in when you are done editing upload the document back into iRIS.	Check-in Document...
Revert to the document stored in iRIS.	Undo Check-out Document...
Comments:	

- Click 'Browse' or 'Choose File' to find the document on your computer and make sure to upload the revised document. Then click 'Save Selected File'



- Click 'save changes' in the top right corner of the screen



The screenshot displays a document management interface. On the left, a form contains the following fields: 'Document Title' with the text 'Questionsfortesting', 'Version Number' set to '1.1', 'Version Date' set to '01/26/2021', and 'Category' set to 'Recruitment Document'. Below these are 'Description', 'Workstation for editing' (with a 'Check-out Document...' button), 'Edit in browser' (with an 'Edit in browser' button), and 'Comments'.

In the top right corner, a 'Save Document' button is highlighted with a red rectangular border. Below it is a 'View the document' button with a document icon.

- **Single Browser:** If there is another stipulation/pre-review comment requesting revisions you have not already addressed in the document, and you have already checked the document back in, you will need to click on the new version that was created and continue to edit it by using the check-in/check-out process previously described.
- **Two browsers:** If there are multiple stipulations/pre-review comments requesting revisions for this document, we recommend you make all edits before checking the document back in.
- Note the HRPP does not recommend logging out the system with a document 'checked-out'. Please ensure all documents have been 'check-in' before logging out to avoid potential system issues.

- Revise the applicable sections of the application/protocol and make sure to click ‘save section’ before leaving a section to avoid losing information. When your revisions are complete, go to the last section of the application/protocol (i.e. ‘Application Questions Complete’) and click ‘save and continue’.





Section view of Application

- 19.0  Review and Procedures
- 20.0  Compensation
- 21.0  Costs
- 22.0  Privacy and Confidentiality
- 23.0  Record Retention
- 24.0  Sharing Data and Biological Samples
- 25.0  Publication
- 26.0  Data Security
- 27.0  Potential Reporting Obligations
- 28.0  Certificate of Confidentiality
- 29.0  Risks
- 30.0  Benefits
- 31.0  Training and Oversight
- 32.0  Application Questions Complete**

32.0 Application Questions Complete

32.1 Having completed the application questions, please return to section 1.0 to confirm that you have selected the appropriate review level, then return to this section to complete the application.

32.2 Click the box below to close all help text notes (required):

If the application is complete and ready to be submitted, please click "Close Help Text, Examples, Links". If you are revising the application in response to submission corrections or review response, you can click "Re-open Help Notes" to make all help notes visible again.

Close Help Text, Examples, Links
 Re-open Help Text, Examples, Links

32.3 Please click **Save & Continue** to proceed to the Initial Review Submission Packet.

The Initial Review Submission Packet is a short form filled out after this application has been completed. This is where you will attach documents.

- To add the newly revised application/ protocol to the submission click on the check box under ‘select’, then click ‘add attachment’

Attaching Study Application ✕

 Select the application that you would like to attach and then click **Save Attachment**  **Add Attachment**

Select	Show Rev.	Edit/View	Form Name	Approved	Create a Revised Application
<input checked="" type="checkbox"/>			HRPP and IRB Application and Protocol Form (Version 1.5)	No	

Adding a new document

- If you have been asked to upload a new document that was not previously submitted, you will need scroll to 'Submission Components' the bottom of the 'Stipulations and Comments' page, and click on 'Add New Component'

Display Submission Components ⓘ

Compare Item(s) Items in List View **Add New Component** Clear Viewed Item(s) Create PDF Packet

Compare	Include in PDF Packet	Revise/Attach	Revisions	Current Submission Components (All Rounds)	More Details
Submission Form(s)					
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	IRB - Pre-Review Correction Form - IRB - (Version 1.0) - You already viewed this item	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Initial Review Submission Packet - (Version 1.0)	<input type="checkbox"/>
Application					
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	HRPP and IRB Application - (Version 1.1)	<input type="checkbox"/>
Consent Form(s)					

- Choose the type of document you have been asked to upload

Select an attachment type

Select the type of attachment you would like to add to this submission:
(Click on the radio button and it will transition you to next page)

Informed Consent

Other Study Document

- You will be given the option to add one or multiple documents

Attach Study Document(s) X

i Instructions

- Select the document(s) that you would like to attach
- Click the **Add a New** button to add a new document.
- Click the **Add Multiple** button to add multiple new documents.

++ Add Multiple Documents **+ Add a New Document**

Show Rev.	Edit/View	Version	View File	Title/Category	Last Modified by	Date Modified	Create a Revised Document
No documents have been added.							

- Enter the document title, version, version date, category, and then browse your computer to upload the document file. If you are only uploading a single document (i.e. you did not choose 'add multiple documents', then you will click 'Drag your file here or click in this area' in order to browse and upload from your computer.
- Then click 'save record(s)' or 'save document'

Instructions

- Browse for files in your local machine.
- Records with invalid file path will not be added.
- All fields other than file path will be automatically populated if not entered.

+ Add New Records
✖ Delete Record(s)
Save Record(s)

Document Title	Version	Version Date	Category	File path
<input type="checkbox"/> Recruitment Instructor	1.0	08/20/2019	Recruitment Document	Choose File
<input type="checkbox"/> Recruitment Whole Class	1.0	08/20/2019	Recruitment Document	Choose File
<input type="checkbox"/>	.0		--none--	Choose File No file chosen

*Document Title:

*Version Number: .0

Version Date:

Category: --none--

Description:

Load the document into iRIS:

Drag your file here or click in this area.

Add in browser:

- The far left column will confirm when the document has been attached to the submission. If the document has not been attached to the submission, the box in the column next to the new document will have a check box. To attach the document click on the checkbox, then click 'attach'

Attach Study Document(s)

Instructions

- Select the document(s) that you would like to attach
- Click the **Add a New** button to add a new document.
- Click the **Add Multiple** button to add multiple new documents.
- Click the **Attach** to attach checked documents.
- Click the **Add Revision** button to create a revised document.

Add Multiple Documents
Add a New Document
Attach

<input type="checkbox"/>	Show Rev.	Edit/View	Version	View File	Title/Category	Last Modified by	Date Modified	Create a Revised Document
<input type="checkbox"/>			1.0 03/16/2021		New Interview Guide	Tiffany Andrews	03/16/2021 12:15:14 PM	Add Revision
Already Attached			1.0 11/16/2020		Questionsfortesting * This document was part of this submission. Questionnaire	Tiffany Andrews	11/16/2020 11:16:47 AM	Add Revision
Already Attached			1.0 11/16/2020		Recruitmentfortesting * This document was part of this submission. Recruitment Document	Tiffany Andrews	11/16/2020 11:16:56 AM	Add Revision

Submitting the response back to the HRPP

- When you are ready to submit your response to stipulations/ pre-review comments and the revised documents to the HRPP office, you will click 'save and continue' in the top right corner on the 'Stipulations and Comments' page.

Section view of the Form | Entire view of the Form

1.0 Notification of Pre-Review Comments
2.0 Stipulations and Comments

2.0 Stipulations and Comments

Stipulations that must be addressed:

Stipulation 1 out of 1:

Description:
Revise section 8 to say OSU are not the only researchers conducting the study.

Stipulation Type: (Stipulation must be addressed)

Operation	Action Status	Component Name	Action
Modify Existing Attachment	Action Complete	HRPP and IRB Application (Version 1.1) HRPP and IRB Application (Version 1.0) Section: Extent of the Review Required by OSU Question: Are OSU-affiliated individuals the only people conducting study activities; including recruitment, obtaining consent, data collection, data analysis, data or sample sharing or storage?	Compare Application Version <input checked="" type="radio"/> Complete Action <input type="radio"/> Incomplete Action

Do you accept this Stipulation? N/A Yes No

Links to Components (These are the items that are linked to this stipulation)

Done

Print Friendly | Refresh Constant Fields | Save Section | **Save and Continue to Next Section**

- If you are the PI, you will see the 'Signoff and Submit' button. If you are a study team member, the button will read 'Notify PI for signoff'. If you are notifying the PI for signoff, they will receive an email and a task requesting that they submit the response.

Section view of the Form | Entire view of the Form

1.0 Notification of Pre-Review Comments
2.0 Stipulations and Comments

Form has been Completed!

Continue to Next Screen to Submit Your Form

Print Friendly | Signoff and Submit

Exit Form
Signoff and Submit

- The PI will now 'approve' the submission, then click 'save signoff'



Study Title: Test -
Submission Reference Number: 002835



Include in PDF Packet	Submission Component Name
Submission Form(s)	
<input type="checkbox"/>	Pre-Review Correction Form - IRB
<input type="checkbox"/>	Initial Review Submission Packet
Application	
<input type="checkbox"/>	HRPP and IRB Application

Submission Form(s):

Tiffany Andrews as Principal Investigator do you Approve or Deny this submission? **Approve** Deny

Comments: 

