

Review Response Submission Form

- The “Review Response Submission Form” in INSPIR II is equivalent to the “Modification Memo Reply” in INSPIR I.
- This form is used to reply to the IRB and address the issues raised when the IRB conditionally approves the submission, defers it, or returns it for administrative modifications.

My Assistant

Study Assistant

Add a new Study

My Studies

My Appointments

Your current Department is BU - MED - [redacted]


Your current review board is IRB Your current committee is Panel Green

Worklist Filter: All

Move to Complete

Incomplete Tasks **Complete Tasks** **Not Opened Correspondence** **Previously Opened Correspondence**

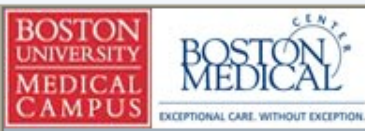
1 result(s) found... 1 - 1

<input checked="" type="checkbox"/>	Open	Task Type	Z A Received		Tasks
<input type="checkbox"/>		Submission Response	04/05/2011 11:31 AM EDT	<input type="checkbox"/>	<p>IRB returned the submission with the outcome of Conditionally Approved-Pending Changes</p> <p>Study Title: [redacted]</p> <p>Principal Investigator: [redacted]</p> <p>Submission Type: [redacted]</p> <p>Reference Number: [redacted]</p> <p>IRB Number: [redacted]</p>



If you have a "Submission Response" task under the "Incomplete Task" tab, click on the icon under Open to access the "Review Response Submission Form". Skip the next 2 slides to slide # 5.

If you don't have a "Submission Response" task under the "Incomplete Task" tab, proceed to the next slide.



Account: [Redacted] Department: [Redacted] Navigation: Home

Home Logout Help

My Studies Back

Display my studies by: IRB Number Filter my studies by study status: All Find by IRB Number: [Redacted] Find by Study Nickname: [Redacted]

1 result(s) found...

Table with 8 columns: Click to open, Study Status, IRB Number, IRB Expiration, Principal Investigator, Study Title/ Study Nickname, Copy Study, Delete Study. Row 1: Open, Approved / C, [Redacted]

Click on Open



Account: [Redacted]
Department: [Redacted]
Navigation: Home > my studies

Home Logout Help

Submissions Back

Table with 2 columns: Study Status (Pending - Submitted for Initial Review), Study Title [Redacted], Expiration Date:

Submissions Study Management

Main content table with columns: Protocol Items, Submission Forms, Outstanding Submission(s). Includes a 'Process' button and a 'Respond to Review' button. A blue arrow points to the 'Process' button with the text 'Click here to open Submission Response Form'.

Form

No recommendation entered.

Stipulations

- 1. [MODS REQUESTED 11/3/2010]
Please attach the NIH subaward to this protocol so that the IRB can...
Stipulation Type: Stipulation must be addressed
* Do you accept the Stipulation?(provide explanation)

Yes

Read the IRB's stipulations and Comments. Change the answer for "Do you accept the Stipulation?" to either "Yes" or "No". And click on the "Details" button to write your response.

Comments that must be addressed

No Stipulation entered.

Comments

No Stipulation entered.

Response Comments

Provide a summary of the changes or corrections you made in response to the recom...

[Click here to access the text editor.](#)

Scroll down and click here to open the Rich Text Editor.

BOSTON UNIVERSITY MEDICAL CAMPUS **BOSTON MEDICAL CENTER** EXCEPTIONAL CARE. WITHOUT EXCEPTION.

Account: [Redacted] Department: [Redacted] Navigation: Home

Home Logout Help

IRB PI: [Redacted] **Review Response Submission Form** Back

Printer Friendly Save Form

Form

Review Outcome Letter

Review a copy of the outcome letter:

View Letter	Date Sent	Letter Title
	03/08/2011 06:45:53 AM EST	Modification Memo
	10/02/2010 05:33:05 PM EDT	Pending Letter

In most cases, you will need to make changes to the application, consent forms, or study attachments. If this is the case, click on the green button to access the previous submission.

Previous Submission

A copy of the last submission has been created. Open it to make changes or attach revised documents.

[Click here to edit/view a revised copy of the Initial Review Submission Form.](#)

Recommendations

No recommendation entered.



Account: [Redacted]
Department: [Redacted]
Navigation: Home > review response

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IRB PI: [Redacted] Initial Review Submission Form

Back

Printer Friendly

Refresh Constant Fields

Save and Continue to the Next Section

Close Form

- Section view of the Form
- 1.0 Initial Review Submission Packet
- 2.0 Application Form
- 3.0 Consent Documents
- 4.0 Other Study Documents

Entire view of the Form

1.0 Initial Review Submission Packet

1.1 Study Title:

ATHEROSCLEROSIS RISK IN COMMUNITIES: NEUROCOGNITIVE STUDY

1.2 IRB Number:

H-29325

1.3 Principal Investigator:

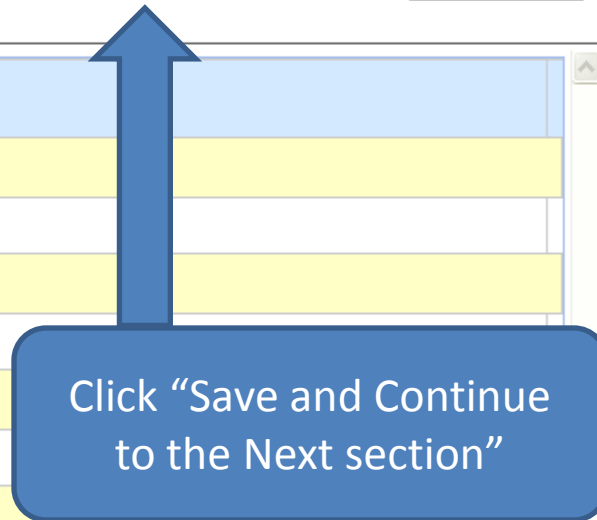
SESHADRI, SUDHA

1.4 Lay Summary:

Click here to edit the Master Lay Summary.

1.5 Special processing instructions or information about the submission:

Click here to access the text editor.



Click "Save and Continue to the Next section"

Section view of the Form

Entire view of the Form

- 1.0 Initial Review Submission Packet
- 2.0 Application Form
- 3.0 Consent Documents
- 4.0 Other Study Documents

2.0 Application Form

2.1 Attach the IRB application you completed for this protocol:
(For an Initial Submission the application will automatically attach for you)

[Click here to create a revision to the attached application.](#)

Show Rev.	Edit/View	Version	Title
		1.760116	Study Application (Version 1.760116)

To view the application (read-only) click on Edit/View.

To make changes to the application, you need to create a revision of the application by clicking on the green button.





This is the application list page. You can add/create a revision and attach it, or attach an existing one if it had been already created.

Return to your

[Home](#) [Logout](#) [Help](#)IRB PI: **Attach Study Application**[Back](#)

Click the *checkbox* to select the application(s) to attach.
Click the **Save Attachments** to attach or unattach forms.
Click the **Delete Revision** button to delete the selected application.

[Save Attachments](#)

	Show Rev.	Edit/View	Form Name	Create a Revised Application
<input type="checkbox"/>			Study Application (Version 1.769477)	 Add Revision

To add/create a new revision click here. Then click OK to confirm. This will take into the Application.



Account:
Department:
Navigation:

If instead of the previous screen shot you see this one, with no "Add Revision" to the right, this means a revision already exists that had not been submitted.

IRB
PI: Attach Stu

Click the **checkbox** to select the application(s) to attach.
Click the **Save Attachments** to attach or unattach forms.
Click the **Delete Revision** button to delete the selected application.

Delete Version

Save Attachments

	Show Rev.	Edit/View	Form Name	Create a Revised Application
<input type="checkbox"/>			Study Application (Version 1.769478)	

Click on Edit/View. This will take into the Application.

You will always need to convert to the most recent revision of the application form whenever there is one. So every time you get the popup saying "A new version of the form has been published...", Click on OK to close the popup, and then don't forget to click on the "Convert to the New Form Version" button. If you don't get this popup, skip to the next screen shot.

Navigation: Home > my study > study mgmt. > review > change request > attach

IRB PI: **Study Application** Back

Print Friendly Convert to the New Form Version 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 KSP Information
- 5.0 IAA
- 6.0 COI & Study Site Information
- 7.0 Funding Source
- 8.0 Review Path Determination
- 9.0 Study Summary
- 10.0 Purpose
- 11.0 Protocol Risk/Subjects
- 12.0 Design/Procedure
- 13.0 Sample Size/Data Analysis
- Potential

Entire view of the Application

1.0 Message from webpage

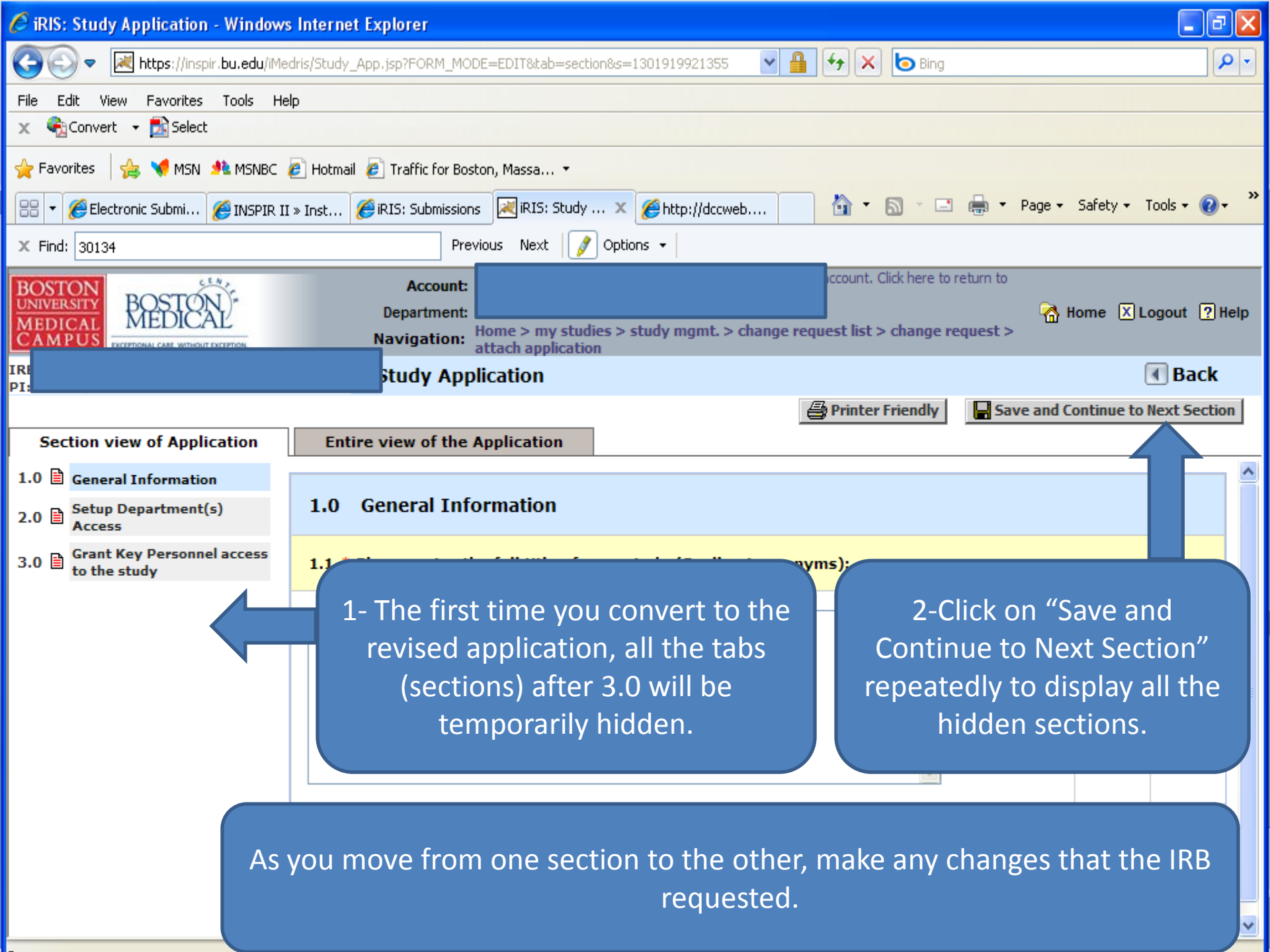
1.1 A new version of the application form has been published. Please click on the button **Convert to the New Form Version**. Then click through the wizard to verify that the application is complete.

OK

1.2 * Please enter the Study Nickname you would like to use to reference the study:

29779

* This field allows you to enter an abbreviated version of the Study Title to quickly identify this study.



1- The first time you convert to the revised application, all the tabs (sections) after 3.0 will be temporarily hidden.

2- Click on "Save and Continue to Next Section" repeatedly to display all the hidden sections.

As you move from one section to the other, make any changes that the IRB requested.

BOSTON UNIVERSITY MEDICAL CAMPUS BOSTON MEDICAL EXCEPTIONAL CARE. WITHOUT EXCEPTION.

Account: [Redacted] Department: [Redacted]

Navigation: Home > my studies > study mgmt. > review response > change request

Home Logout Help

Attach Study Application Back

After you get to the last section of the application and click "Save and Continue to Next Section", the system will bring you back to this page.

<input checked="" type="checkbox"/>	Show Rev.	Edit/View	Form Name	Revision	Application
<input checked="" type="checkbox"/>			Study Application (Version 1.769478)		

1-Make sure this check box is checked before clicking "Save Attachments"

2- Click on "Save Attachments" to attach this revision to the submission.

Delete Version Save Attachments



Account: [Redacted]
Department: [Redacted]
Navigation: Home > review response

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IRB PI: [Redacted] Initial Review Submission Form

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Printer Friendly Refresh Constant Fields Save and Continue to the Next Section Close Form

Section view of the Form

Entire view of the Form

- 1.0 Initial Review Submission Packet
- 2.0 Application Form
- 3.0 Consent Documents
- 4.0 Other Study Documents

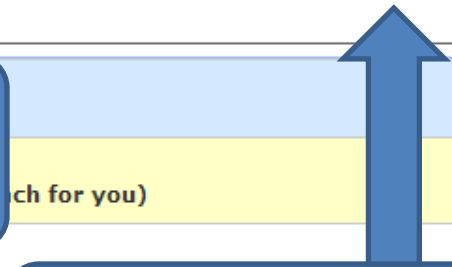
2. [Redacted]
2. [Redacted]

If successfully attached, the revision should show up here.

Click here to create a revision to the attached application.

Show Rev.	Edit/View	Version	Title
		1.760116	Study Application (Version 1.760116)

Click "save and Continue to the Next Section"





Account: [Redacted]
Department: [Redacted]
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IRB PI: [Redacted]

Initial Review Submission Form

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Printer Friendly

Refresh Constant Fields

Save and Continue to the Next Section

Close Form

Section view of the Form

Entire view of the Form

- 1.0 Initial Review Submission Packet
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- 4.0 Other Study Documents

3.0 Consent Documents

3.1 Attach the informed consent documents (consent/assent forms, consent scripts) to this protocol:

[Click here to attach a new informed consent.](#)

No informed consent has been associated with this submission.

Click on "Save and Continue" when you're done.

If you need to add or make changes to the consent form(s), click on this button. Click on one of the links below for instructions on how to:

- [Add a new consent Form](#)
- [Revise a consent form](#)



Account: [Redacted]
Department: [Redacted]
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IRB PI: [Redacted]

Initial Review Submission Form

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Refresh Constant Fields

Save and Continue to the Next Section

Close Form

- Section view of the Form
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- 2.0 Application Form
- 3.0 Consent Documents
- 4.0 Other Study Documents

Entire view of the Form

4.0 Other Study Documents

4.1 Attach the other study documents (e.g. protocol, investigators brochure, recruitment case report forms, study handouts or other miscellaneous documents):

Click here to attach any study document.

Show Rev.	Edit/View	Ver	Category	Title
		1.760 02/11	1 Section K2 : HIPAA Form(s)	HIPAA Exempt For [Redacted]
				Scope of work.doc

Click on "Save and continue" when you're done.

If you need to add or make changes to a Study Document, click on this button. Click on one of the links below for instructions on how to:
[-Add a new document](#)
[-Revise an existing document](#)



Account: [Redacted]
Department: [Redacted]
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IRB PI:

Initial Review Submission Form

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Printer Friendly Close Form

- Section view of the Form
- 1.0 Initial Review Submission Packet
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- 4.0 Other Study Documents

Entire view of the Form

Form has been Completed!

Exit Form

Click "Exit Form"

Form

No recommendation entered.

Stipulations

1. [MODS REQUESTED 11/3/2010]
Please attach the NIH subaward to

Stipulation Type: Stipulation must

* Do you accept the Stipulation?(provide

Yes

1- Make sure you answered with "Yes" or "No" the question "Do you accept the Stipulation?" for each one of the Stipulation.

2- Click on "Save Form"

Comments that must be addressed

No Stipulation entered.

Comments

No Stipulation entered.

Response Comments

Provide a summary of the changes or corrections you made in response to

Click here to access the text editor.

If you want to add/edit your response in the "Response comments", scroll down and click here to open the Rich Text Editor.



Account: [Redacted]
Department: [Redacted]
Navigation: Home

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IRB PI: [Redacted]

Review Response Submission Form

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Printer Friendly

Form

Form has been Completed!

Click on one of these buttons to proceed

- Exit Form
- Signoff and Submit
- Return to Form



Account: [Redacted]
 Department: [Redacted]
 Navigation: Home > my studies

Under someone else's account. Click here to return to your

If you decided to send later, here is where you send it to the PI for signoff and then to the IRB, when you are ready to do that.

IRB PI: [Redacted]

Submissions

Expiration Date:

Submissions Study Management

Protocol Items	Submission Forms	Outstanding Submission(s)											
<ul style="list-style-type: none"> Application Informed Consent Other Study Documents Miscellaneous Study Correspondence Submissions History Study Notebook 	<ul style="list-style-type: none"> Adverse Event Form Change Request & Amendments Initial Review Submission Form Protocol Deviation/Violation Form Protocol Exception Form 	<table border="1"> <thead> <tr> <th>Track Location</th> <th>Ref Number</th> <th>Request Type</th> <th>Process</th> </tr> </thead> <tbody> <tr> <td>Routing In Process</td> <td>760116</td> <td> Click on the hyperlink to edit/view the submission. IRB has requested a Submission Response for Initial Review Submission Form </td> <td> Send Submission </td> </tr> </tbody> </table>	Track Location	Ref Number	Request Type	Process	Routing In Process	760116	Click on the hyperlink to edit/view the submission. IRB has requested a Submission Response for Initial Review Submission Form	Send Submission			
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