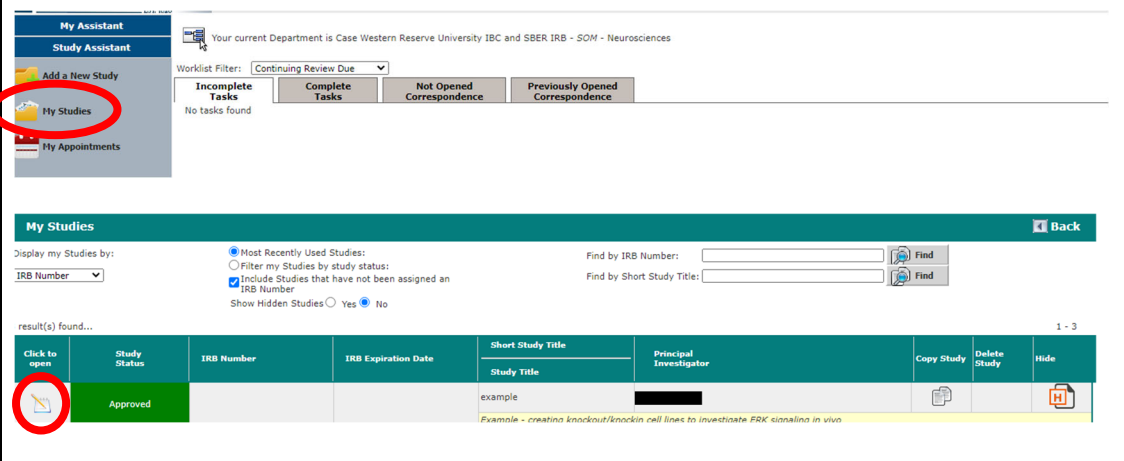
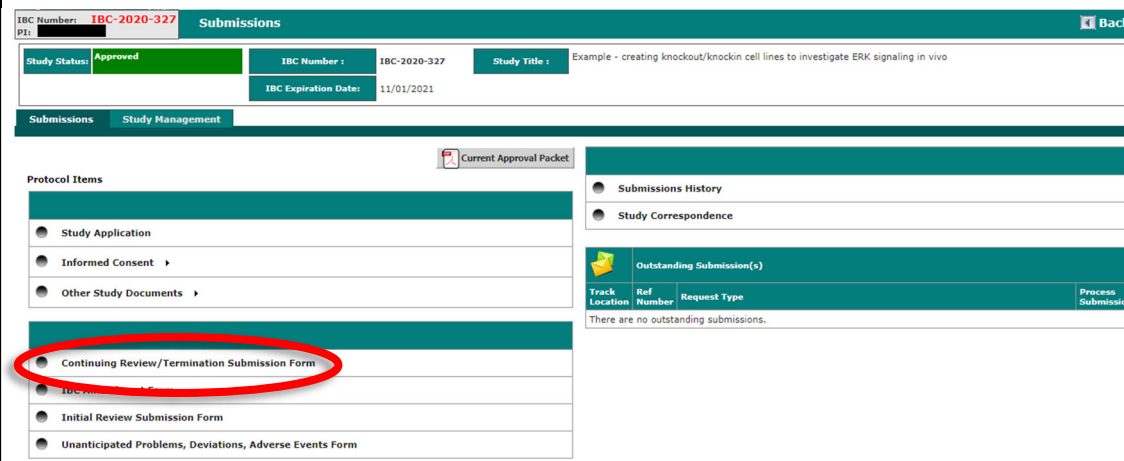
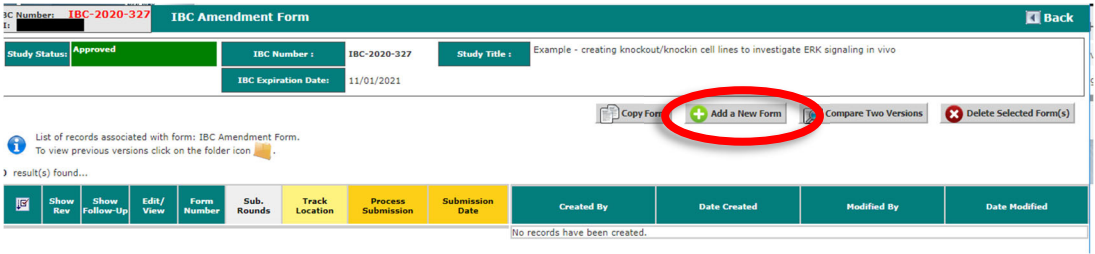


IBC Continuing Review Submission

- Continuing Reviews (CRs) must be reviewed and approved at an IBC meeting, which occurs monthly. It is important to determine the meeting date prior to the expiration of the study.
- The CR submission should be received by the IBC office one month prior to the meeting date.

How do I submit a Continuing Review?

Step 1	<p>Log into iRIS: https://spartaIBC.case.edu. On the Home screen, click My Studies on the left, and open the study that is due for continuing review.</p>  <p>The screenshot shows the 'My Assistant' interface. On the left sidebar, 'My Studies' is circled in red. The main area shows a 'Worklist Filter' set to 'Continuing Review Due' and a table of tasks. Below that, the 'My Studies' section is visible with search filters and a table of study results. One study row is circled in red, showing a status of 'Approved'.</p>
Step 2	<p>On the left-hand side of the screen, on the lower section, select IBC Continuing Review form.</p>  <p>The screenshot shows the 'Submissions' page for a study with IBC Number IBC-2020-327. The 'Protocol Items' list on the left includes 'Continuing Review/Termination Submission Form', which is circled in red. Other items include 'Study Application', 'Informed Consent', and 'Other Study Documents'.</p>
Step 3	<p>Click the button to Add a New Form.</p>

	 <p>The screenshot shows the 'IBC Amendment Form' interface. At the top, it displays the IBC Number (IBC-2020-327) and the Study Title (Example - creating knockout/knockin cell lines to investigate ERK signaling in vivo). Below this, there are buttons for 'Copy Form', 'Add a New Form' (circled in red), 'Compare Two Versions', and 'Delete Selected Form(s)'. A table below lists records associated with the form, with columns for 'Show Rev', 'Show Follow-Up', 'Edit/View', 'Form Number', 'Sub. Rounds', 'Track Location', 'Process Submission', 'Submission Date', 'Created By', 'Date Created', 'Modified By', and 'Date Modified'. The table is currently empty, with a message 'No records have been created.'</p>
<p>Step 4</p>	<p>Complete the Continuing Review Form. Click Save and Continue to move through the pages.</p> <p>Be sure to complete Section 4.2, providing an update from the last approval.</p>
<p>Step 5</p>	<p>If you need to edit the protocol, please select one of the first 6 boxes.</p> <p>Key Personnel – individuals who have iRIS accounts and access to the protocol Lab/study Personnel – individuals who are conducting experiments but do not need access to the protocol in iRIS</p> <p>For Clinical Trials, you <u>must</u> check the “Clinical Trials Details” box in Section 5.1.</p> <p>Summarize any changes to the protocol in the text box.</p> <p>**All changes must also be made in the study application, see Step 7.</p> <div data-bbox="326 1199 1386 1850"><h3>5.0 Additional Protocol Changes</h3><p>5.1 Please note if any of the following areas of your approved protocol require updating:</p><p>If this is a clinical trial, please check 'Clinical Trial Details' below even if there have been no changes to the original protocol.</p><ul style="list-style-type: none"><input type="checkbox"/> Key Study Personnel (have account in iRIS)<input type="checkbox"/> Funding source/new grant<input type="checkbox"/> Lab/study personnel<input type="checkbox"/> StudyPlan/Design (the nature of the recombinant material/location of recombinant experiments)<input type="checkbox"/> Recombinant Nucleic Acid Details (change in virus/pathogen/cel line/gene of interest)<input type="checkbox"/> Animal Details (change in species)<input type="checkbox"/> Clinical Trials Details<p>5.2 If applicable, provide a detailed description of the proposed changes to the IBC protocol.</p><div data-bbox="347 1619 865 1829"></div></div>

Complete the Clinical Trials Information page, and indicate if there are any study team changes or changes to the approved IBC protocol. There are also sections to upload any revised documents.

6.0 Clinical Trial Information

6.1 How many patients have been enrolled in this study during the last year?

At all sites:

At University Hospitals:

6.2 Have any adverse events occurred over the past approval period? *(If yes, please attach an Adverse Events Report below.)*

Yes No

How many of these occurred at University Hospitals?

6.3 Was an adverse event report made?

Yes No

6.4 To whom were the reports sent?

Please check all that apply.

CWRU IRB
 CWRU IBC
 FDA
 NIH Office of Biotechnology Activities
 Other:

6.5 Do you need to update your approved protocol to reflect any modification made in the last year?

Yes No

6.6 Do you need to make any changes to the study personnel listed on the approved protocol?

Yes No

6.7 Please use the link below to attach any additional documents.

Select or Revise Existing
+ Add a New Consent

Detach	Version	Title	Category	Language	Expiration Date	Consent Outcome	Checked Out	View Document
No Consent(s) have been attached to this form.								

6.8 Please use the link below to attach additional documentation related to the continuation of this study.

Select or Revise Existing
+ Add a New Document
++ Add Multiple Documents

Detach	Version	Title	Category	Expiration Date	Document Outcome	Checked Out	View Document
No Document(s) have been attached to this form.							

Step 6

Changes to Study Personnel reflect any key personnel that will need access to the study in iRIS. They must have an account in the IBC system to be added. Otherwise, they can be added to the study team member page within the study application.

Step 7


To edit the IBC study application, you will need to click the button to attach the application.

Entire view of the Form

8.0 Protocol Modification




8.1 You indicated that certain areas of your IBC protocol require updating.

Please click the link below to be taken to a screen that will allow you to revise your application to reflect the changes you wish to make. You do not need to alter any section other than that you wish to update. Your original and/or previously modified application(s) will remain unchanged and still be available to you.

 [Click here to attach the application.](#)

Application has been associated with this submission.


8.2 Please click the link below to be taken to a screen that will allow you to upload your study documents.



 [Select or Revise Existing](#)  [Add a New Document](#)  [Add Multiple Documents](#)

Detach	Version	Title	Category	Expiration Date	Document Outcome	Checked Out
No Document(s) have been attached to this form.						

Then select "Add Revision"

Attaching Study Application

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




Select	Show Rev.	Edit/View	Form Name	Approved	Create a Revised Application
Already Submitted			Study Application (Version 1.0)	Yes	 Add Revision

And Confirm.

Step 8

You will now have an editable study application, and you will need to select the sections on the left that you need to update. Be sure to hit Save and Continue in the upper right on each page there are changes.

IBC Number: **IBC-2020-327** Study Application (Version 1.1)

Section view of Application | Entire view of the Application

1.0 General Information

* Please enter the full title of your study:

Example - creating knockout/knockin cell lines to investigate ERK signaling in vivo

* Short Title For Your Reference Only:

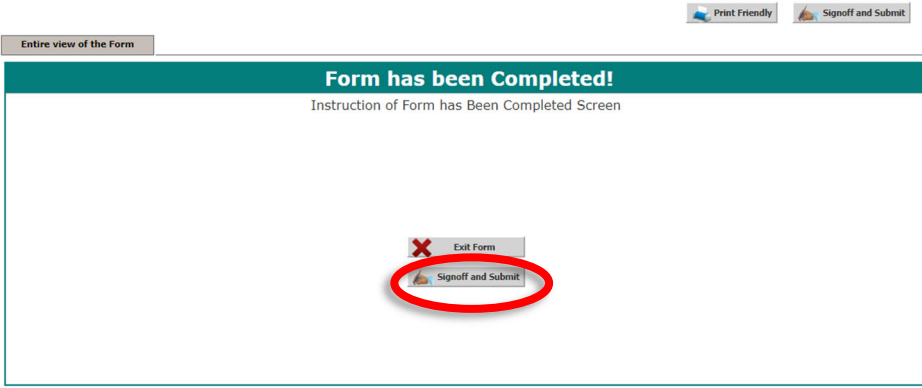
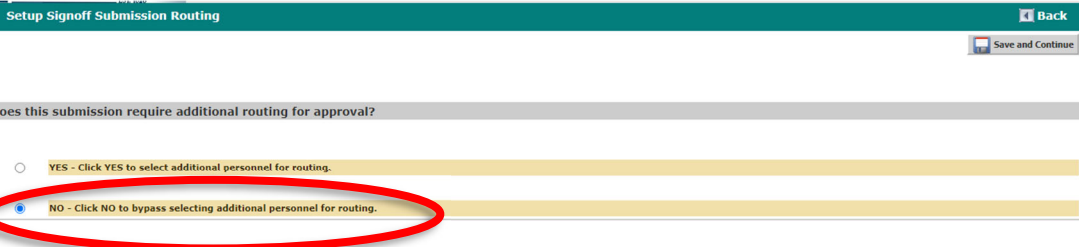
example

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

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case-ibc@case.edu

Step 9	Once you have completed the changes, hit Save and Continue through the end of the form. You will then be taken back to the IBC Continuing Review, and will see the revised application attached. Hit Save and Continue.
Step 10	Complete the Compliance Verification page. Hit Save and Continue.
Step 11	<p>The form has been completed. If the PI created the form, then there will be a button to Signoff and Submit. If someone else created the form, there will be a button to Notify PI for signoff. The PI can login to iRIS, and there will be a task on the Home page for Submission Routing Signoff.</p> 
Step 12	<p>At Signoff, no additional routing is needed.</p>  <p>Everything attached to the Continuing Review Submission form will be listed on the signoff page. The PI will need to click the button for “Approve” at the bottom of the signoff page, and provide a CWRU ID and password. Hit Save Signoff in the upper right.</p>

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Submission Routing Signoff Back Save Signoff

Study Title: Example - creating knockout/knockin cell lines to investigate ERK signaling in vivo
Submission Reference Number: 012418 Printable Version

Include in PDF Packet	Submission Component Name - Version
Submission Form(s)	
<input type="checkbox"/>	IBC Amendment Form - (Version 1.0)
Application	
<input type="checkbox"/>	Study Application - (Version 1.1)

Evan Deneris as Responsible/Principal Investigator, do you Approve or Deny this submission? Approve Deny

This form requires your electronic signature. Please enter your User ID & Password: User ID: Password: Save Signoff

More questions? Contact the Institutional Biosafety Committee:
case-ibc@case.edu