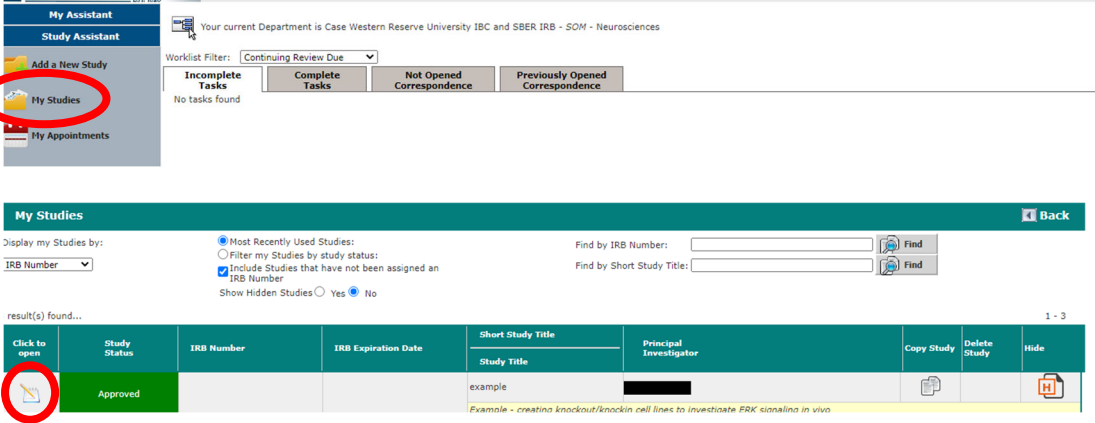


IBC Amendment Submission

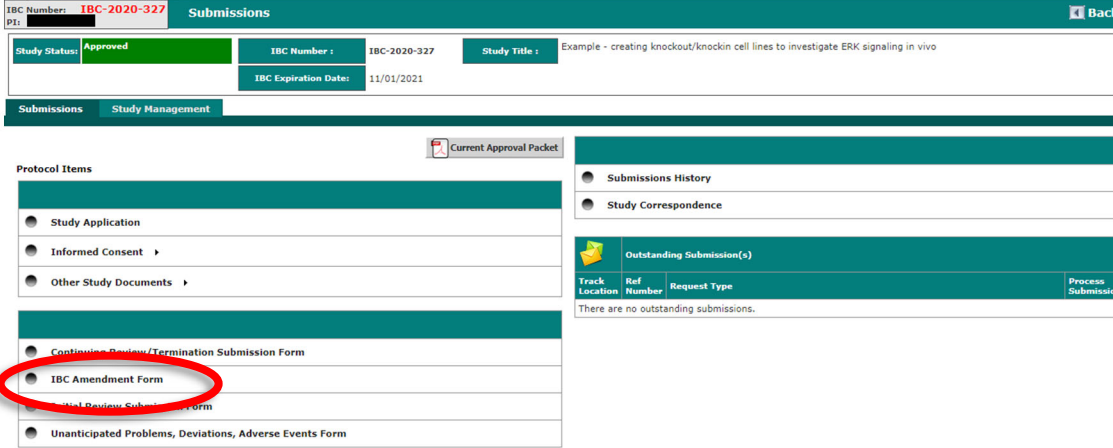
- When a study is changing after initial approval, an amendment requesting changes must be submitted **prior** to the implementation of these changes.
- Amendments limited to personnel and funding changes will be reviewed and approved administratively. All other amendment must be reviewed and approved at an IBC meeting; the amendment submission should be received by the IBC office one month prior to the meeting date.

How do I submit an Amendment?

Step 1 Log into iRIS: <https://spartaIBC.case.edu>. On the Home screen, click My Studies on the left, and open the study that you need to modify.



Step 2 On the left-hand side of the screen, on the lower section, select IBC Amendment form.



The screenshot for Step 2 shows the 'Submissions' page for study IBC-2020-327. Under the 'Protocol Items' section, the 'IBC Amendment Form' is highlighted with a red circle. Other options include 'Study Application', 'Informed Consent', 'Other Study Documents', 'Continuing Review/Termination Submission Form', 'Final Review Submission Form', and 'Unanticipated Problems, Deviations, Adverse Events Form'.

Step 3

Click the button to Add a New Form.

The screenshot shows the 'IBC Amendment Form' interface. At the top, there is a header with 'IBC Numbers: IBC-2020-327' and 'IBC Amendment Form'. Below this, there are fields for 'Study Status: Approved', 'IBC Number: IBC-2020-327', and 'Study Title: Example - creating knockout/knockin cell lines to investigate ERK signaling in vivo'. There is also a field for 'IBC Expiration Date: 11/01/2021'. A toolbar contains several buttons: 'Copy Form', '+ Add a New Form' (circled in red), 'Compare Two Versions', and 'Delete Selected Form(s)'. Below the toolbar, there is a section for 'List of records associated with form: IBC Amendment Form.' and a table with columns: '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 currently shows 'No records have been created.'

Step 4

Complete the Amendment Notification Form. Click Save and Continue.

For personnel changes:

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

The screenshot shows the 'CWRU IBC Amendment Notification Form'. At the top right, there are buttons for 'Print Friendly', 'Save Section', and 'Save and Continue to Next Section' (circled in red). The form is titled '1.0 CWRU IBC Amendment Notification Form'. It contains several sections: '1.1 What sections of your IBC protocol will be changed? (Check all that apply.)' with checkboxes for 'Key Study Personnel (PI, CO-1, coordinator - individual has account in iRIS)', 'Lab/Study Team Members (research staff, graduate students)', 'Funding Source/ New Grant', 'StudyPlan/Design (the nature of the recombinant material/location of recombinant experiments)', 'Recombinant Nucleic Acid Details (change in virus/pathogen/cell line/gene of interest)', 'Animal Details (change in species)', and 'Clinical Trials Details'. '1.2 Provide a detailed description of the proposed changes to the IBC protocol.' with a text area. '1.3 Will your proposed amendment change the Risk Group or Biosafety containment level of your experiments?' with radio buttons for 'Yes' and 'No'. '1.4 Does this amendment request require approval from any other regulatory bodies?' with checkboxes for 'None', 'IRB', 'IACUC', 'EHS', and 'Other:'. Below this is a text field for 'Other, please explain:'. '1.5 If yes, have you received approval?' with radio buttons for 'Yes' and 'No'.

Step 5

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

IBC Number: IBC-2020-327 IBC Amendment Form - (Version 1.0) Back

Print Friendly Save Section Save and Continue to Next Section

Section view of the Form Entire view of the Form

1.0 CWRU IBC Amendment Notification

2.0 Application Modification

2.0 Application Modification

2.1 By clicking the link below you will 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. If your only modifications are to your Key Study Personnel, you do not need to modify your application at this time.

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

2.2 Do you have any additional study document to attach?

Yes No

Then select “Add Revision”

Application Modification

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
Already Submitted			Study Application (Version 1.0)	Yes	Add Revision

And Confirm.

imedris-test.cwru.edu says

Confirm the adding a revision.

Are you sure you want to create a revision?

Step 6

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.

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

Print Friendly Save Section Save and Continue to Next Section

Section view of Application Entire view of the Application

1.0 General Information

2.0 Setup Department(s) Access

3.0 Grant Key Personnel access to the study

4.0 Case Western Reserve University Application

5.0 Clarification of Need for Review by the CWRU IBC

6.0 CWRU IBC - General Information

7.0 CWRU IBC - Study Team

8.0 CWRU IBC - Funding

9.0 CWRU IBC - Study Description/Plan

10.0 CWRU IBC - Animal Details

CWRU IBC - Recombinant Nucleic Acid/Recombinant Material Det...

11.0

12.0 Next steps:

13.0 CWRU IRB has moved to SpartaIRB.case.edu

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.

Step 7

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 Amendment form, and will see the revised application attached. Hit Save and Continue.

BC Number: IBC-2020-327
IBC Amendment Form - (Version 1.0)

Print Friendly Save Section Save and Continue to Next Section Back

Section view of the Form Entire view of the Form

1.0 CWRU IBC Amendment Notification

2.0 Application Modification

2.0 Application Modification

2.1 By clicking the link below you will 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. If your only modifications are to your Key Study Personnel, you do not need to modify your application at this time.

Detach Revise/Attach Edit/View Print Study Application (Version 1.1)

2.2 Do you have any additional study document to attach?

Yes No

Step 8

You will see the Next Steps page, hit Save and Continue.

BC Number: IBC-2020-327
IBC Amendment Form - (Version 1.0)

Print Friendly Save Section Save and Continue to Next Section Back

Section view of the Form Entire view of the Form

1.0 CWRU IBC Amendment Notification

2.0 Application Modification

3.0 Next steps

3.0 Next steps

3.1 Thank you for creating your request to modify your IBC application. By clicking 'Save and Continue' above, you will be taken to the Routing and Signoff screens. You will be notified electronically once the IBC has received your request. If you have any questions, please contact Colleen Karlo at 368-0838.

Step 9

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.

IRIS USER GUIDE

CWRU ADMINISTRATION OFFICE

case-ibc@case.edu

IBC Number: IBC-2020-327 IBC Amendment Form - (Version 1.0) Back

Print Friendly Signoff and Submit

Section view of the Form Entire view of the Form

1.0 CWRU IBC Amendment Notification
2.0 Application Modification
3.0 Thank you- end

Form has been Completed!
Instruction of Form has Been Completed Screen

Exit Form
Signoff and Submit

Step 10 At Signoff, no additional routing is needed.

Setup Signoff Submission Routing Back

Save and Continue

Does this submission require additional routing for approval?

YES - Click YES to select additional personnel for routing.

NO - Click NO to bypass selecting additional personnel for routing.

Everything attached to the Amendment 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.

Submission Routing Signoff Back

Save Signoff

Printable Version

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

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

Evan Deneris as Responsible/Principal Investigator or 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