AMENDMENT SUBMISSION FORM

It is highly recommended that you make all changes to the study application PRIOR to starting the amendment application.

Login Information

The link to the iRIS website is https://www.irb.nih.gov. This will bring you to the main login page. The system works best using either Internet Explorer 9.0 or higher for PC users or Safari 6.0 or higher for Mac Users. The system may also be used in Google Chrome or Mozilla Firefox but users have noted some errors when using the system in those browsers. The users username and password are their NIH credentials. Remember, the system is behind the NIH firewall and you must be logged into VPN to access the system from outside the NIH network.

After logging in you are in the iRIS Home Page. This is where you will manage all studies you are associated with using the Study Assistant.

Navigation Information
For creating a new study

Displays all studies that you are listed as a KSP (PI, AI, study contact, etc.)

From any iRIS screen you can return to the home page by selecting the Home icon in the upper right-hand corner. Breadcrumb links will also appear at the top of the page as you navigate through the forms.

When navigating within the system, please use the back button located in the upper right-hand corner of the screen instead of the browsers back button.
To view all studies where you are a KSP, click the “My Studies” button on the main page. This page displays the Protocol Title, Study Status, IRB Number, IRB Expiration Date, and Principal Investigator. To open a protocol, click on the notepad icon under “Click to Open”. To “Hide” a protocol, select the Hide Button on the far right of the list. If selected, this protocol will no longer appear in the list. You can show hidden studies by selecting Yes to Show Hidden Studies in the top search box.

To open a protocol

If you click the notepad, this will bring you to the main home page for the Protocol. From this screen you can select a form for submission, review the submission history, view study documents, and make edits to the Study Application. It will also show any outstanding (pending) submissions waiting for approval. The forms are listed in Alphabetical Order.

From the main protocol page, click on the Amendments hyperlink under IRB Forms. This will open the main Amendments landing page.
On this page, any amendments will be listed in a table. To create a new amendment, click the “Add a New Form” button in the upper right-hand corner.

**Section 1.0 General Protocol Information**

**Section 1.1-1.4.** These fields are pre-populated from the Study Application. No edits can be made on this form. To change any information, update the Study Application then relaunch the form.

**Section 1.5 Protocol Version and/or Consent Date.** Enter the date that is on the FRONT PAGE of the most recent Protocol or Consent.

**Section 1.6 Are you submitting an amendment for a project which previously received an exemption?** Indicate Yes or No **Note:** If yes, the page will skip sections 1.7-1.9.
Section 1.7 Version Letter/Number. This is the next sequential letter or number. For approved protocols, the most recent amendment number will be the last letter in the IRB number. For example, 11C0136M. The version letter entered on this screen would be N as it is the next letter.

Section 1.8 Listed below are outstanding stipulations from previous actions. This pulls from the previous action.

Section 1.9 Does the Amendment require Scientific Review? Indicate Yes or No

Section 1.10 Are there any changes to Key Study Personnel (NIH or Non-NIH) Indicate Yes or No

Section 2.0 NIH Employee and Non-Employee Key Personnel Changes

Note: this section only appears if Yes was answered for Section 1.10.
Section 2.1 NIH Employee KSP Changes  Reminder: This section is for NIH Employees as listed in their NED directory entry. To add NIH staff, click the “Add” button next to the appropriate category.

To select the investigator, you only need to enter the name; the search field defaults to iRIS Database; select Find button.

If the investigator does not have an iRIS account, you will need to select LDAP Directory (this pulls from NED). Note: When adding investigators using the LDAP Directory, you will need to submit a request to nihirbsupport@nih.gov to request account activation. Include in the request the investigator name, their role, and Institute/Branch name.

After finding the investigator(s) name, Select User by clicking on the green check mark.

<table>
<thead>
<tr>
<th>Check for Multiple</th>
<th>Select User</th>
<th>Training</th>
<th>User Name</th>
<th>Branch</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>✔</td>
<td></td>
<td>Tessema, Naol</td>
<td>OD (primary)</td>
</tr>
</tbody>
</table>

You will now choose their role from the pick list.

A) Additional Investigators

<table>
<thead>
<tr>
<th>Add</th>
<th>Name</th>
<th>Role</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Tessema, Naol</td>
<td>Associate Investigator</td>
</tr>
</tbody>
</table>

Continue adding additional personnel as necessary by selecting the Add User button and repeating the above steps. You can add all names first then select the roles.
If you need to remove someone that you have added in error, put a check in the box to the left of the name and select the **Remove** button.

To Remove Existing Personnel from the list, select the “Select” button in the last section

This will open a list of the NIH Personnel. To remove check the box to the left of the name then hit the “Save Selections” button.
Section 2.2 Are there any changes to Non-NIH KSP? Indicate YES or NO. Note: All changes to this section must be made in the Study Application.

Section 2.3 Are all KSP allowed BTRIS access? Indicate YES or NO. If no, enter the names of individuals who SHOULD NOT have access.

Section 2.4 PI Training Certification. Check the box to indicate the PI is attesting that ALL investigators have met the requirements for the Protection of Human Subjects. If they cannot, enter an explanation in the box provided.

Section 3.0 Amendment Information

Section 3.1 Provide a justification for all changes. Enter all changes with justification in this section. It is acceptable to copy and paste from the Amendment Cover Memo. Formatting tools are available in the box.
Section 3.2 Will the changes alter the risk/benefit assessment as defined by 45 CFR Part 46.111? Indicate YES or NO. If yes, please enter an explanation.

Section 3.3 Are there changes to the Informed Consent Documents? Indicate YES or NO. If yes, Section 3.4 will appear.

Section 3.4 Are subjects enrolled in the study? Indicate YES or NO. If yes, complete additional information.
Section 3.5 Addition or Changes to Recruitment Materials/Participation Letters/Information Sheets? Indicate YES or NO

Section 4.0 Research Sites

Section 4.1 Changes in the research sites? Indicate YES or NO.

Section 5.0 Tech Transfer

Section 5.1 Does the amendment impact or require a Tech Transfer Agreement? Indicate YES or NO. If yes, complete additional information.
Section 6.0 Study Population

Section 6.1 Changes to Accrual Ceiling. Indicate YES or NO.

Section 7.0 IND/IDE/Commercial

Section 7.1 Change in or addition of an IND/Biologic/Device or Tobacco Product? Indicate YES or NO. If yes, enter all applicable changes on the table below.
Section 7.2 Change in or addition of a commercial product? Indicate YES or NO. If yes, complete all applicable changes in the table.

Section 8.0 Conflict of Interest

Section 8.1 Is this a covered protocol? This information is taken from the study application and cannot be changed in the amendment form.
Section 9.0 Amendment Attachments

Section 9.1 Attach Revised Study Application Click the grey bar to attach the revised study application.

Select the correct version and click “Save Attachment”
Section 9.2 Attach the following (if applicable). Attach any additional study documents for the amendment submission. Place a check mark next to the documents on the list of documents. If other, specify in the box.

In the system, consent/assent forms are uploaded separately from the other study documents. Add the consents to the first section. To attach, click on the “Add a New Consent” button.
Select the second option to add a document from your computer and click the “Next Screen” button. This will open the attachment page.

Complete all required fields for the Consent. Enter the Consent Title. Select Browse to find the file on your computer. Enter the Version Number and Version Date. Note: The system automatically defaults to Version 1.0. Select type (tracked or clean) and language from the dropdown menus. If the language you need is not listed, submit a help desk ticket to have it added. Make sure to hit Save Consent to save this file. If you need to add additional Consents, repeat the process above.
For all other document types, enter the into the second table. In this section, you may enter single documents or multiple documents at a time. **Note:** If you are attempting to enter multiple documents, be aware that the size limit is 30mb per upload. Also, DO NOT attempt to enter more than 5 documents at a time. There is no warning if you are over the size limit and the documents will not save.

Single Document: Select browse to attach the document. Enter the Version number and Version Date. Select the Category from the dropdown menu. Make sure to hit Save Document.

Multiple Documents: Enter the Version Number, Version Date, and Category for each document. Hit the browse button next to each row to select the document from your computer. Hit the Save Documents to complete the upload.
Once all documents have been added click on the “Save and Continue to Next Section Button” This will bring up the completion page. Click “Signoff and Submit” if you are ready to submit to the IRB. Click “Exit Form” to save the form without submitting.

To signoff, the following page will appear when you Select “Signoff And Submit”. Select YES to Select individuals for signature.
A list of Signers from the Study Application will populate. Select the appropriate names and hit Save and Continue.

If additional signers are required beyond those who were selected on the previous page, they will be entered here. To add an additional signer, select the “Add Signoff” button.
This will open the search page where you can search for the individual. The system defaults to the iRIS directory for search. You may also search from the ldap directory. To select an individual, click the green check mark to select user.

To add additional individuals repeat the process. Once all signers have been added select the “Save and Continue” in the upper right hand corner.

This will bring up the final screen. Review the information to make sure all signatures are listed. To add additional signers, click on the grey boxes next to the sections. Once all your selections are complete change the No to a Yes in the green highlighted field and select “Save and Continue”
Click here to add any additional individuals

Once the “Save and Continue” has been selected, the submission has now been routed for Signature.

If the Principal Investigator is the person completing the form, they will automatically be routed to the signoff page for their approval. To approve, check the box next to the attestation. Select the Approve button, and then select “Save Signoff”