CU-p IRBNet Instructions for Submitting an Application for IRB review

CREATING AND SUBMITTING A NEW PROJECT (Your project is sometimes called “application” or “package”).

1. **Log in** to IRBNet and click on the “Create New Project” button in the left side navigation menu.

2. Fill in the Create New Project page: Enter Project Title and Principal Investigator (PI) name. Keywords are optional. If there is a funding agency known now or will be submitted to in the near future, this should be listed in the “Sponsor” box, otherwise leave this blank. Entering the TITLE and PI fields are required.

   Your internal reference number is a combination of your CU department name, the date that you first create your project (written as YYYYMMDD), and your faculty advisor last name or the PI last name. For an example: EDD-20151022-Bullis. You can write your internal reference number in that empty field if you wish.

3. You will be automatically directed to the “Designer Page”. This is where you build your project with the forms you need to complete your Application.

4. You download the forms (documents) that you require, and upload all completed documents.

   *See below in TABLE 1 a list of the required documents. You can use documents as forms/templates, and these forms/templates are described in TABLE 1.*

   **You download in step 1,** fill in, and save to your computer.

   *Note: as a “best practice” record-keeping method for saving your various IRB Application Documents, we suggest using titles that include the date that you first created your IRB application in the IRBNet system (YYYYMMDD) and your last name.

   **You upload the completed form in step 2.**

   If you already have your document that does not need a template (such as your recruitment brochure), you skip to step 2 and just upload the document.

   If you prefer receiving a file with all templates/forms available, you can request this by writing irb@cu-Portland.edu .

   When you upload (ADD or ATTACH) in step 2, you will be asked to give a document type as a descriptor. Suggestions for this is shown in the table below.

   Repeat this step to upload other forms and documents.
5. **Review your work** to be certain you have all forms and documents complied. After you **compile your project/application**, or when you want to take a break and pause your work, you can logout of IRBNet. When you logout, any and all attached forms and documents will be saved and available for your review/change when you log back in.

6. **Share your project** (if this is appropriate). For others to have access, to read, write, or have full access to your Project, you must give them (your advisor or faculty chair, your co-PI, or a key investigator in the project) Share your project. Each person must register in IRBNet before you can grant them access.

   **In the Project Administration menu**, click on the “**Share this Project**” button and click “Share.”
   - **To search for individuals**, enter “Concordia University - Portland” or CU-p IRB. Alternatively, you could search for an individual at a different institution if that intuition has been set-up as an affiliated institution in the IRBNet system. If you cannot find a person, this means they have not registered.
   - **Choose the appropriate level of access** for each individual. PIs must be given ‘Full’ access. Key Investigators who are not PIs of this specific project should be given ‘Read’ access and might also be given ‘Write’ access. However, it is good practice to communicate among your investigation team, because more than one person making changes in your application can lead major errors or other problems.

7. **Sign the Package**: The PI must either submit the package to the IRB or sign the package before another researcher submits it on their behalf.

8. **Send Mail**: You may send email messages to other project personnel via IRBNet. You can notify them the package is complete, ready for their review and/or signature, or needs additional documents. In the Project Administration menu, click on the “**Send Project Mail**” button. Select the recipients, enter your message and hit “Send”.

9. **SUBMIT YOUR PROJECT Package/Application**: You submit by clicking on the **PROJECT ADMINISTRATION** menu. If you are the PI or the PI has signed the package and you are ready to submit, click on the “**Submit this Package**” button in the Project Administration menu. If the CU-p IRB is not already pre-selected, do a search for “CU-p IRB” and select the CU-p IRB. Click “**Continue**”.
   - **Select submission type**: In these instructions, we have been focusing on a “New Project”. If this is the case, then click on “New Project”.
   - **Add notes** you would like the administrator to read or relay to the IRB.
   - Click “**Submit**”.

**Watch for emails from the CU-p IRB that will communicate the process/progress.** Within one week after the SUBMISSION, the CU-p IRB is likely to send you an email indicating that your Project/Application is assigned for review. This could be an expedited or full IRB Committee Member review. As a rule-of-thumb, expedited reviews require four (4) weeks for review and full reviews require six (6) weeks for review.
TABLE 1. THE CONTENTS FOR A FULL (COMPLETE) IRB APPLICATION, available at IRBNet.org: The following documents need to be uploaded. The table below shows the document needed and a description of the document type you might use (shown as a drop down list to choose from). You can give your own title however you wish, but it would be good to be descriptive of the content; for example, “Research Description Form” or “Cover Letter.” Do not worry about the document type—that is, whatever document you load will be visible and described by your title, but the table below shows the best type of description wording to choose for each document.

<table>
<thead>
<tr>
<th>Document to upload (saved to your computer)</th>
<th>Document type</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Research Proposal Narrative Template</td>
<td>Proposal</td>
<td>The template gives you detailed instructions.</td>
</tr>
<tr>
<td>2 Cover Letter</td>
<td>Cover Letter</td>
<td></td>
</tr>
<tr>
<td>3 Investigator Assurance</td>
<td>Investigator Assurance</td>
<td>If you cannot get your department officials to sign on the same form as you, this is okay. You will then have two uploads: for example “investigator assurance 1” and “investigator assurance 2”</td>
</tr>
<tr>
<td>4 Targeted Enrollment Table</td>
<td>Protocol</td>
<td>You pick either 5a or 5b. Use the standard form for most studies—the two population is used for case-control types of study designs</td>
</tr>
<tr>
<td>5 Consent Form ...</td>
<td>Consent Form</td>
<td>You can use the downloads available to help you construct your consent form. The 5a document gives an example for a minimum risk social science study. There are other documents to help you. If you need more help, or consultation on developing an assent form, contact the IRB Director at <a href="mailto:obranch@cu-portland.edu">obranch@cu-portland.edu</a></td>
</tr>
<tr>
<td>6 Institutional Permission Letter for off campus research</td>
<td>Letter</td>
<td>If you enter into an institution that is not Concordia University, then you need permission. If this is standard research in a United States Institution, a simple letter from the director or other authorized individual is okay. If this is an international study, we will need the letter to say that the work has been reviewed by their institutional review board or equivalent. As in all cases, studies with vulnerable subjects and/or sensitive questions will need higher level of authorization and review before the research will be approved.</td>
</tr>
</tbody>
</table>
| 7 Project Specific Research Tools            | [name this as you wish to be descriptive] | You can add as many as you want. For example, you can say “Recruitment Brochure,” “Tool1,” and/or “Tool2” .. and just continue uploading until all important/pertinent documents are loaded. Likely documents include:  
- Recruitment material  
- Survey Instruments — Copies of widely used standardized tests are not necessary.  
- Questionnaires  
- Interview Questions/Potential Questions/Protocols/Range of Topics  
- Debriefing Materials (if applicable) |

If you have any questions, please consult your faculty advisor (do this first if you have a faculty advisor or department advisor) and/or contact the CU-p IRB Director at irb@cu-portland.edu.
REVISITING AN EXISTING PROJECT IN IRBNET, Re-submission

Follow these steps to submit additional forms or modify your existing forms; either in response to an IRB review or researcher initiated.

1. Log in to IRBNet (www.IRBNet.org) and click on the title of the project you need to revise.
2. Click on the ‘Designer’ button in the Project Administration menu. Follow step 3a or 3b below depending on what you’re submitting.
3. Make changes, which can be divided into two steps: a) changing forms already submitted/reviewed and b) adding a document or form to your project.

3a. If you are making changes to any forms the IRB has already reviewed, make the changes to that form and highlight in yellow or use track changes. Save the form to your computer. (If the form you need to revise is not saved on your computer, you may download a copy of it by clicking on the sheet of paper icon next to that form in Step 2 on the ‘Designer’ page. Make your changes, highlight and save to your computer.) When you are ready to attach your revised file, click on the pencil icon next to the form (*see note).
3b. If you are adding a document to your protocol that the IRB has never reviewed, click on the “Add New Document” button under Step 2 (*see note).

*The first time you select the “Add New Document” button or use the pencil icon to replace a form, IRBNet will tell you the current package is locked. This is correct; it simply means you can’t change any documents in previous packages since they have already been reviewed by the IRB. Below that will be a button which says “Create a New Package”. Click on it. Next you will see a list of all packages in the Project history with the one you just created (‘New Document Package’) at the top with a status of Work in Progress. Click on ‘New Document Package’. You should be automatically directed back to the ‘Designer’ page.

4. Proceed with attaching your documents that you are adding or that you revised (see #3, above).
5. Share your project to new individuals if appropriate: If you are updating the Research Personnel List to add individuals who will be consenting or collecting data from research participants, you must grant them access to the protocol in IRBNet and they must be registered in IRBNet. In the Project Administration menu, click on the “Share this Project” button and select the “Share” option. Enter “CU-p IRB” or “Concordia” in the search box and select “Concordia University – Portland IRB (CU-p IRB)”. Search for individuals. If you cannot find them, they have not registered yet. Choose the appropriate level of access (see definitions of these levels on Share Project page).
6. Sign the Package, if necessary: If new personnel are added to the project, they must sign. If no new personnel are added to the project, it is NOT NECESSARY to sign the package again.
7. Send Mail: You may send email messages to other project personnel via IRBNet. You can notify them the package is complete, ready for their review and/or signature, or needs additional documents. In the Project Administration menu, click on the “Send Project Mail” button. Select the recipients, enter your message and hit “Send”.
8. Submit the Package: If you are the PI or the PI has signed the package and the package is ready to be submitted, click on the “Submit this Package” button in the Project Administration menu. If the UNCO IRB is not already pre-selected, do a search for “UNCO IRB” and select the UNCO IRB. Click “Continue”. Select submission type “Amendment/Modification” and add any notes. Click “Submit”.

Watch for emails from the CU-p IRB that will communicate the process/progress of the re-submission review. Please note that the review required for your modification is determined both by the initial review process used for your protocol and the scope of your requested modifications. For example, adding or changing research tools or components of a Full Review protocol will require Full Review by the Board; adding personnel, deleting components, or correcting grammar or language, could be handled using an Expedited review process.