

Instructions for Submitting a Request for an Exemption from IRB Review for a Retrospective Chart (or Biospecimens) Review

REQUIRED STUDY DOCUMENTS

- Submissions for an exemption for secondary research, e.g. a retrospective chart or biospecimens review require submission of a mini protocol.
 - You can find the template to use to create your protocol here:
<https://irbo.nih.gov/confluence/display/IRBO/Templates+Forms+and+Guidelines>
 - Please review the instructions in the template carefully. Then use the template to create a complete protocol. Delete all instructional language.
 - If your project will involve contractors, students or fellows (not NIH FTEs), collaborators at other institutions, or subcontractors from commercial companies, be sure to address the roles of these individuals and organizations (vs. NIH's role) under each section of the protocol.
 - If individuals are reviewing identifiable medical charts or biospecimens off site, they are required to obtain an exemption through their own institution.
- You must also upload a blank data collection sheet (see other requirements in the Protocol Template if you plan to use CRIS for your study).

IRIS ACCOUNTS

- The following individuals will need iRIS accounts prior to a new request for determination being submitted: The study contact (requestor), all of the members of the study team, including the PI (an NIH FTE who will act as the project lead) and your CD or Branch Chief.
 - If any of these individuals do not yet have an iRIS account, you will need to submit a request for a new NIH user account for them **and receive a response that the account has been activated**, before submitting. Please visit <https://iris.helpdesk.nih.gov>. Click on the tab for iRIS Accounts and then Request.

SUBMITTING IN IRIS

- All requests for exemptions must be submitted via the study application and the initial review submission form in the electronic IRB submission system (iRIS).
- iRIS, the electronic IRB submission system can be accessed here: <https://irb.nih.gov/>
- If you run into any issues while completing your submission, please email iris_training@od.nih.gov.
- Click on "Create A New Study"

Study Application

- Select "Study Application", and click on "Start selected Application"
- Section 1: If your project involves COVID-19, be sure to mention COVID-19 in the title and abbreviated title; click "Save and Continue to Next Section"
- Section 2: Only change if inaccurate; click "Save and Continue to Next Section"
- Section 3: Click on "Setup Study Personnel" in right corner

- Go through and type in last name, first name for the first member of the team, e.g. the PI. **Be sure to also add your CD or Branch Chief as “the Designated Branch/IC approval”, so you can route the submission to them for sign off as required.**
- Click on “Find User/Search Directory”

Select



- When the applicable name populates, click on
 - Then select the appropriate role for the person in the drop down.
 - Principal Investigator, NIH Investigators (**NIH FTEs**), Research Staff (**Non-Investigator NIH FTEs**) and NIH investigators who are....(**non-NIH FTEs**) should be included in their respective sections.
 - Select the specific title in the drop down next to the role
 - Be sure to click “yes” to “Would you like to include as a Study Contact” for anyone you want to receive communications/determinations about the project
 - Click “Save” and then repeat until the entire team has been added
 - Review to be sure all required staff have been included
 - When you are done, click on “Close Setup of Study Personnel”
 - Click “Save and Continue to Next Section”
- Section 4: Ignore; click “Save and Continue to Next Section”
 - Section 5.6: Precis: Briefly describe your project, the aims and the methods
 - Section 5.7: Select “Yes”; click “Save and Continue to Next Section”

Initial Review Submission Form

- Section 1.6: Select a research protocol for consideration of an exemption
- Confirm that all research staff are up to date with training and if so, check the box.
 - All individuals listed as staff on a request for an exemption for *prospective data collection* must have taken the most recent version of the **CITI Biomed 101** training.
- 1.12: Select “No”
- Click “Save and Continue to Next Section”
- 2.1: Check off all of the relevant documents you wish to upload, i.e. Other (Data Collection Sheet) and the protocol
- Upload each document separately here
 - Click on “Add Multiple Documents”
 - Add and upload your protocol and the data collection sheet as **separate documents** with the applicable version number, date and category
 - Click “Save Documents”
- When you are done, click “Save and Continue to Next Section”
- Click on “Signoff and Submit”
- Be sure to check off the Department Administrator (Branch Chief or CD) for submission routing and signoff. If his or her name is not already visible, please click on “Add Additional Personnel to the Routing List”
 - Go through and type in last name, first name.
 - Click on “Find User/Search Directory”

Select



- When the applicable name populates, click on

4 May 2020

- Then select the appropriate role for the person in the drop down.
- Click “Save – Add to Routing List”
- Click “Save – Signoff Routing List”
- Answer “Yes”, to please verify the list above represents the finalize Personnel for review and signoff
- Click on “Save – Start Signoff Routing”
- If you are the PI you will see a screen that asks you to approve or deny, click “Approve” and click on “Save Sign Off”