

Instructions for Submitting a Request for an Exemption from IRB Review for Prospective Data Collection

REQUIRED STUDY DOCUMENTS

- Submissions for exempt human subjects research, e.g. for prospective data collection involving surveys, interviews, or benign behavioral interventions 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 engaged in human subjects research activities off site, they may be required to obtain an exemption through their own institution.
- You must also upload all recruitment materials (e.g. email templates, flyers), "consent language", instructions to the subjects, and study instruments.

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 Social & Behavioral Educational Modules** training.
- 1.12: Select “Yes”
 - If you feel that your project meets one of these subcategories of Clinical Research listed, select the applicable subcategory.
 - Write your IC name in the box
 - Obtain a Z number from your branch and enter it here or write N/A
- 1.15 Study Enrollment Table:
 - If your subjects will be coming to the Clinical Center click “No” and enter your estimated planned enrollment numbers for each gender, racial and ethnic subcategory in the table.
 - If your subjects will be enrolled remotely or in person at another site in the US, click “Yes”, check “Other Domestic Sites”, and enter your estimated planned enrollment numbers for each gender, racial and ethnic subcategory in the table. (Do the same steps for the NIH CC and/or Foreign Sites as applicable.)
- Click “Save and Continue to Next Section”
- 2.1: Check off all of the relevant documents involved in your project, i.e. consent language, patient recruitment material (e.g. invitation email), Other (screening questions/questionnaire), protocol and any study instrument(s)
- Upload each document separately here

- Click on “Add a New Consent”
 - Click on “Add an informed consent from an existing electronic document” you already have; click “Next Screen”
 - Be sure to include a meaningful title, and the version number and date which matches what is in the document itself, and choose “Clean consent”; drop the file or click to upload it; then click “Save Consent”
- Click on “Add Multiple Documents”
 - Add and upload your protocol, recruitment materials, and study instrument(s) 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”
- When the applicable name populates, click on 
- 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”