

## **Instructions for Submitting a Request for Determination of Not Human Subjects Research**

- The use of de-identified specimens or data (or specimens or data from deceased individuals) for research is considered “not human subjects research”. As of Jan. 1, 2019, studies involving purely de-identified and de-linked specimens or data, no longer require a prospective submission for a determination per NIH policy.
- If you aren’t sure if what you are doing is human subjects research or an external site is **requiring** that you provide proof of a determination, so that you can receive specimens or data, please review the steps required to receive a determination below.
  - Guidance on determining whether your project involves human subjects or not is available here:  
<https://irbo.nih.gov/confluence/display/IRBO/Templates+Forms+and+Guidelines#Template+FormsandGuidelines-Guidance>
- The *Not Human Subjects Research Application* form can also be used to request determinations for projects that involve prospective collection or use of biospecimens and/or data but are not considered research at all. In this case, a determination of “Not Research” will be provided.

### **IRIS ACCOUNTS**

- The following individuals will need iRIS accounts prior to a new request for determination being submitted: the study contact (requestor), 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 determinations of "Not Human Subjects Research" must be submitted via the “Not Human Subjects Research 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](mailto:iris_training@od.nih.gov).
- Click on “Create A New Study”

#### Not Human Subjects Research Application

- Select “Not Human Subjects Research Application”, and click on “Start selected Application”
- Section 1: If your project involves COVID-19, be sure to mention COVID-19 in the full 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 lead project member, e.g. the PI and other project members, as you wish. **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”
- 
- 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**), and Designated Branch/IC Approver, 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: Respond to all questions from 4.3 – 4.14
  - If you don’t know the answers, you will need to put in placeholder responses and click on “Save Section” and “Back” and come back to it again as the form will not save unless fully completed.
  - If you don’t understand the questions, please contact [IRB@od.nih.gov](mailto:IRB@od.nih.gov).
- Click “Save and Continue to Next Section”

#### Initial IRB Review Submission Form

- Click “Save and Continue to Next Section”
- 2.0: If you wish to upload a separate description of the project, check “Protocol as a single document”
- If you wish to upload any other document, check “Other”
- If you check, “Other”, please include the names of the documents that you are uploading under “Specify other documents attached:”
- If your project involves fetal tissue, be sure to review the requirements and upload the completed Investigator Attestation I, which can be found here:  
<https://oir.nih.gov/sourcebook/ethical-conduct/special-research-considerations/policies-procedures-use-human-fetal-tissue-hft-research-purposes-intramural/procedures>
- Click “Add a New Document”
  - Drop the file or click inside the box to upload a document
  - Update the version number and version date and choose a category;
  - Click on “Save Document”
  - Repeat these steps for each document you wish to upload
- Click “Save and Continue to Next Section”
- Click on “Signoff and Submit”
- Be sure to select the Department Administrator for submission routing and signoff.
  - If his or her name is not already visible, please click on “Add Additional Personnel to the Routing List”

- Enter last name, first name and 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: Branch Chief or Clinical Director
- Click “Save – Add to Routing List”
- Click on “Save – Signoff Routing List”
- Select “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”