HUMAN SUBJECTS RESEARCH DETERMINATION REQUESTS

GENERAL INFORMATION

What Requires IRB Review?

Did you know that under IRB rules . .

- Not all interactions with human beings are considered “Research”
- Not all uses of data collected from human beings are considered “Research”

If your project is not considered Human Subjects Research (HSR) under the IRB rules, you do not need to submit an application to the IRB office.

If your project is considered HSR under the IRB rules, you must submit an application and get a review determination/approval from the IRB before you can begin your project.

In many cases, identifying an activity or investigation as HSR is relatively straightforward. There are, however, several common types of activities involving human subjects, human specimens or identifiable data, that often do not meet the regulatory definition of HSR and, therefore, do not require IRB review.

Examples of activities that do not require IRB review:

- Case studies
- Quality improvement projects
- Program evaluations
- Classroom activities
- Public health practice

Not Sure if your Study Requires IRB Review/is HSR?

Submit a HSR Determination Request (xForm) through IRBManager by following the instructions provided in this guide.

Already Know your Study is HSR?

If you are confident that your activity/investigation is indeed HSR, please submit your study for IRB review using one of the application forms found here.

GENERAL xForm TIPS

Contact Not Found: If you receive the error message “Contact not found” when entering the e-mail address of the PI in the xForm, this means that the individual is not a contact in the IRBManager System. There will be a link provided at the top of the form for you to click to add the contact to the system as needed. Once the contact is added to the system, you may then re-enter the e-mail address to continue the submission process. For more instructions on this process, click here.
Show Help: On certain sections, you will see a “Show Help” tool that you can click on for additional guidance related to that section to appear.

Add Note: Certain sections have the “Add Note” (green arrow) option. This option is available for you to provide additional clarification, if necessary, but does not substitute for listing the information in the provided fields.

If you do not answer the required questions in the appropriate fields, you will receive an error message (like the one pictured below) that will prevent you from moving forward with the application.

Incorrect Information: If the information listed in the form is deemed insufficient or incorrect, the form will be sent back to the submitter/PI for revisions/clarifications prior to issuing a determination. Please review the guidance provided in the xForm and below to ensure that the form is accepted for processing.

INSTRUCTIONS FOR HSR DETERMINATION REQUESTS

Starting an xForm Procedure:

Step 1: Log into IRB manager: https://lsuhsc-no.my.irbmanager.com/

a. Follow login instructions as listed in the quick start guide found here.

Step 2: Click on Does My Study Require IRB Review? on the left side of your screen under "Actions" to be brought directly to the HSR Determination Request xForm
OR (STEP 2 OPTION):

2a You can click on Start xForm to be brought to a screen similar to the one shown in 2b below.

2b Select the HSR xForm by clicking on the form’s title (purple link):

Once you are brought to the HSR Determination Request xForm (by either pathways listed above), a screen similar to the image below will appear:

Step 3: Enter the Title of the Proposed Title of the Research and click “Show Help” when available for specific details related to each section.

Step 4: Enter the e-mail address of the PI.

Step 5: Select the Method of HSR Determination. Currently only one option is available but that may change or continue to expand over time.

Step 6: Press “Next” to be brought to the next page.

Step 7: Answer the questions as they appear and press “Next” to advance the xForm.
Submitting the Form

After you have responded to all of the required questions, press “Next” one more time and then click “Submit” for the form to be sent to the IRB for processing.

Once you submit the form you will get the following message:

IRB Review Stage

After the xForm has been submitted, you can check the status of it by visiting your dashboard and referencing the "xForm" section. It will be listed under the # “xForms being processed at a later stage.”
Upon clicking on the # “xForms being process at a later stage,” the “Stage” column will provide the current status of the application.

If it is with the IRB, it will say “IRB Specialist Review”

### DETERMINATION NOTIFICATION AND XFORM

You will receive updates regarding the submission through e-mail notifications. You can also check the status of the xForm by visiting your dashboard as shown above.

Once a FINAL determination has been made by the IRB (HSR or Non-HSR), you will receive an e-mail similar to the one below that will include a link to the xForm you submitted as well as your official IRB Determination. **This IS YOUR OFFICIAL IRB HSR DETERMINATION.**

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**EXTERNAL EMAIL: EVALUATE**

Hello,

The Human Subjects Research (HSR) Determination Request for the study below has been reviewed by the IRB and has been determined to be Human Subjects Research.

Study Title: test  
Principal Investigator: Rome, Kadie  

**Final IRB Determination**  Human Subjects Research

IRB Reviewer Comments (if any): Submit an Exempt Application

You can access the xForm associated with this determination by clicking on the following link or visiting your dashboard:  
Human Subjects Research Determination Request

If your proposed activity is determined to be HSR, submit an appropriate study application to the IRB for review. [Click here](#) for submission details.

If your activity is determined Non-HSR, you may conduct the project within the parameters described in the HSR Determination Request application. If you intend to modify the project in any way (changes in study process, involvement of humans, etc.) please consult with the IRB Office or submit another HSR Determination Request so that the IRB staff can evaluate whether or not the study continues to fulfill Non-HSR criteria.

To access the xForm associated with this determination, select one of the following options:

**OPTION 1:** Click on the link in the determination e-mail to be brought to the xForm OR
OPTION 2: Click on the **#xForms** under **My Docs & xForms** tab on left side of menu:

Click on **#xForms**, a screen will appear similar to the one below, which shows all xForms associated with you as a user (submitter), including completed forms – find the HSR form and click on it:

Viewing and Saving a Copy of the xForm

Upon opening the completed xForm, scroll to the bottom xForm to download a pdf as needed.

If you have any questions about IRBManager please visit our [website](#) or contact the LSUHSC-NO Office of Research Services by e-mail: [IRBOffice@lsuhsc.edu](mailto:IRBOffice@lsuhsc.edu)