

Human Subjects Research Database (HSRD) Annual Check-in – Principal Investigator

Updating the HSRD Annual Check-in – Step by Step Instructions

The IRB system is available at <https://irb.energy.gov>

The HSRD Annual Check-in is for studies where a continuing review is **NOT** required. According to DOE Order 443.1C, all human subject research projects (even exempt) must be reported annually for the HSRD. In order to meet this requirement, the HSRD Annual Check-in was created. The steps for updating the HSRD for your study are listed below.

For studies that follow the Pre-2018 regulations or a 2018 regulation study requiring continuing review, the HSRD Annual Check-in does not apply.

If you do not know your IRB administrator, please visit the DOE website that lists the site IRB administrators at <https://science.osti.gov/ber/human-subjects/IRBs>.

HSRD Annual Check-In Deadline Reminder

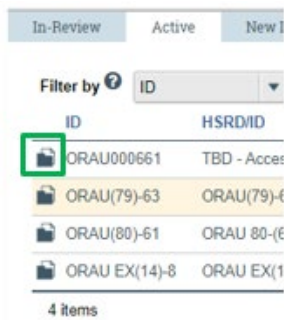
You will receive 3 email reminders to fill out the HSRD Annual Check-in for your projects. The first one goes out 30 days before the check-in is due, with subsequent reminders 14 and 7 days before the deadline. Every year, you will receive the reminders until you submit a closure to the IRB.

Note: If a Modification is submitted, this pushes back the HSRD email reminders. The check-in should be done annually based on the initial study approval date, even if you do **not receive the HSRD email reminders.**

Finding your Study

In the IRB workspace, click on the Active tab. A list of your studies will show.

Click the folder icon before the ID to open your study.

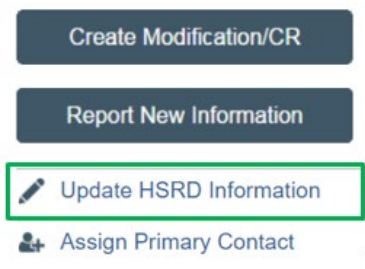


Filling out the HSRD Annual Check-in Activity

Update HSRD Information

The Update HSRD Information activity will only appear for studies that follow the 2018 regulations, no continuing review required.

Click on the “Update HSRD Information” button in the Activities section. It will open as a pop-up window. This is where you will update the HSRD information for the year.



Answers to some questions are pulled from the parent study, while other answers will need to be added during the check-in with the latest information (e.g., project status/results). Some of the answers pulled from the parent study are read-only while others are editable and can be updated if needed. If you skip a question that is required, the system will ask you to enter something.

NOTE: Depending on your answer to some questions, information may appear instructing you to submit a Modification, Closure, or an RNI to the IRB.

The HSRD update asks the following questions (questions marked * are required):

- *Include in HSRD Data
- Date HSRD Data Last Updated:
- If this project was previously reported to the HSRD please make sure the HSRD ID is the same. If this is a new project please enter the HSRD ID you would like used for this study. If you don't enter information here, the current Project ID number will be used. <read only>
- *HSRD Category:
- *HSRD Sites: <read only>
- Funding Sources:
- *Current Total FY funding from all sources not previously reported
- *Total project funding received in the last 3 FY (excluding current FY)
- Please explain the funding amount listed if zero or empty
- *HSRD Abstract
- *Project Status/Results
 - *Provide a brief summary of research activities since last reporting period [e.g., relevant recent literature, results, where you are in the project, etc.).*
 - *Please **do not** only post "study is ongoing or study is complete", this will be returned to you to update.*
- *Has the Conflict of Interest (COI) changed?
 - *Answer yes: If COI has changed, please contact your IRB Administrator.*
- *Is your study still ongoing?
 - *Answer no: If your study is closed, please submit a closure activity. On the study workspace, click "Modification/CR" button. Select Continuing Review for the purpose of the submission. On the Continuing review page for question 3, make sure to check the first four Research Milestones and the box "I acknowledge that this study will be closed" and submit the study.*
- *Has anything changed since the study was last reviewed?
 - *Answer yes: Please submit a protocol modification after completion of this form.*

Some typical types of changes include, but are not limited to: Principal Investigator change, Annual funding or total funding. Information typically updated annually for the HSRD is: Funding information (annual and total); total number of subjects, and any change in scope/abstract. Please ensure that these and any other updates are included in the system. For these types of changes, please select "Other parts of the study."

- *Do you expect anything to change in the next year?

- Answer yes: If yes, describe the changes (if changes do happen, please submit a modification prior to implementing changes)
- *Subjects enrolled at investigator’s site
- *Subjects enrolled at the investigator’s site since last approval
- *Subjects enrolled study wide
- *Number of subjects approved for the study <read only>
- *Have any problems occurred (noncompliance, adverse event, and/or anticipated problem)?
 - Answer yes: Please submit a Report New Information after completion of this form (return to the study workspace and click on the “Report New Information” button.

Once all information has been entered, click the “OK” button at the bottom to close the pop-up window. An email will be sent to the IRB Coordinator. The IRB Coordinator will request clarification from you if needed.

Clarification requests

If the IRB Coordinator requires additional information for any of your responses, he/she will send a clarification request to you. You will receive a system-generated email from the IRB Coordinator listing the issue to be fixed. Either click on the link in the email to go directly to the study or go back to the Active tab to find your study.

The clarification request will also show in the history.

History	Funding	Project Contacts	Documents	Follow-on Submissions	Reviews	Snapshots
Filter by ? Activity <input type="text" value="Enter text to search for"/> <input type="button" value="Q"/> <input type="button" value="+ Add Filter"/> <input type="button" value="x Clear All"/>						
Activity	Author	Activity Date				
Request HSRD Information Clarification	Hendricks , Jennifer	4/9/2020 9:01 AM	Need to add more information to the project status/results field.			

Open up the project workspace and click on the Update HSRD Information activity again. Your previous responses will **not** carry over, so you will need to enter all responses again. However, a copy of your previous responses can be accessed from the History tab. If you need to copy any text, click on the Update HSRD Information link in the history. It will show the information you provided when you previously updated the HSRD information. Simply copy and paste into the new Update HSRD Information activity and submit.

History	Funding	Project Contacts	Documents	Sites	Follow-on Submissions	...
Filter by ? Activity <input type="text" value="Enter text to search for"/> <input type="button" value="Q"/> <input type="button" value="+ Add Filter"/> <input type="button" value="x Clear All"/>						
Activity	Author	Activity Date				
Request HSRD Information Clarification	Hendricks , Jennifer	4/9/2020 12:24 PM	Need to add more information to the project status/results field.			
Updated HSRD Information	Hendricks, PI	4/9/2020 12:23 PM				

If you have any questions about which process you have to follow, please contact your site IRB Administrator.