HSRAP
3.0

Human Subjects Research Application Portal (HSRAP) 3.0

USER GUIDE

OFFICE OF THE SCIENCE ADVISOR, POLICY, AND ENGAGEMENT

About Human Subjects Research Application Portal (HSRAP)

Every research project involving human subjects that is conducted or supported by the EPA must be approved by the Human Subjects Research Review Official (HSRRO) before any work involving human subjects can begin. Some projects will require multiple levels of review and approval prior to the HSRRO; the specific path for review may vary depending on the origin and nature of the research. The Human Subjects Research Application Portal (HSRAP) is the online submission system that supports this review process and documents the necessary approvals.

The HSRRO and other EPA reviewers use information provided through the HSRAP to ensure that proposed studies are in compliance with Federal regulations (40 CFR 26) and Agency policies. This information will include a detailed description of the research plan (frequently contained in an IRB application), consent forms, documentation of IRB approval, and other related materials. Typically, this will require the person creating the HSRAP submission to upload existing documents.

The amount of information entered into HSRAP has been kept to a minimum to avoid duplication, and primarily serves to identify the project and the investigators and highlight key elements for the reviewers. This information also tells the system which approvers need to review the proposed project and in what order. Once the submission is complete, it will be automatically routed through the pre-determined list of reviewers, ending with the HSRRO.

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Getting Started

About the EPA's Business Automation Platform (BAP)

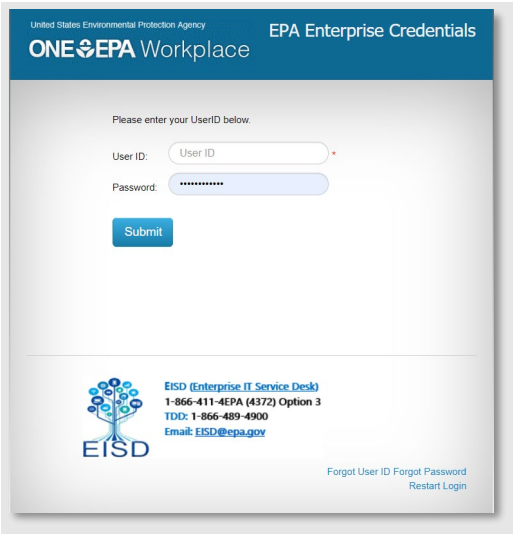
In 2017 the Office of Environmental Information (OEI) established the Agency's Business Automation Platform (BAP), based on the Force.com platform from Salesforce, an industry-leading application Platform as a Service (aPaaS) provider. The BAP supports all EPA Offices and Regions by supporting development and hosting of applications for business processes, data collection, reporting, and workflow automation.

The BAP allows development and deployment of forms, workflow automation, and reports in a declarative environment, i.e., without writing programming code. This saves the Agency time and money. It also lets application owners and developers avoid getting bogged down in infrastructure provision and management, as Salesforce handles that for them. The BAP helps you build your application with modern frameworks that handle security, user access, user interface, reporting, etc. All you have to do is concentrate on your business logic.

For more information, visit the BAP Community SharePoint. If you have any specific questions, email BAP-Support@epa.gov.

Accessing the BAP

To access the BAP, go to https://epabap.lightning.force.com. Internal EPA network users will need their EPA LAN ID and password.



Getting Started

Requesting External User Access to the HSRAP Application

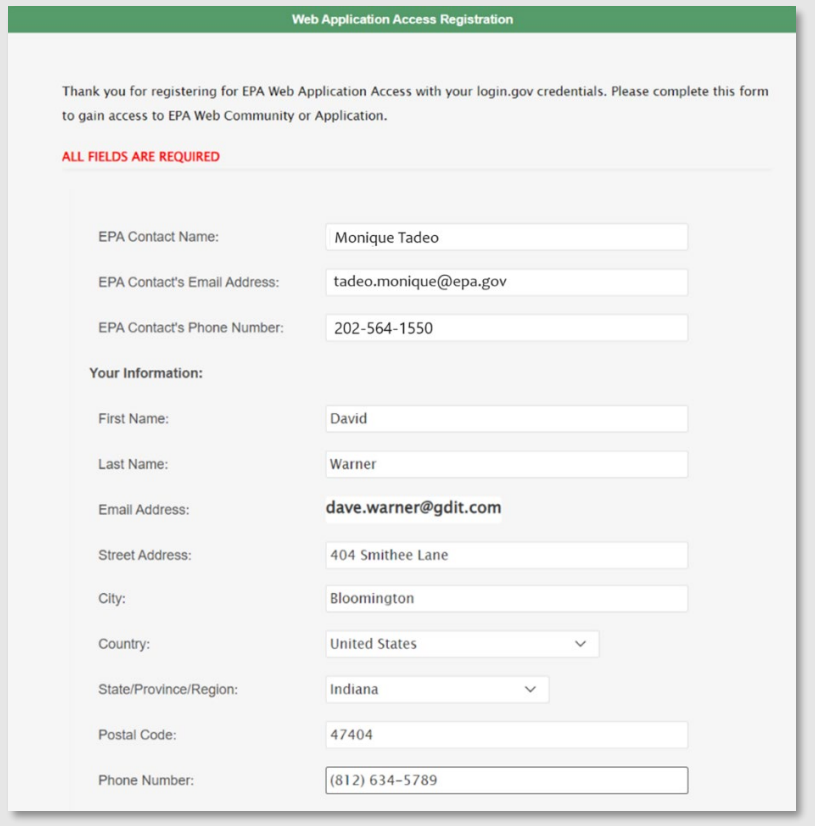
External users who do not yet have access to the BAP and the HSRAP application will need to register for access by doing the following:

1. Go to https://waa.epa.gov/.

2. Login using your Login.gov account. If you do not have a Login.gov account, sign up for an account, then login using your chosen credentials.

   *(**PLEASE NOTE:** All external users will need to use Login.gov to access the registration page.)*

3. After logging in, the Web Application Access Registration Form will appear. Fill out the information on this form. *(**PLEASE NOTE:** For EPA Contact Name, Email Address, and Phone Number, enter Monique Tadeo, tadeo.monique@epa.gov, and 202-564-1550, as shown in the screenshot below.)*



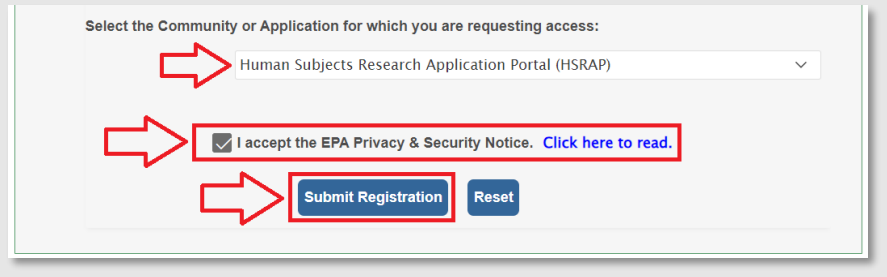
Getting Started

Requesting External User Access to the HSRAP Application (continued)

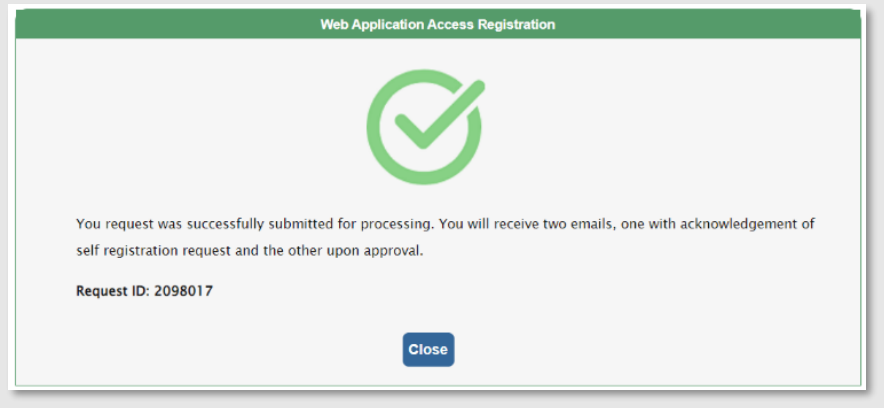
4. At the bottom of this form, in the drop-down menu labeled **Select the Community or Application for which you are requesting access**, select **Human Subjects Research Application Portal (HSRAP)**. Then click the checkbox next to **I accept the EPA Privacy & Security Notice**.

   *(**PLEASE NOTE:** The link to read this notice is to the right of the checkbox.)*

   When finished, click **Next**.



5. A confirmation screen will appear. Take note of the Request ID number shown on the screen. Click the **Close** button when finished.

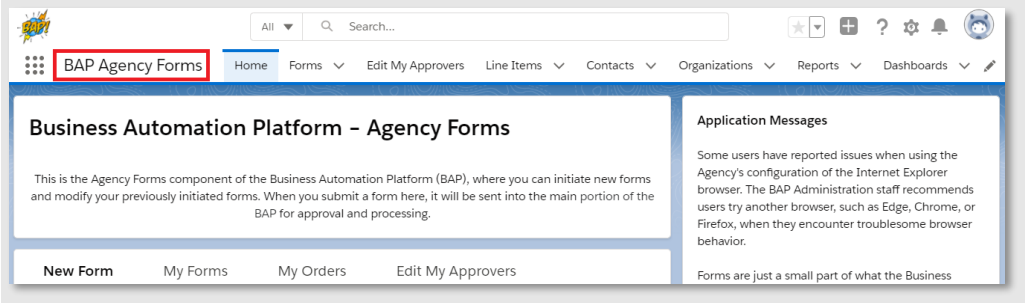


Your request will then be reviewed, and if approved, you will receive further instructions via email on how to access the HSRAP application on the BAP.

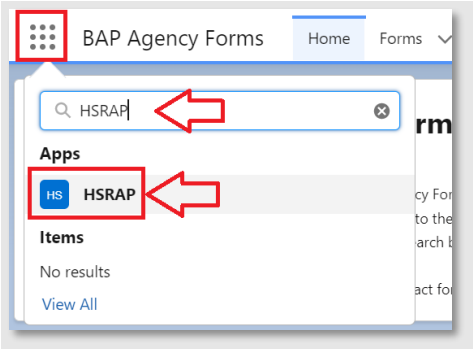
Getting Started

Accessing the HSRAP Application Within the BAP

The Human Subjects Research (HSR) form is in the HSRAP application. In most cases, when logging into the BAP, **BAP Agency Forms** will appear as the default app. The app name is located at the top left-hand corner of the BAP window.



To open the HSRAP application, click on the App Launcher waffle to the left of the app name, then select HSRAP from the drop-down menu. If you do not see HSRAP in the drop-down menu, type HSRAP in the search bar to bring it up.



Getting Started

Accessing the HSRAP Application Within the BAP (continued)

If you cannot find the HSRAP application through this search bar, you will need to fill out a User Provisioning Form to gain access to the application. Perform the following steps:

1. Go to the **BAP User Provisioning Form** at this link. Login with your EPA LAN ID and password, if needed.

2. Complete the form as follows:

Question	**Response**
Purpose	Provide Access
Person requiring access	Enter your name here
Reason for requesting/removing access	Application
Select an application	HSRAP
Select Permission Set	HSRAP – HSR Edit
Select Group	HSRAP Users

3. Review the submission for accuracy, then click **Next**.

The approval process may take 24 to 48 hours. For more information on filling out a User Provisioning Form, consult the *BAP Navigation and User Provisioning Guide* at this URL:

https://usepa.sharepoint.com/:b:/r/sites/oei_Community/BAP/Shared%20Documents/BAP%20Info%20and%20Documentation/BAP-Type-3-Navigation-and-User-Provisioning-Guide.pdf

Getting Started

Prepare for your Request

- ✓ Click here to review the guidance for Human Subjects Research on the EPA intranet.
- ✓ Gather IRB information. (e.g., location, date of most recent approval, protocol number assigned by IRB)
- ✓ Gather supporting documents to upload. (e.g., IRB approval letter, IRB application, consent forms, grant application, Federalwide Assurance (FWA) number of the research institution, etc.)
- ✓ Be prepared to enter a brief description of the research to include the purpose, participants (human subjects), and procedures of the research.

Request Overview

To complete the HSR request, you must provide information in 7 sections:

Section 1: General Information and Location

Section 2: Personnel

Section 3: Screening Questions (to Determine if Your Project is HSR)

Section 4: IRB Information (to Include the FWA number)

Section 5: Research Description

Section 6: Supporting Documents

Section 7: Submission

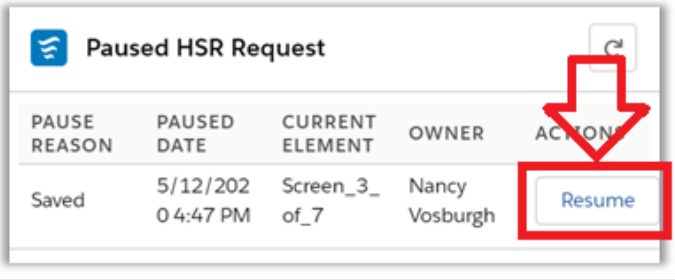
Getting Started

Navigation

New: Starts a new Human Subjects Research request.

Pause: Saves the information up to your current point so you can leave and come back.

Resume: After pausing your request, click on the Resume button to start where you left off.



Next: Saves the information entered on the current page and moves to the next section.

Previous: Saves the information entered in the current section and moves to the previous section.

Mouse over the lowercase "I" in the shaded circle found throughout HSRAP to learn more information.

Acronyms

Acronyms used in HSRAP and/or this manual

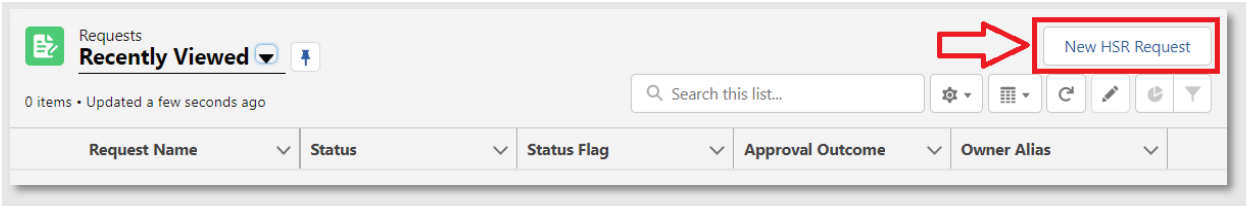
FWA	Federalwide Assurance (Through the FWA, an institution commits to the Department of Health and Human Services (HHS) that it will comply with the requirements in the Federal Policy for Protection of Human Subjects)
HSR	Human Subjects Research
HSRAP	Human Subjects Research Application Portal
HSRRO	Human Subjects Research Review Official for EPA
HSO	Human Subjects Officer for program office or region
IRB	Institutional Review Board
QAPP	Quality Assurance Project Plan
MTA/CRADA	Materials Transfer Agreement/Cooperative Research and Development Agreement
NHSR	Not Human Subjects Research
PI	Principal Investigator

Completing an HSR Request

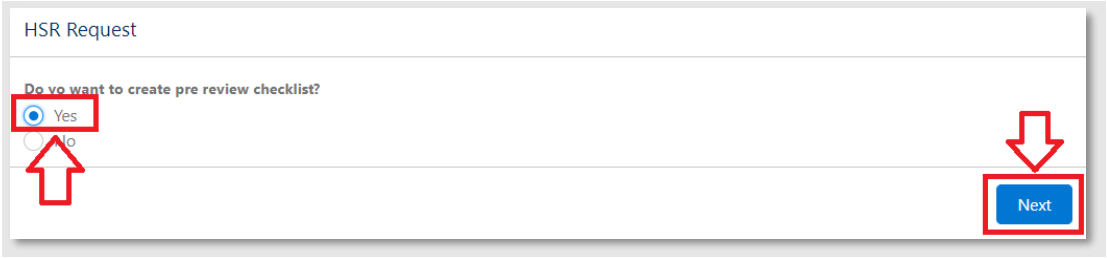
Start a New HSR Request

Inside the HSRAP application, click on the **Requests** tab.

From the Requests tab you can open an HSR request that you have already started or begin a new one. To start a new HSR request, click on the **New HSR Request** button.



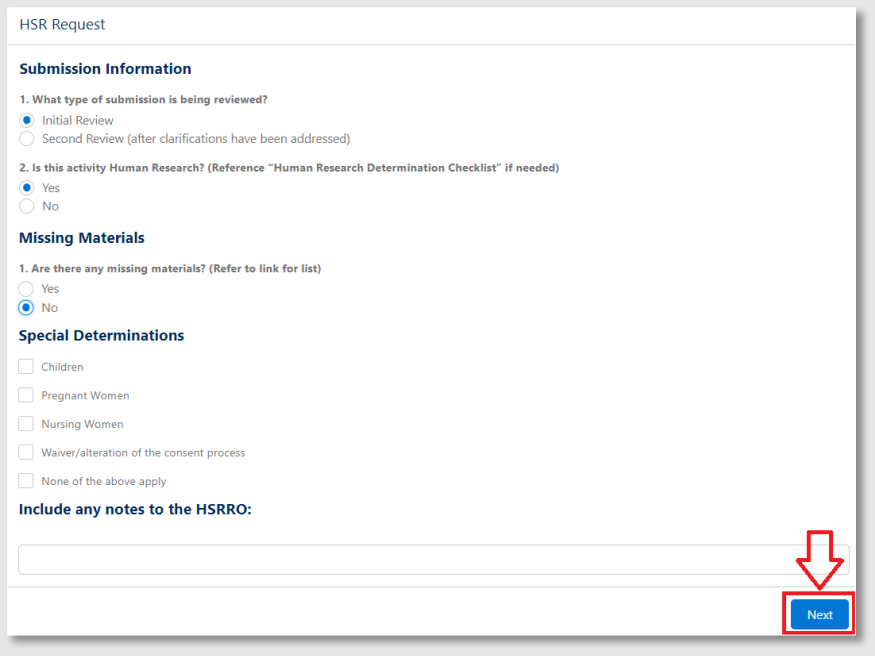
Before beginning the form, HSOs will be asked if you want to create a pre review checklist. Select **Yes**, then click **Next**. *(**PLEASE NOTE:** PIs will not see this step and do not have to complete a pre-review checklist.)*



Completing an HSR Request

Start a New HSR Request (continued)

The next screen will prompt you for some general information about the study, including submission information and any missing materials or special determinations required in the study. Here you will also be able to add notes to the HSRRO about your application.



Fill out this information, then click **Next**.

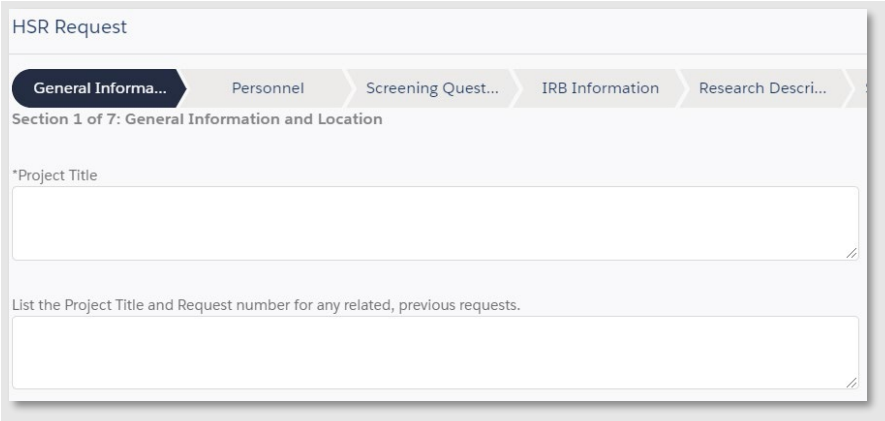
Completing an HSR Request

Section 1: General Information

1. Provide the title for your project.

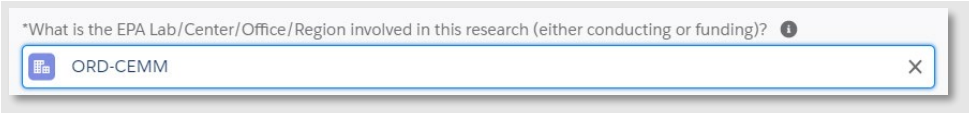
   PLEASE NOTE: *Fields marked with an asterisk are required before submission. However, it is possible to click Next and Pause without answering all required fields; the fields are only required before final submission.*

2. Next, indicate if there are existing or previous HSR requests that are related to this new request by providing the project title and/or the HSR request number. This is *not* a required field.



3. When asked, "What is the EPA Lab/Center/Office/Region involved in this research (either conducting or funding)?", please type in the **acronym** for the lab, center, or office (e.g., ORD-CEMM). For regions, please type "region" then the number of the region.

   See the example below. If you would like to change your answer, click on the X in the far right side of the field.



Completing an HSR Request

Section 1: General Information (continued)

5. Complete the rest of the questions in this section and click **Next** to save your work. If you wish to close the request and plan to return to it later, click on the **Pause** button in the bottom, left hand corner.

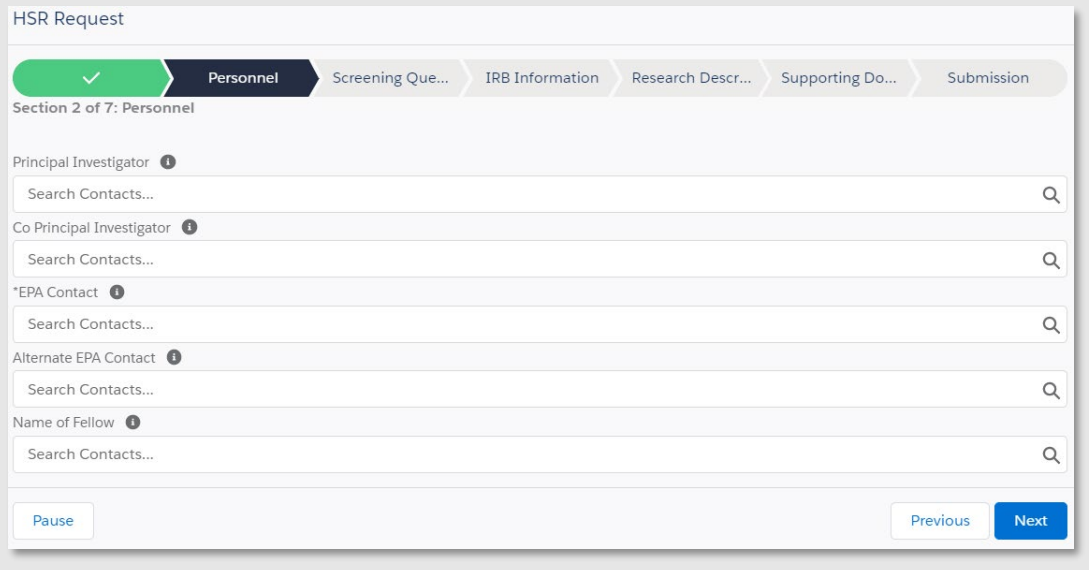
Section 2: Personnel

1. Enter the name of the Principal Investigator by typing in the first few letters of their name, the field will search and display possible matches.

   ***PLEASE NOTE**: if the contact is not available in the lookup, you will need to request that the contact be added to the system. See the Appendix for instructions.*

2. Identify the EPA contact, typically the Project Officer for extramural studies or the Study Coordinator for intramural projects.

3. If there is a Co-Principal Investigator, Alternate EPA contact, or Name of Fellow, include them as well, but they are not required.



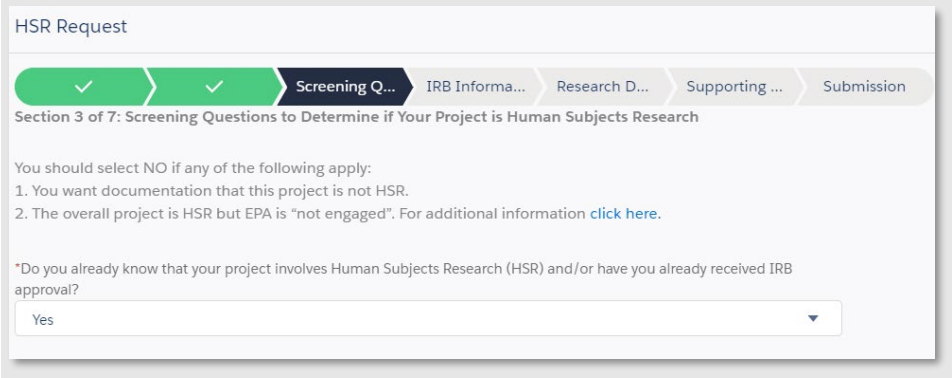
Completing an HSR Request

Section 3: Screening Questions to Determine if your Project is a Human Subjects Research Request

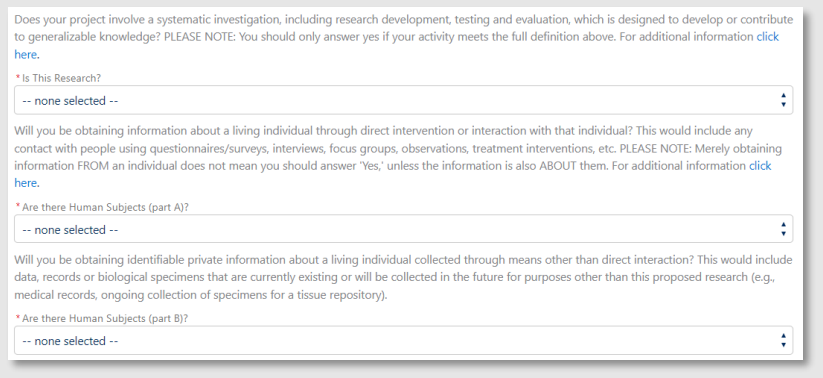
1. First, indicate whether you already know that your project involves Human Subjects Research (HSR) and/or if you have you already received IRB approval. You should select NO if any of the following apply:

    - You want documentation that this project is not HSR.
    - The overall project is HSR, but EPA is "not engaged."

2. If the answer is Yes, select **Yes** from the drop-down menu, click **Next**, and proceed with the HSR request.



3. If the answer is No, select **No** from the drop-down menu and click **Next.** On the ensuing screen, three additional questions will appear. These questions will help determine if the project is HSR, or if it is Not Human Subjects Research (NHSR).



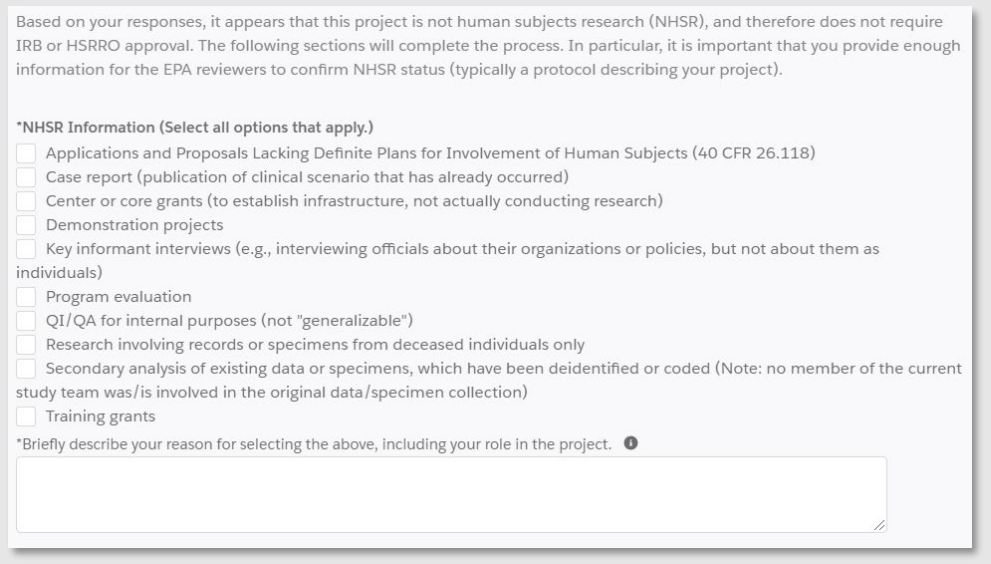
Read each option carefully and select all options that apply. When complete, Click **Next**.

Completing an HSR Request

Section 3: Screening Questions to Determine if your Project is a Human Subjects Research Request (continued)

PLEASE NOTE: *These answers must be consistent with the information provided to and from the IRB, or you will encounter problems in subsequent sections.*

4. If your project appears to be Not Human Subjects Research (NHSR), on the ensuing screen, check the boxes from the list of activities that best describe your project. Then in the form at the bottom of the screen, briefly describe your reason for checking the boxes from the list that describes your project, including your role in the project.



5. Click the **Next** button in the bottom right-hand corner of the screen to resume the request.

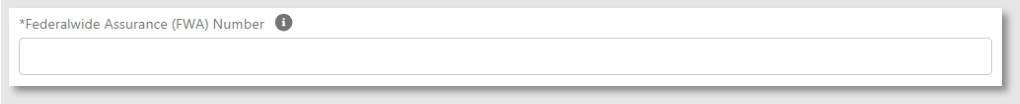
Completing an HSR Request

Section 4: IRB Information

1. Most HSR requests Institutional Review (IRB) is UNC Chapel Hill, therefore this question is asked first. If the IRB is a different institution, please answer **No**. Otherwise, please answer **Yes** and fill out the remaining fields.

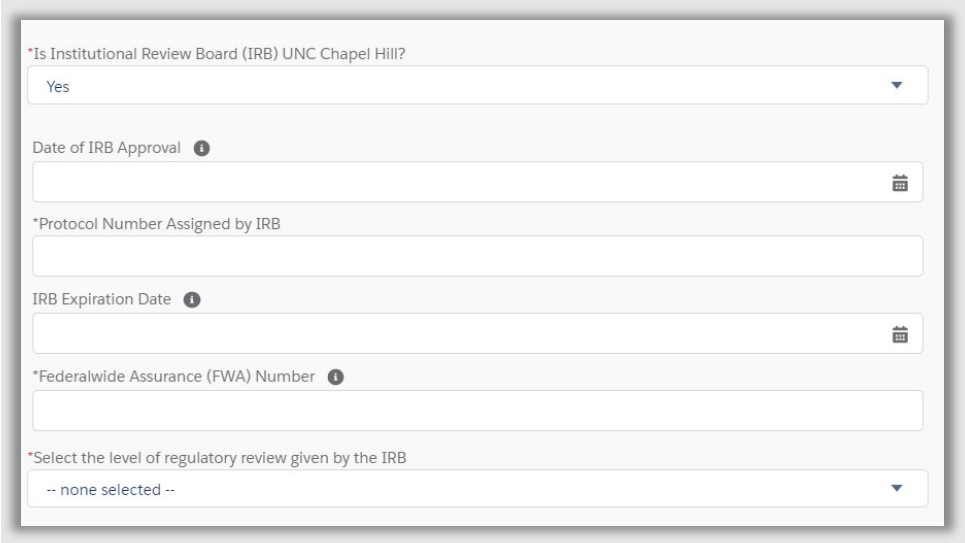
2. Then provide the most recent IRB approval date, the protocol number assigned by the IRB, and the IRB Expiration Date.

3. Provide the Federalwide Assurance (FWA) number for the institution conducting the research.



4. Select the level of regulatory review that was given by the IRB.

   PLEASE NOTE: *the response to this question is critical in determining how your submission will be reviewed and should match IRB documentation.*
   a. *Convened IRB*
   b. *Exempt from Regulation*
   c. *Expedited Review*
   d. *Not Human Subjects Research*



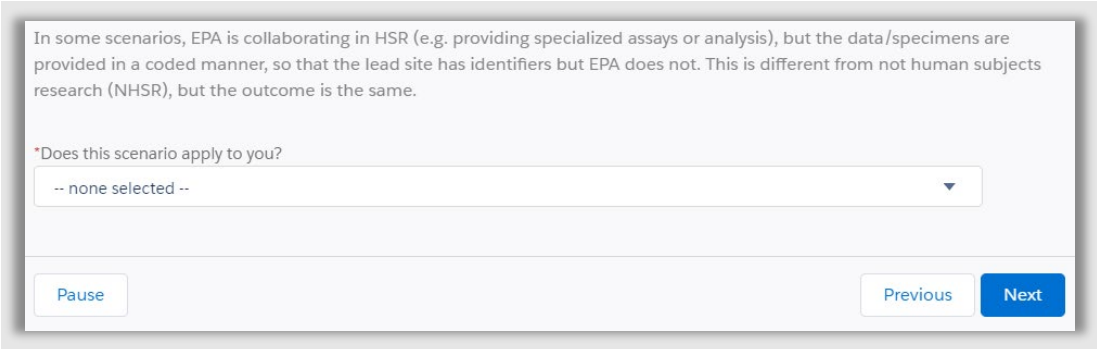
Completing an HSR Request

Section 4: IRB Information (continued)

5. Lastly, in some scenarios, EPA is collaborating in HSR (e.g., providing specialized assays or analysis), but the data/specimens are provided in a coded manner, so that the lead site has identifiers, but EPA does not. This is different from not human subjects research (NHSR), but the outcome is the same.

   Indicate here whether that scenario applies to your project.

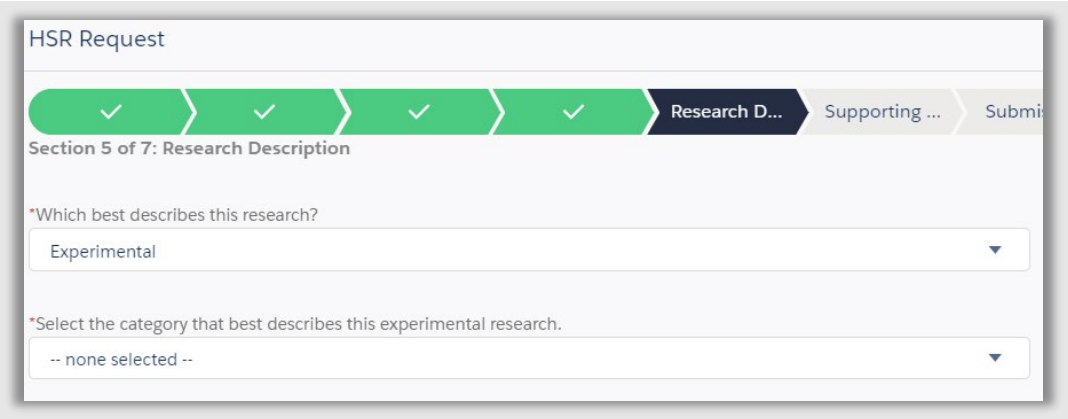
6. Click **Next**.



Completing an HSR Request

Section 5: Research Description

1. Indicate which best describes the research for this project.
    a. Experimental (subjects' environment is manipulated or altered in some way)
    b. Non-Experimental (observational, environment not manipulated)



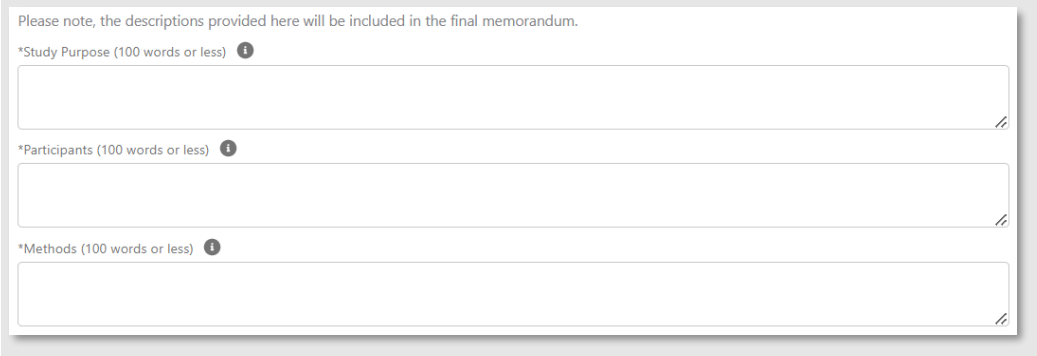
2. If your research is **Experimental**, you will be asked to select the category that best describes your research from this list.
    a. Intentional Controlled Exposure (e.g., chamber studies)
    b. Other Interventional Study (e.g., randomized or community trial)
    c. Modifying Subjects' Behavior (e.g., walking or driving different routes than usual)
    d. Other

3. If your research in **Non-Experimental** (observational), you will be asked to select the category that best describes your research from this list.
    a. Case-control, cohort or x-sectional epidemiology study
    b. Panel study (longitudinal sampling of selected individuals)
    c. Database study (secondary analysis of existing data)
    d. Other data collection (surveys, interviews, questionnaires)
    e. Other

Completing an HSR Request

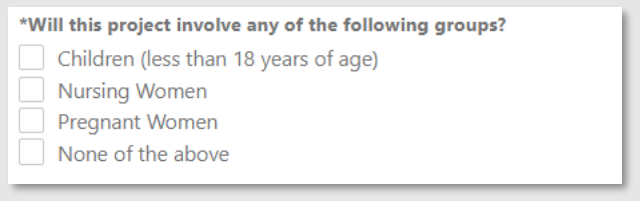
Section 5: Research Description (continued)

4. Include a brief description in the three text boxes provide: Study Purpose, Participants, and Methods.



NOTE: The description you provide will be included in the final decision memorandum and should be written with this purpose in mind.

5. Indicate which of the protected groups will be involved in the project, if any.



EPA human subjects research regulations (40 CFR 26 Subpart B) ban certain experiments involving vulnerable populations. Under no circumstance shall EPA conduct or support research involving intentional exposure of any human subject who is a pregnant woman (and therefore her fetus), a nursing woman, or a child. Intentional exposure of a human subject means a study of a substance in which the exposure to the substance experienced by a human subject participating in the study would not have occurred but for the human subject's participation in the study. Please contact your Human Subjects Official or the EPA Human Subjects Research Review Official should you have any questions about these EPA specific regulations.

When finished with this section, click **Next**.

Completing an HSR Request

Section 6: Supporting Documents

In general, you should attach any documents that would help reviewers understand your study, bearing in mind that the HSRAP fields in the previous sections do not contain sufficient detail to complete this review. At a minimum, this would include the IRB APPLICATION, IRB APPROVAL LETTER, and CONSENT FORMS (if any). You should also include master protocols, grant applications or institutional agreements, recruitment materials, surveys, questionnaires where relevant. Translations of materials recorded in other languages should also be included.

If this is a request for determination that a project is NOT human subjects research (NHSR), there may or may not be IRB-related materials. In this case, there should be a protocol that describes what you are doing in sufficient detail for the reviewer to confirm NHSR status.

If this study involves the Center for Public Health and Environmental Assessment (CPHEA) at EPA, please include the CPHEA Fact Sheet (examples available from your management).

For a full list of required documents, please visit the following URL:

https://work.epa.gov/human-subjects-research/required-documents-and-approvals

PLEASE NOTE: *This page can be accessed only by EPA network users.*

For EPA staff, please refer to this link: https://work.epa.gov/human-subject-research/required-documents-and-approvals

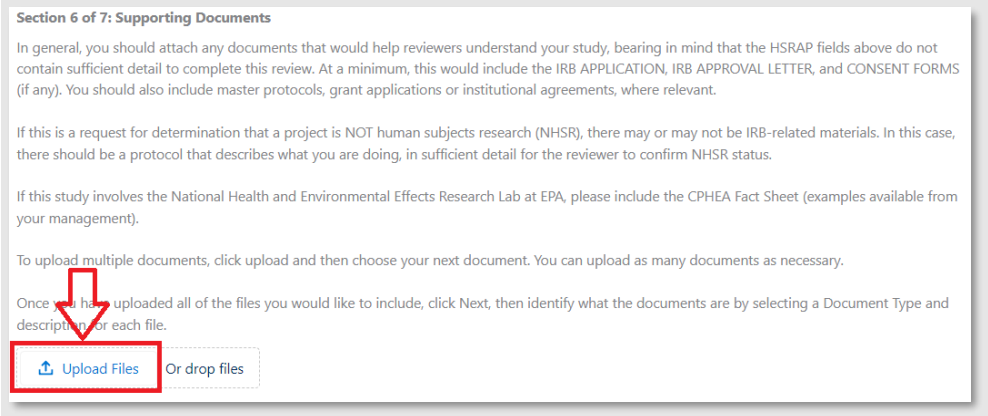
Completing an HSR Request

Section 6: Supporting Documents

For non-EPA staff who do not have access to the intranet, please see below for the list of required documents:

Attachments	EPA intramural human subjects research	EPA extramural human subjects research	EPA not engaged, but supporting others' HSR	Interaction with individuals or identifiable biospecimens but not research.
Protocol[1]	Yes	Yes	Yes	Yes
IRB application	Yes	Yes	N/A	N/A
IRB approval letter	Yes	Yes	Yes[2]	N/A
IRB approved Consent forms	If applicable	If applicable	No	N/A
IRB approved Questionnaire	If applicable	If applicable	No	N/A
Data Sharing Agreement	No	No	Yes	If applicable
Scientific Data Management Plan	Yes	Yes	If applicable	If applicable

1. Click the **Upload Files** button and locate the file on your computer. Click **Done** once the file has been uploaded successfully.



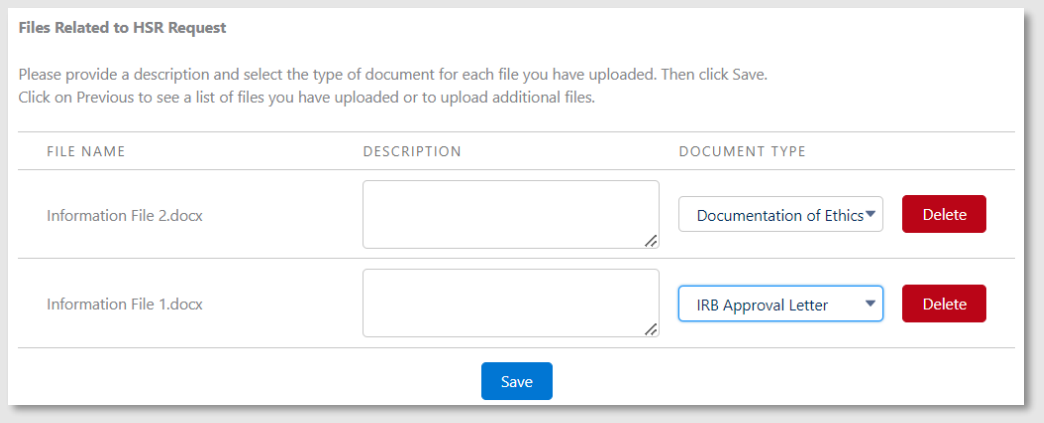
Completing an HSR Request

Section 6: Supporting Documents (continued)

2. To upload multiple documents, click **Upload Files** again and then choose your next document. You can upload as many documents as necessary.

3. Once you have uploaded all the files you would like to include, click **Next**.

4. Select a **Document Type** for each of the files that you have uploaded. If "other" was selected as the document type, enter a brief description, or enter a grant application number or MTA/CRADA number. Otherwise, description should not be necessary, as the document type will be listed.



***PLEASE NOTE**: You can delete files that you no longer want to include or in case you uploaded the same file more than once.*

5. Click the **Save** button. Then click **Next**.

Completing an HSR Request

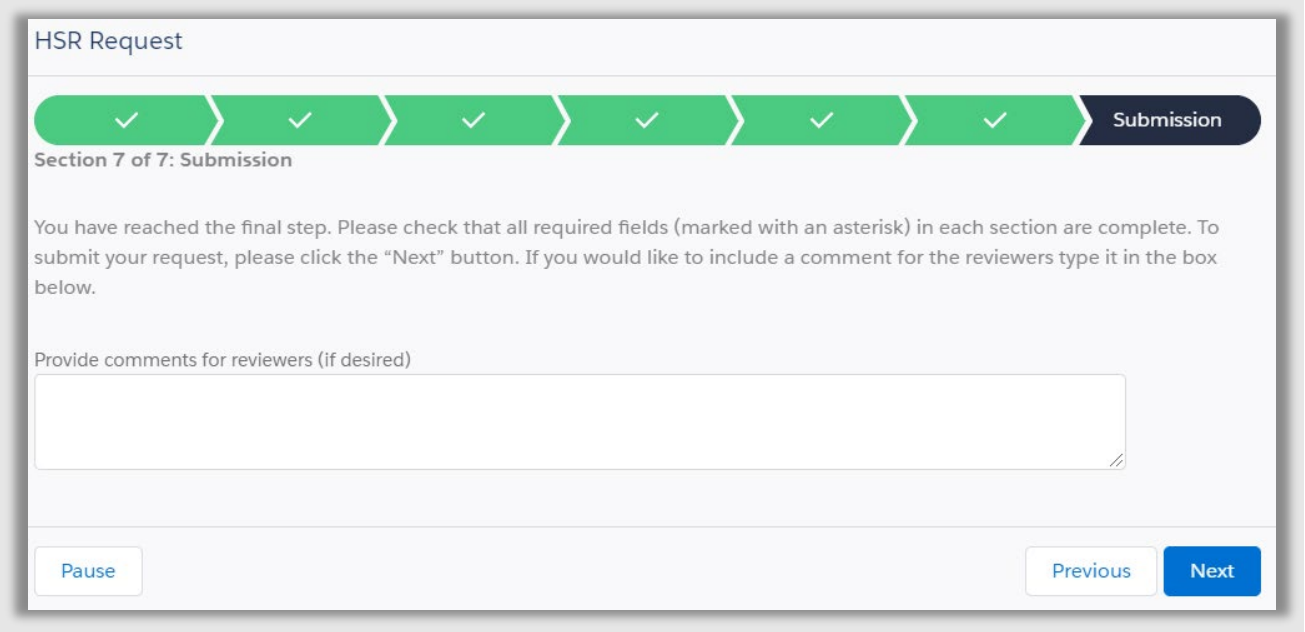
Section 7: Submission

1. You have reached the final section. Please check that all required fields (marked with an asterisk) in each section are complete.

2. If you would like to include a comment for the reviewers type it in the box provided.

3. When you are ready to submit, click **Next**.

4. If there is any information missing, an error will appear. Click **Next** again and you will be taken to the beginning of the request to complete all required fields.



Post Submission

Request Status

Once the HSR request is submitted, only three people will be permitted to see the request during the approval process:

- The organization's Human Subjects Officer (HSO).
- The organization's Division Director.
- The HSRRO, who is the final approver for all requests.

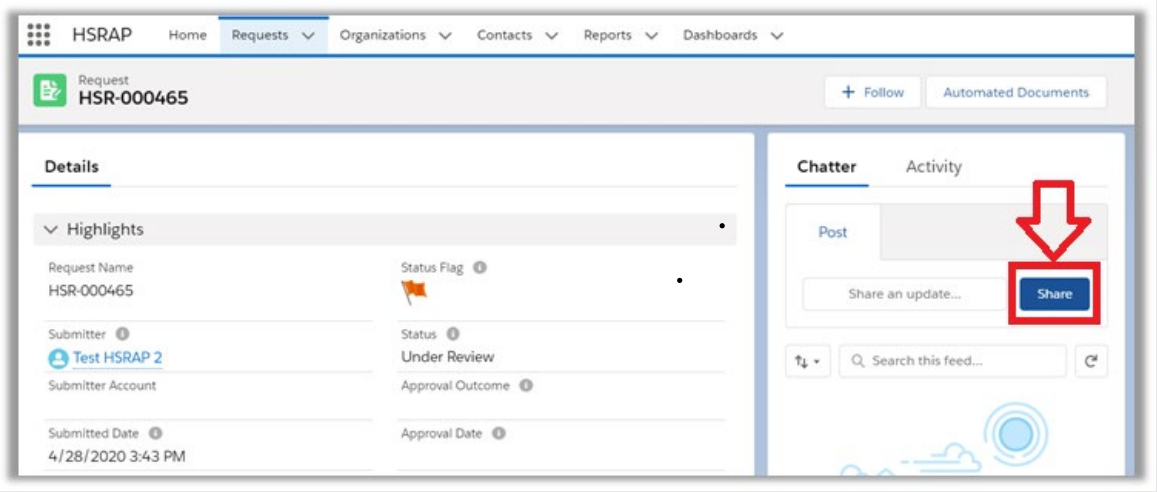
Email notifications will be sent to the requester when a final determination is made or if a reviewer has questions for clarification or needs additional information.

Respond to a Question or Clarification

1. If you receive an email notification that a reviewer has submitted a question or asked for clarification, click on the **link in the email,** which will open your request.

2. On the right side of the page is the **Chatter** section where you can respond to questions from reviewers. Type in the "Share an update…" field.

3. Click the **Share** button.



Post Submission

Final Determination

You will be notified by the EPA HSRRO via email with a memorandum of the final determination for your request. Possible determinations include:

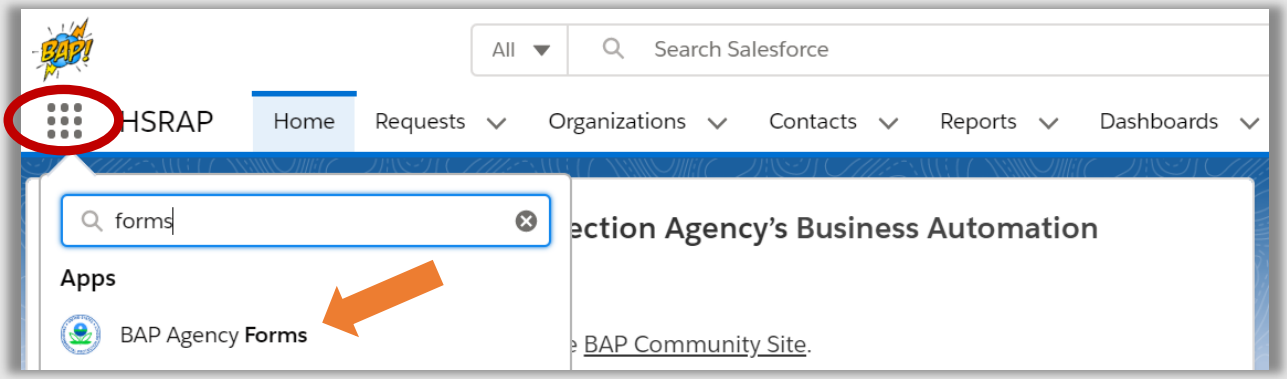
- EPA Not Engaged in the Human Subjects Research
- Non-Human Subjects Research (NHSR)
- Conditional
- Exempt
- Approved

Appendix

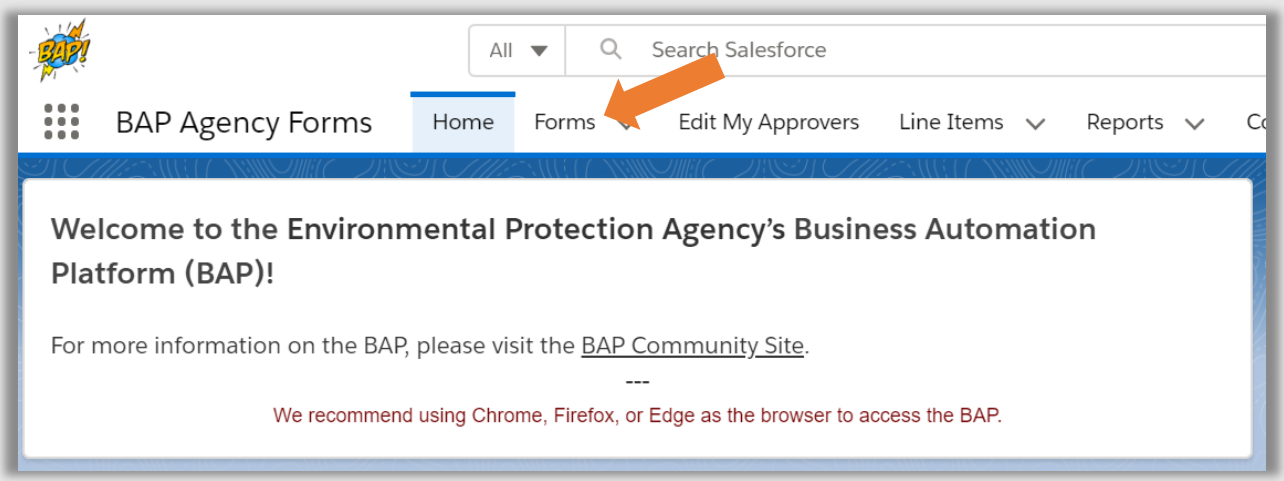
Adding a New Contact or Organization

If you find that in that a contact or organization is not available in a lookup field, you will need to request that they be added to HSRAP.

1. First, click on the App launcher and type "Forms", then click on **BAP Agency Forms**.



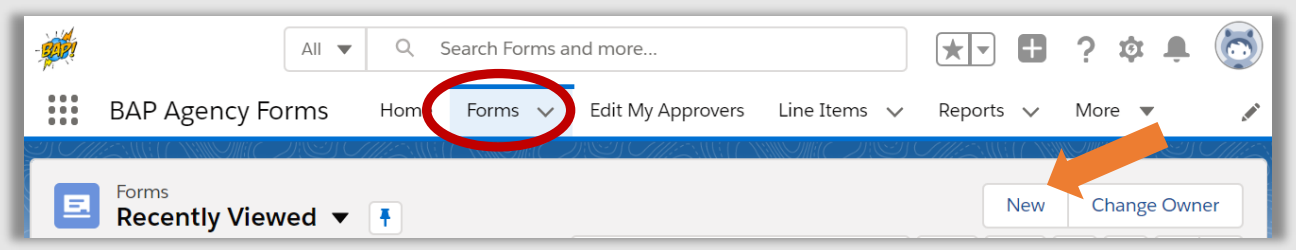
2. Then click on the **Forms** tab.



Appendix

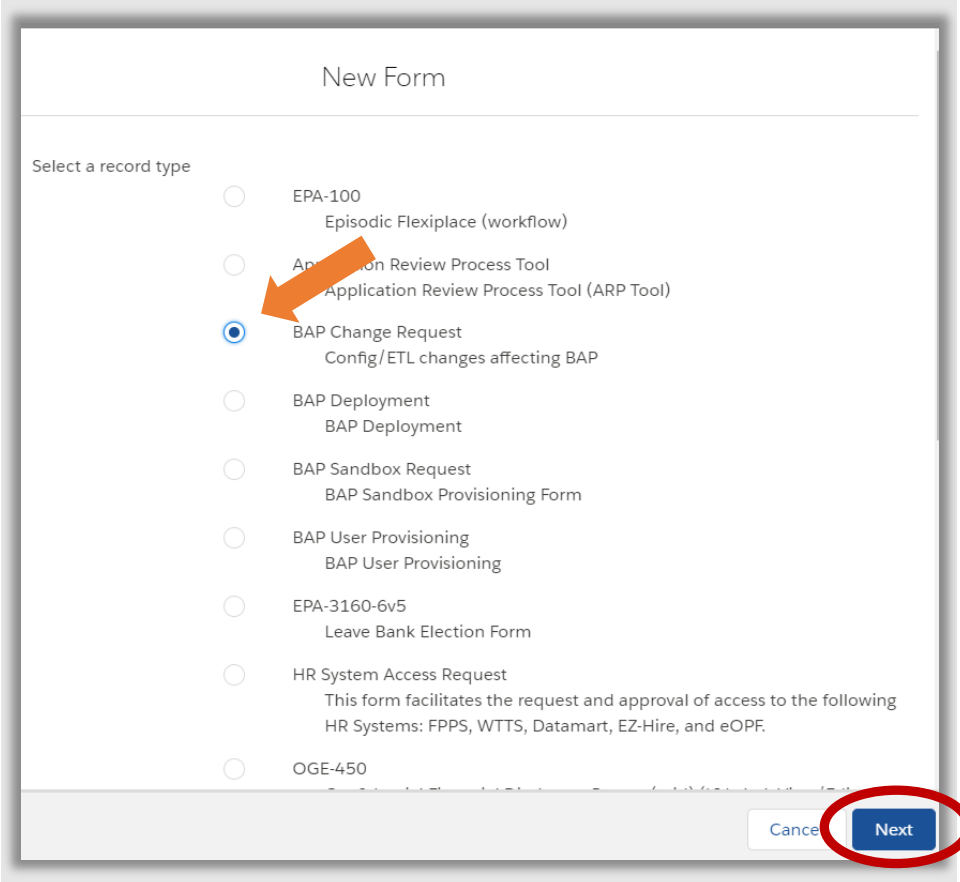
Adding a New Contact or Organization (continued)

3. Click on the **New** button.



5. A new window will open. Select the radio button next to BAP Change Request.

6. Click the Next button.



Appendix

Adding a New Contact or Organization (continued)

7. Complete the form as follows:

Question	Response
Form Type	Leave as Change Request
Name	Enter your name
Person	If adding a new contact, search for their name to make sure it does not already exist
Target Date	Select the next calendar day
Comments	State that you that you would like to add a new contact or organization and specify their name
Related Application	Type in HSRAP and select it from the search results

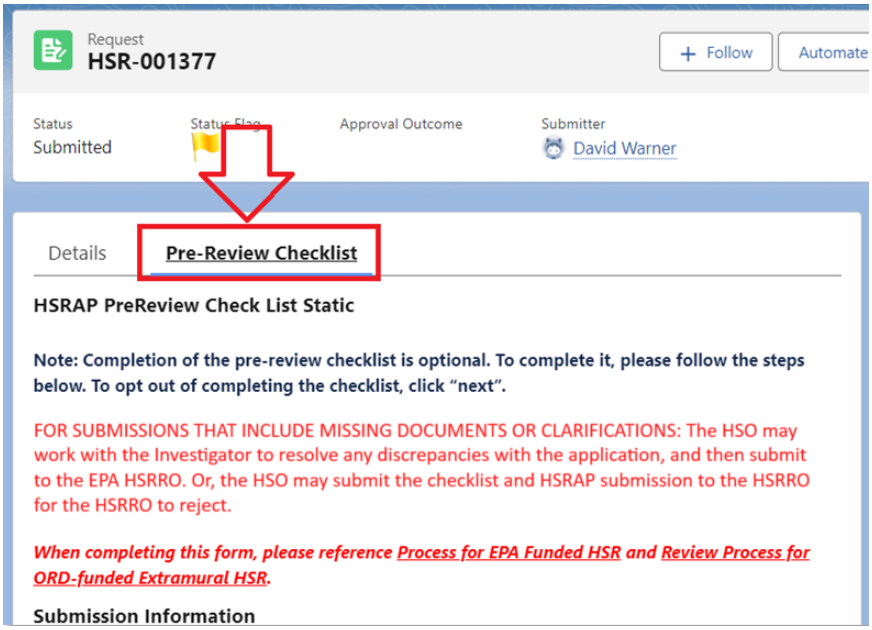
8. Click the **Save** button. The change request will be sent to the HSRRO for approval.

Appendix

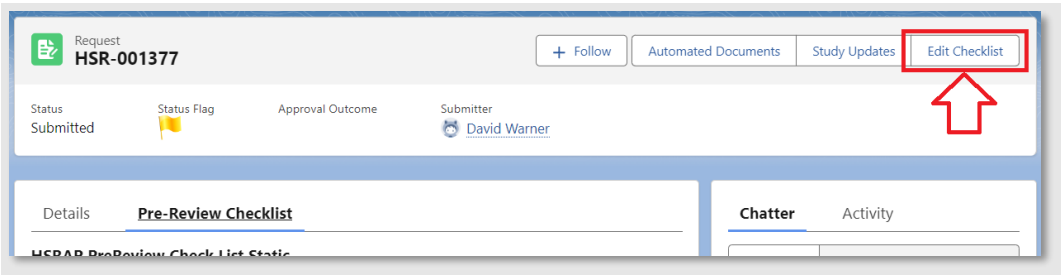
Creating a Pre-Review Checklist

Pre-Review Checklists can be created by the HSO at the beginning of a request or by the HSO when the request is routed to them. The HSRRO may communicate with the HSO via email or Chatter if changes or updates need to be made to the Checklist.

The Pre-Review Checklist for any given Request can be found in a tab on that Request's page.



To edit a Pre-Review Checklist, click on the Edit Checklist button in the top right-hand corner of the Request page.

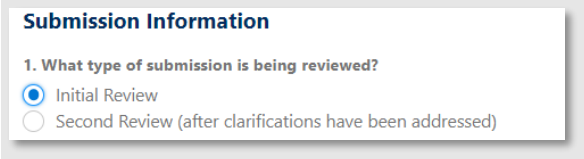


Appendix

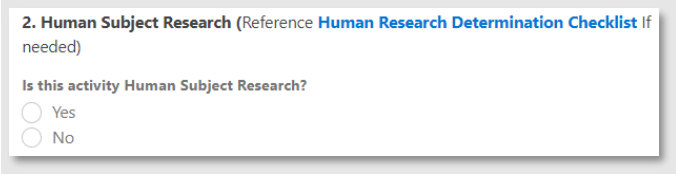
Creating a Pre-Review Checklist (continued)

On the ensuing editing screen, complete the following information:

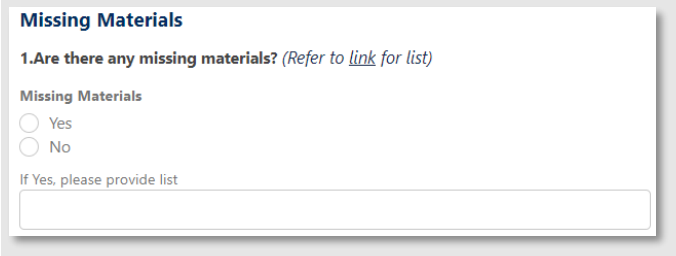
1. What type of submission is being reviewed.



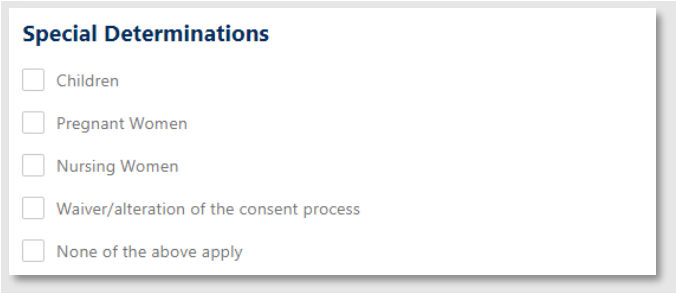
2. Whether the activity is Human Subject Research.



3. Any missing materials that need to be added.



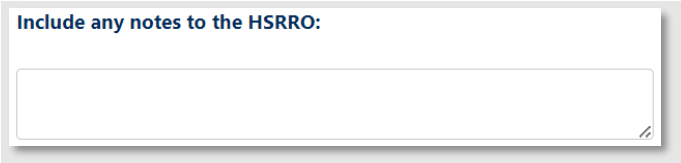
4. Any special determinations for the project.



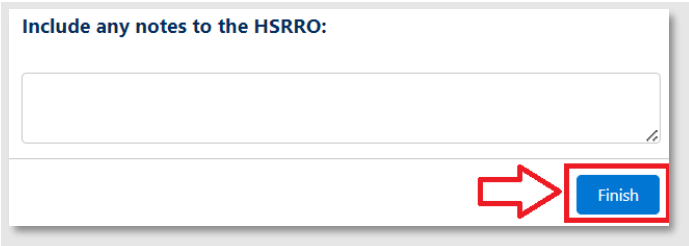
Appendix

Creating a Pre-Review Checklist (continued)

5. Any notes for the HSRRO.



When completed, click the Finish button in the bottom right-hand corner of the window.

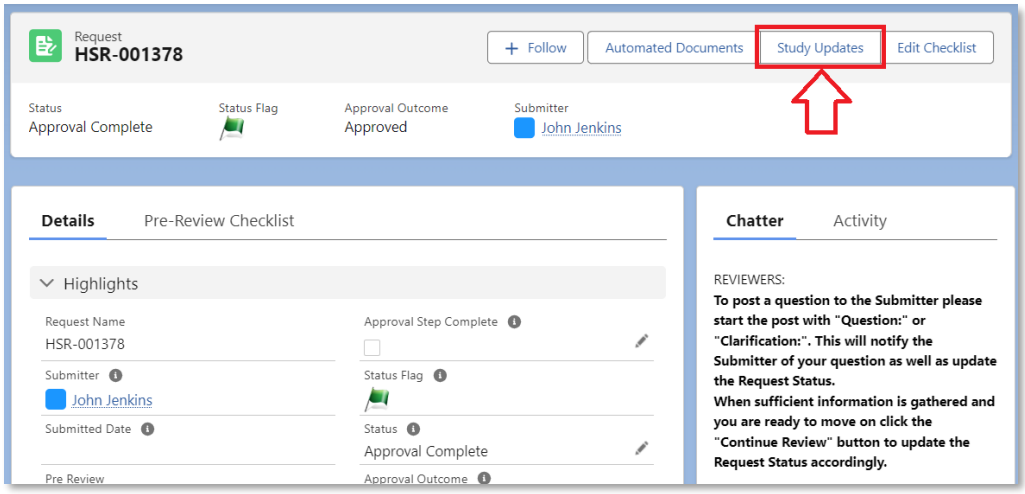


Appendix

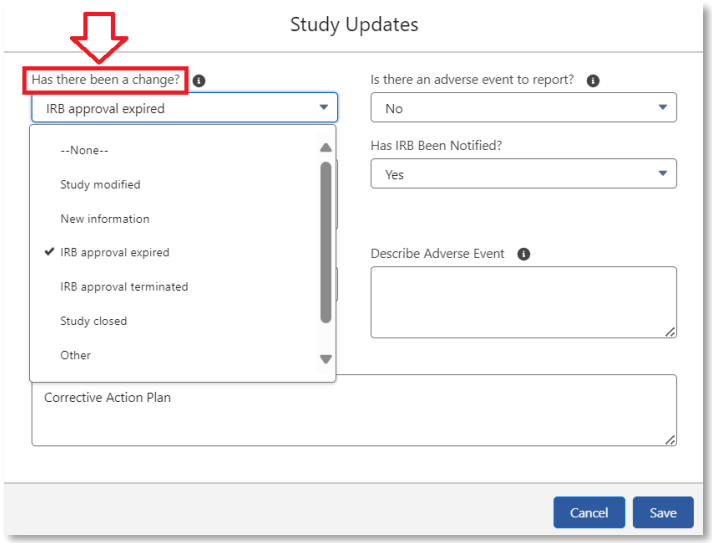
Creating a Study Update

When a change happens during a study, a Study Update can be added to an HSR Request. To add a study update:

1. Go the HSR Request in HSRAP, then click the Study Updates button in the top right-hand corner of the window.



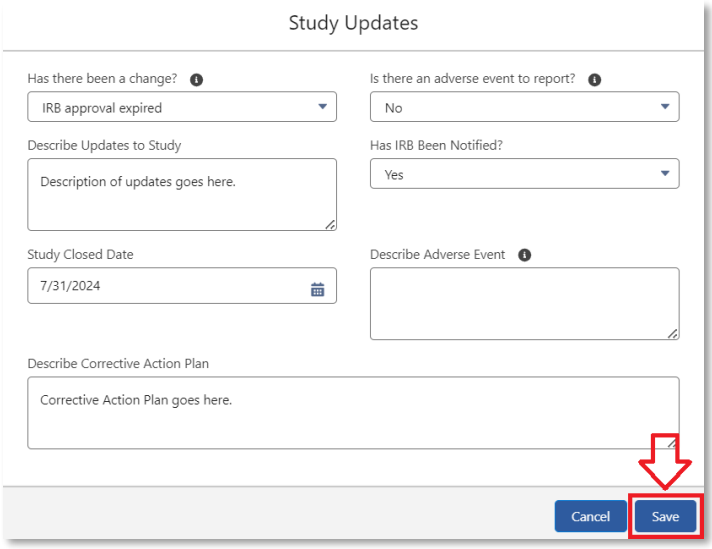
2. A pop-up window will appear. In this window, start by selecting the reason for the update in the **Has there been a change** drop-down menu.



Appendix

Creating a Study Update (continued)

3. Once this is selected, fill in the remaining fields as needed. When finished, click the **Save** button in the bottom right-hand corner of the pop-up window.



4. To verify that the updates have been recorded properly, scroll down to the **Study Updates** section under the **Details** tab of the report.