How to Use the Web-Based OHSRP Request for Determination System

New Submissions

- Use Google Chrome, Safari or Mozilla Firefox (only if Firefox is configured to work with your PIV badge) to enter the website. Do **NOT** use Internet Explorer (IE).
- After reviewing the instructions, click on Start.
- Questions with red asterisks are required. You will not be able to progress or go back if you do not respond to the required questions.
- Click on "Continue" to move to the next page.
- Click on "Back" to return to the previous page or "Save" to save data and return to complete the form later.
- If you want to attach supporting documentation, click on "Browse" to find the document, then click on "Open" and then "Upload Document". Note that you can only load one document per upload field. However, there are multiple locations to upload documents throughout the application.
- Clicking on "Home" at the top of the page will take you to the dashboard that displays your complete list of requests.
- Click on "Submit Application" to route your submission to the senior investigator for approval.
- Upon submission, a confirmation page will load. **Do not leave this page until you have used the link to download the PDF containing your questions and answers.** You are expected to retain a copy of your submission as a research record. This is also a useful reference if you need to answer questions about the submission.
- After you submit your request, an email notification will be sent first to the senior investigator and then his/her supervisor for review and approval. If you are the senior investigator, you will need to approve your submission using the link provided in the email.
- When the senior investigator and supervisor "approve" or "decline" the request, the requestor will be notified. If the senior investigator/supervisor returns the submission to for corrections, you must edit the submission and resubmit it for approval.
- The submission will not be routed to OHSRP for review and a determination, until the Supervisor has approved the submission.
- Upon review by OHSRP, you will either receive an email requesting that you correct the submission or a determination email that will allow you to proceed with your research. If you receive a correction email, click the link in the email to edit the submission make your corrections. Let OHSRP know that your corrections have been made.

- Once you receive a final determination email, print the email to PDF and keep it with the PDF of the submission and any required supporting documentation. Note that you may be asked to provide proof of complete documentation upon request or audit by OHSRP.

Section I – General Information

When entering the requestor, senior investigator, supervisor, and additional investigator fields, you must first enter the desired name in the field and then click the button to search in NED to select the party into the record.

Section II – Special Categories

The activities listed on this page, do not require IRB review nor OHSRP determination, if the research is limited to the listed activities. For more information, see SOP 5 - NIH Research Activities with Human Data/Specimens. If you certify that the proposed project includes only these activities, you will be able to submit your request from this page and will receive an automated determination upon the approval of the SI and Supervisor.

Request for Determination - Collaborations and other entities

- Include any collaborators outside of your IC-based research team, whether in or outside of the NIH.
- Include the contact name for any entities (institutions/ companies/repositories) who will be providing specimens/data to the NIH, even if these entities are not actually collaborating in the research.
- Include entities, including sub-contracting companies, who will be assisting in the research project, e.g. conducting recruitment, screening, informed consent, conducting surveys, interviews, focus groups or other forms of data collection, or analysis.
- "Additional collaborator/entity details" - Include details about the role of the collaborator or other entity in the box.
- "Upload Additional Collaboration Information" - If you have more than three collaborators, please upload an MS Word document or pdf listing the additional collaborators and the required information.

Section III – Research with Specimens and Data

Do I need to upload the de-identification agreement or honest broker agreement and certification when one is required?

> The web-based request for determination system does not require that you upload a de-identification agreement or honest broker agreement and certification. If one is required, you need to execute the agreement or obtain the required documentation and retain it in your records. You also will need to certify in the system that you have obtained this documentation. OHSRP may request proof of this documentation in the future. The template for the De-Identification Agreement and the Honest Broker

Agreement and Certification can be found here:
https://federation.nih.gov/ohsr/nih/formtmp.php

If you are obtaining data or specimens from a restricted-access database, repository or publicly available database/website, please upload a data use/data access/data transfer policy or agreement or a material transfer agreement that explicitly states that no identifiers will be shared with the recipient. We will accept a screen shot from a web site, when no actual policy or agreement is available.

Additional Info: if there is additional information that you need to tell us about your submission, please enter text in the additional info box.

After submission, any additional information or documentation may be submitted via email to OHSRP using ohsrp_determinations@od.nih.gov. Include 'Request for Determination' and provide the 'OHSRP ID number' in the subject line of the e-mail.

Uploading additional materials

If the NIH research team is interacting with subjects or collecting identifiable data through surveys, interviews, or focus groups, you will need to upload:

- any screening questions;
- the information sheet, consent language or instructions; and
- the survey instrument, interview questions or focus group script

In addition, if your research qualifies as 'clinical research' as defined by the NIH, the project requires:

- submission of a Planned Enrollment Report prior to project start and collection and
- submission of cumulative enrollment data to OHSRP on a fiscal year basis until the project stops enrolling

The definition of clinical research can be found here:
http://grants.nih.gov/grants/glossary.htm#ClinicalResearch .

The Planned Enrollment Report and the Cumulative Inclusion Enrollment Report can be found here: https://federation.nih.gov/ohsr/nih/formtmp.php

If the project involves the use of fetal tissue research, you must complete and upload the Investigator Attestation I. The form and other important requirements can be found here: https://oir.nih.gov/sourcebook/ethical-conduct/special-research-considerations/fetal-tissue-research