Manage Approved Study Data/Biospecimens in NICHD DASH Workspace

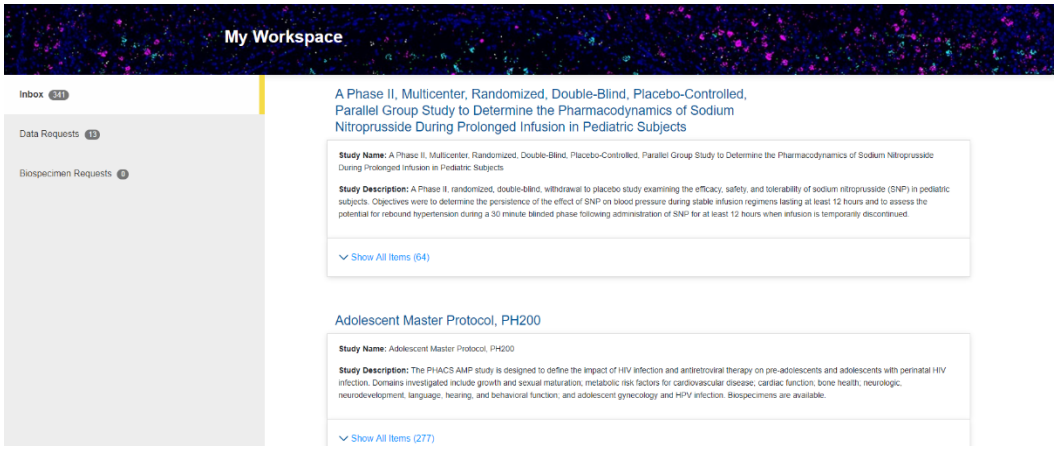
After you receive notification from the NICHD DASH Administrator that your data or biospecimen request has been approved, you can manage the data/biospecimens associated with your request in the NICHD DASH Workspace. To access your Workspace, log in to NICHD DASH and select Workspace located on the top menu bar of NICHD DASH. Note that your Workspace will be empty until after you submit a request and it is approved.

The Workspace has three sections: "Inbox", "Data Requests", and "Biospecimen Requests". After a data request is approved, the study items (datasets, documents, etc.) you put in your cart and requested will be moved to your Inbox. You can download these items from your Inbox.

The "Data Requests" section is where you will be able to manage your Data Use Agreements (DUAs) you executed with NICHD for your data request(s). There are a number of "Actions" you can perform for an approved request, including: modify the Authorized Organizational Representative for a DUA, modify your Research Team (i.e., Affiliates Associates and Collaborators), download a copy of the fully executed Data Use Agreements with Amendments. Each year, a feature will be enabled to submit your Annual Report and when the DUA is close to expiring, DASH provides an option to Renew your DUA. Under Data Requests, you may also "Show All Items" that you are approved to access and move them to the Inbox for download.

The "Biospecimen Requests" section is where you will be able to access and manage the Material Transfer Agreement(s) associated with approved biospecimen request(s).

Figure 1: Workspace in DASH



1. Inbox

Your Inbox function is similar to that of an email inbox. Once your data request is approved, the specific study items you requested are delivered to your Inbox for your use. You may:

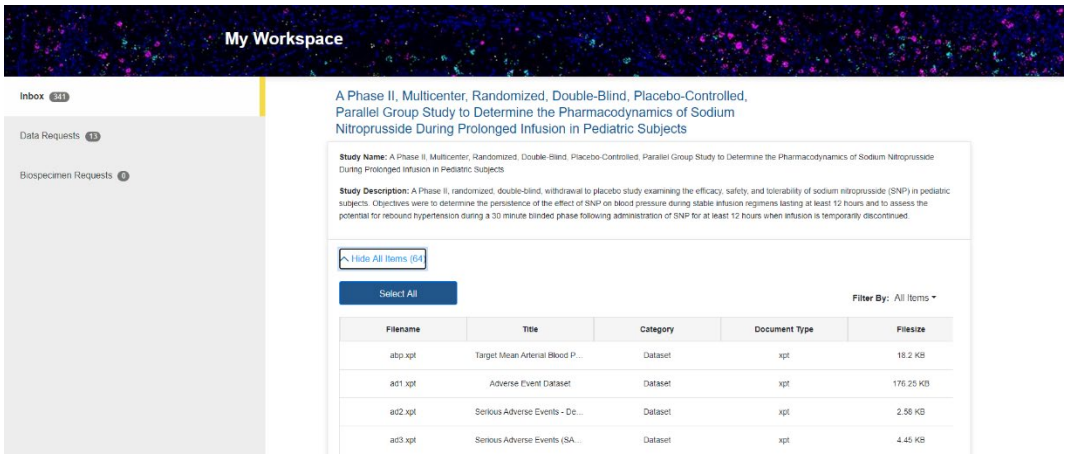
1. Download selected items from your Inbox to your computer. Either click on items to highlight them or click "Select all" to highlight all items. Then click "Download".

   Note: When you click "Download" a pop-up window will inform you that your download is being prepared. Large downloads can take up to 15 minutes. The pop-up will inform you when your download is ready.

2. Remove selected items from your Inbox by highlighting the items and clicking the "Remove" button (which will become active after you highlight at least one item). Removing a study item from the Inbox will not remove it from the "Data Requests" section, where all approved items will continue to be available.

3. Filter Inbox items by category. You can select "Filter By" and then select "All Items", "Datasets", or "Documents".

Figure 2: Manage Study Items in Inbox

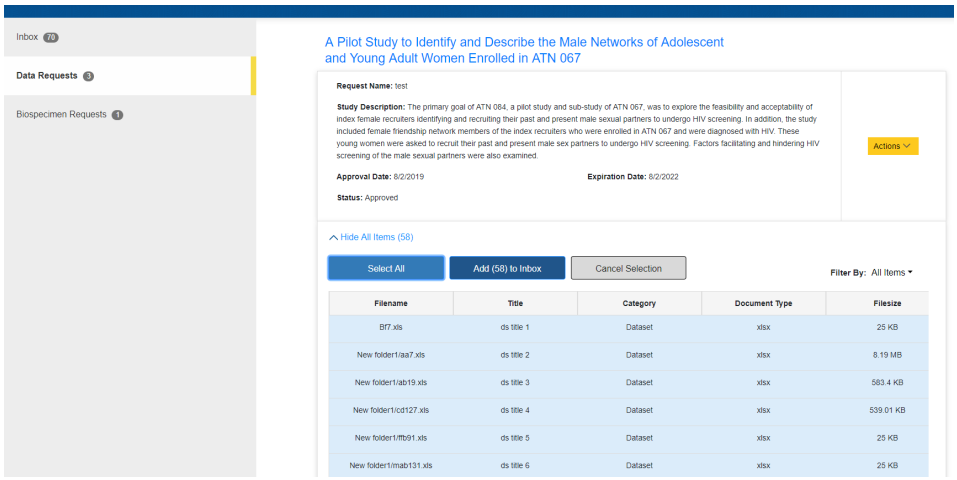


2. Manage Data Requests

The "Data Requests" function is similar to a filing cabinet where all the study items you were approved for and your executed DUAs are stored in DASH. Once your data request is approved, the specific study items you requested and the associated executed DUA are filed in the Data Requests chronologically by approval date. You may:

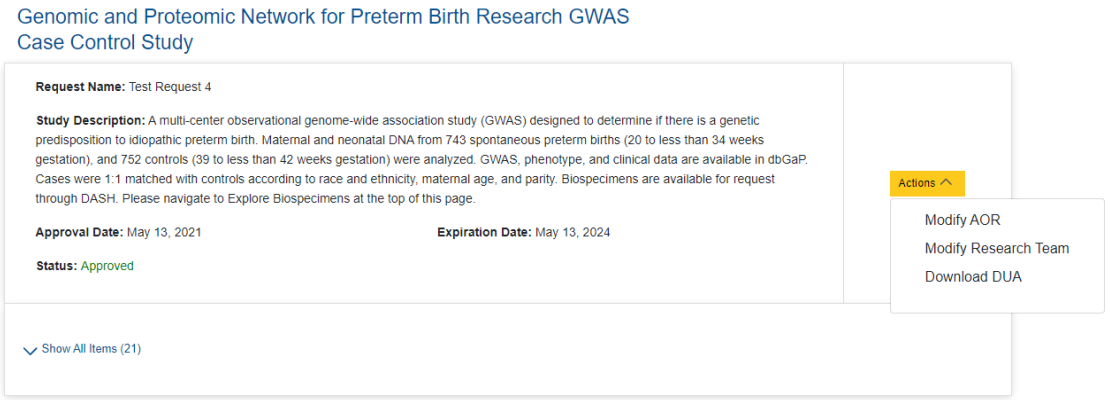
1. Move any study items which are grouped by request on the "Data Requests" page of your Workspace to your Inbox. You can move copies of any of your requested study items by either clicking on items to highlight them or clicking "Select All" to highlight all items. Then click "Add to Inbox" (which will become active after you highlight at least one item).

Figure 3: Move Study Items from Data Requests page to Inbox



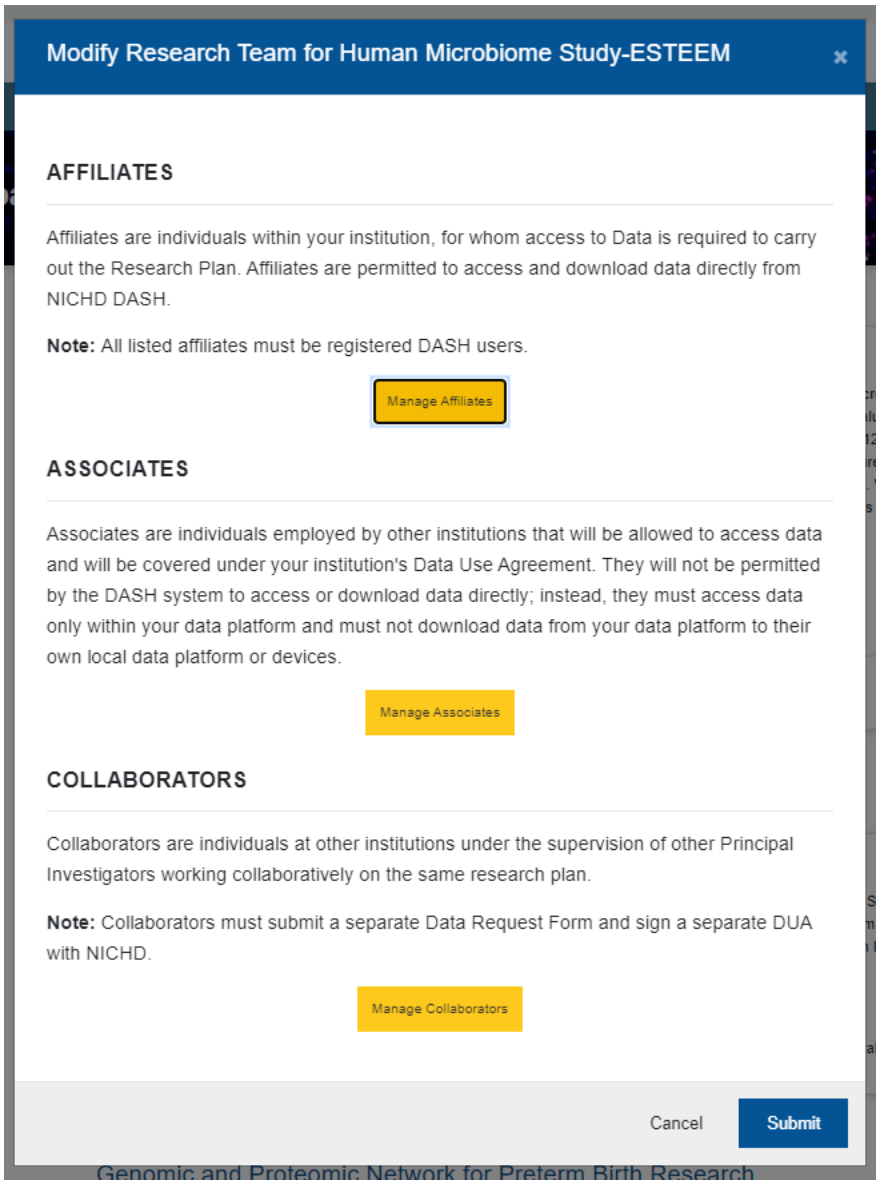
2. Download NICHD DASH Data Use Agreements (DUAs) and associated appendices; these are grouped by request and arranged chronologically on the "Manage Data Requests" page of your Workspace. You can download copies of your DUAs by clicking yellow "Actions" button and selecting "Download DUA" from the dropdown.

Figure 4: Manage Data Requests Actions Dropdown



3. Modify research team such as Affiliates, Associates, and Collaborators associated with a currently active DUA. Click the yellow "Actions" button and then select "Modify Research Team". Once you select the button, the "Modify Research Team" modal will be displayed.

Figure 5: Modify Research Team



3.1. You can manage Affiliates for a currently active DUA. Click the yellow "Manage Affiliates" button on the "Modify Research Team" modal. The section contains a dropdown list of registered users belonging to your institution. You can also remove existing Affiliates by clicking the "X" button next to their name.

3.2. You can manage Associates for a currently active DUA. Click the yellow "Manage Associates" button on the "Modify Research Team" modal. The section contains a form to add Associates and a list of existing Associates. You can remove existing Associates by clicking the "X" button next to their name.

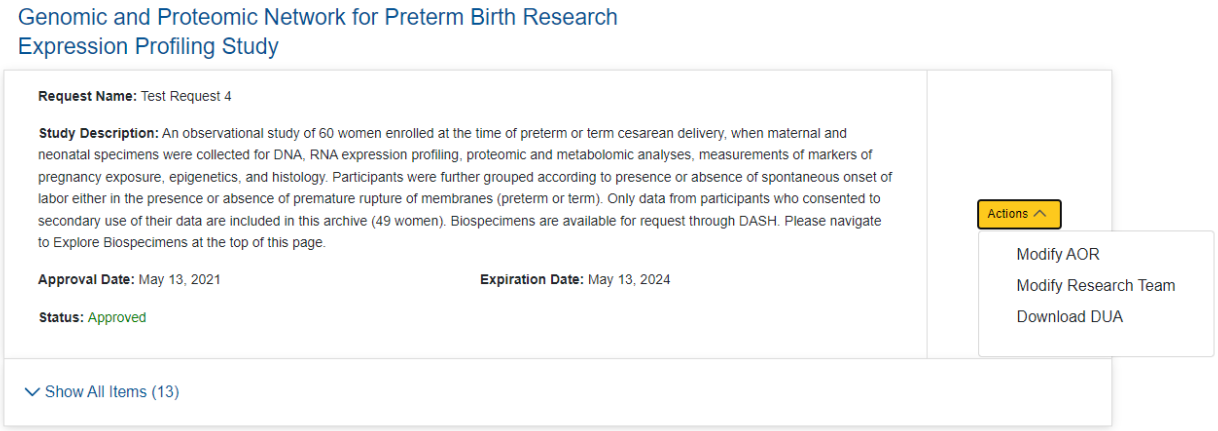
3.3. You can manage Collaborators for a currently active DUA. Click the yellow "Manage Collaborators" button on the "Modify Research Team" modal. The section contains a form to add Collaborators and a list of existing Collaborators. You can remove existing Collaborators by clicking the "X" button next to their name.

3.4. Once you finish making changes to your research team, click the blue "Submit" button at the bottom of the modal. You will receive an email containing an amendment to the DUA reflecting your changes. This amendment will also be added to your DUA which can be downloaded as described above. Please note that since Collaborators are not part of the DUA, the changes to Collaborators are not included in the Amendment.

4. Modify the Authorized Organization Representative for a currently active DUA.

4.1. Click the yellow "Actions" button and then select "Modify AOR" option.

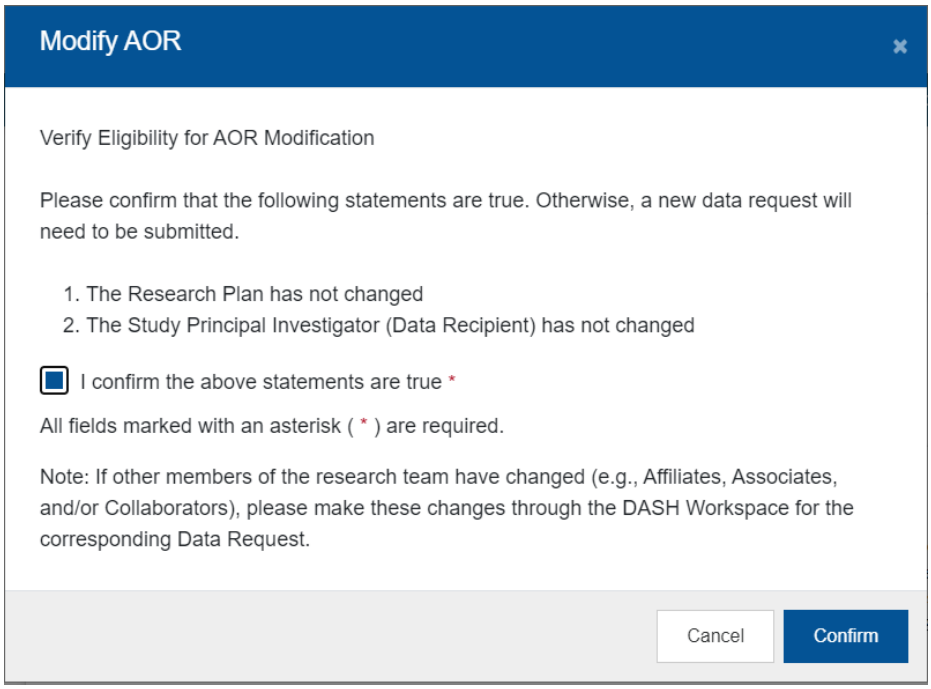
Figure 6: Modify AOR



4.2. System will present the pop-up modal that says "Verify Eligibility for AOR Modification". You will be asked to confirm that Research Plan and Data Recipient have not changed for this request.

4.2.1. If your Research Plan has changed, or if the Data Recipient (Study PI) has changed, then you are required to submit a new data request to DASH.

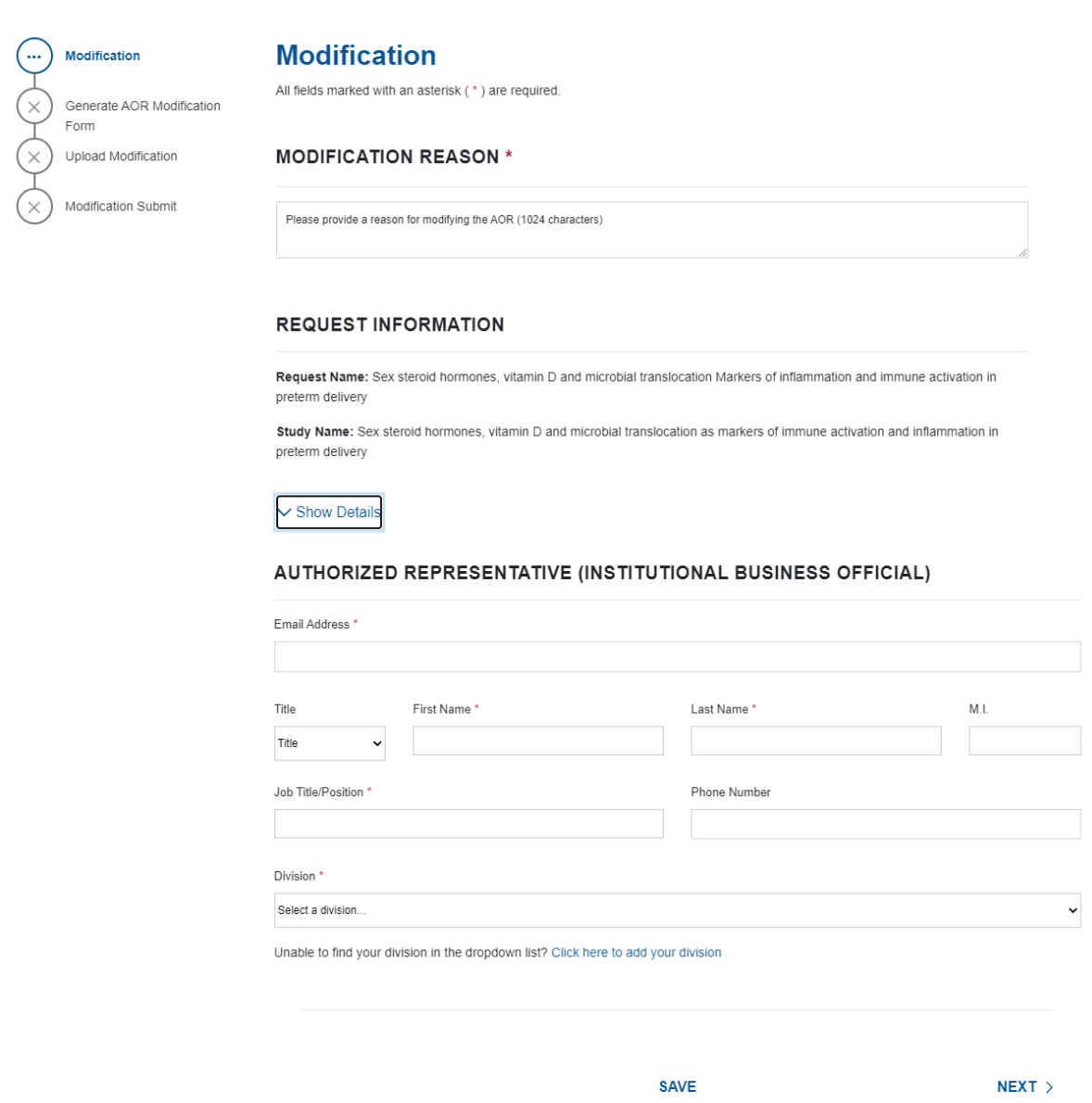
Figure 7: Verify Eligibility for AOR Modification



4.3. System will present the AOR Modification Form prepopulated with information you provided when you submitted the request. The left-hand navigation pane will show you the stage of the AOR modification process you are currently at. All fields marked with an asterisk (*) are required and must be completed to move on to the next page. Fill out the required fields and then click "Next."

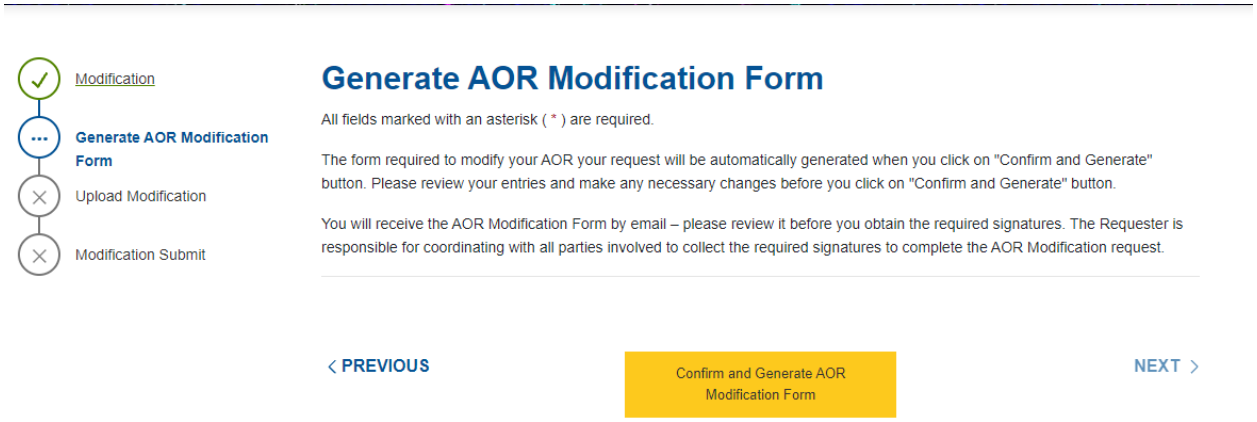
Note: You may start and stop this process at any time. Be sure to click "Save" at the bottom of the window you are working on so the information you entered is available when you return.

Figure 8: AOR Modification Form



4.4. Read the information on the "Generate AOR Modification Form" page, and then click "Confirm and Generate AOR Modification Form." The system will generate the form and send it to you via email.

Figure 9: Generate AOR Modification Form



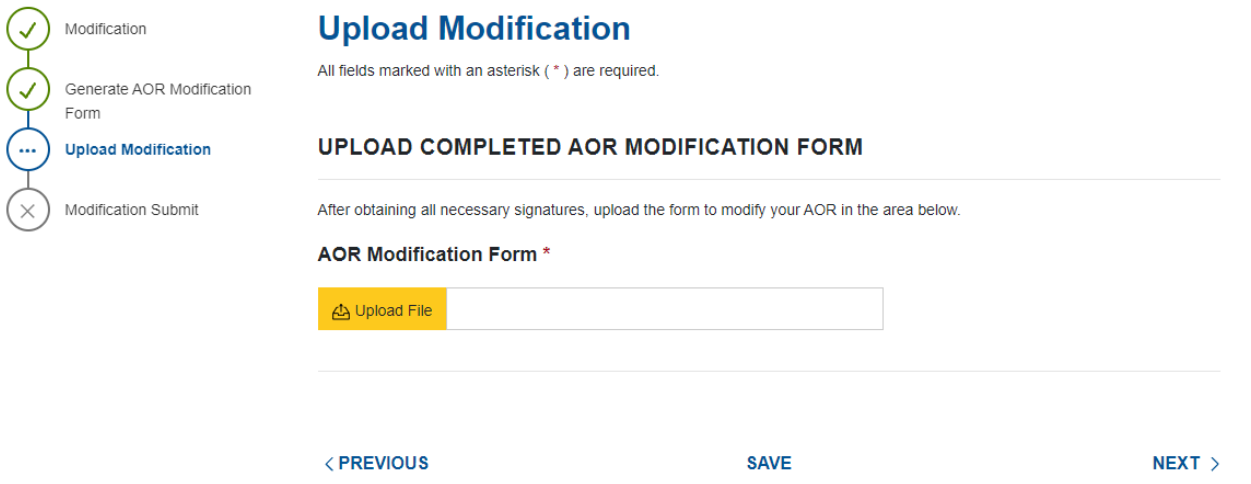
Note: Do not make changes to or add information in the AOR Modification Form you receive. If you make any changes to your document system has generated, your form will be invalidated, and you will need to generate it again. If there are changes to be made, login to NICHS DASH, make the changes to your AOR modification form and generate a new document.

4.5. Please review the AOR modification form prior to requesting the new AOR's signature.

4.6. To upload the form after obtaining the AOR signature, scan your documents and log back in to the NICHD DASH system. Click on "Workspace " at the top of the NICHD DASH homepage to begin and select Data Requests tab. Next to the appropriate request, click the "Actions" dropdown and select "Continue AOR Modification". You will be directed to the "Upload" page.

4.7. Click on the "Upload" button and select the appropriate file saved on your computer. Your file name will appear on the page to verify it has been uploaded.

Figure 10: Upload AOR Modification Form



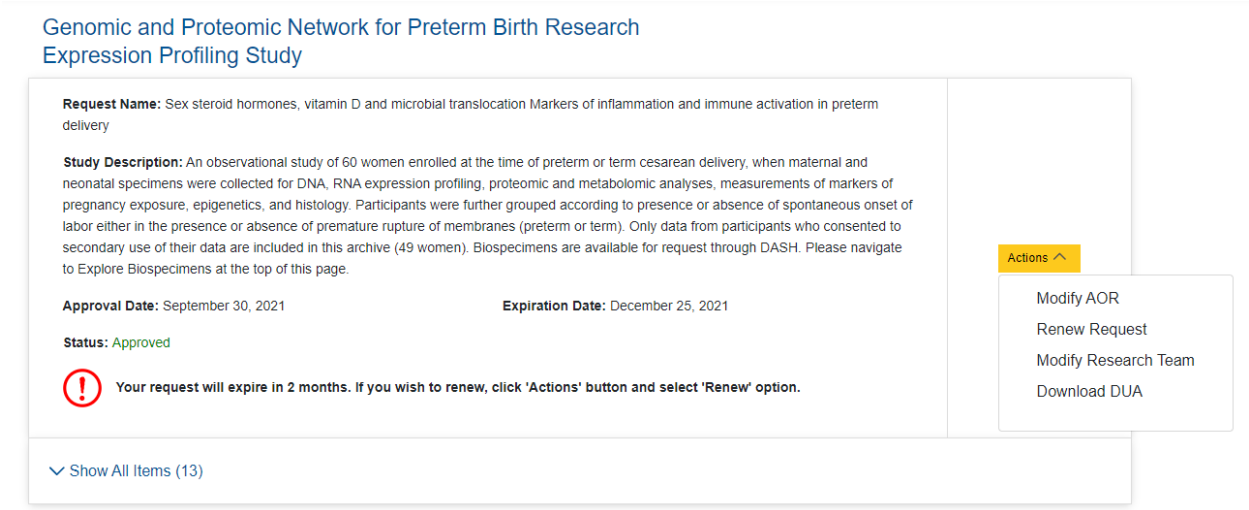
4.8. Once you have uploaded your document, click "Next" to move to the "Modification Submit" page. This page shows all of the information you have entered; please carefully review this page for accuracy and completeness. Then click the "Submit" button to submit your modification request.

4.9. Your modification request will be reviewed by the NICHD DASH Data Access Committee. You will be notified via email if any updates or additional information are needed for your request. You will be notified via email with the approval decision.

5. Renew the DUA that is about to expire.

5.1. 6 months prior to the expiration date you will see a warning on the Data Requests tab of your Workspace. If you do not wish to renew, please ignore the warning. If you would like to renew access to the data for another 3 years, click the yellow “Actions” button and then select “Renew Request” option.

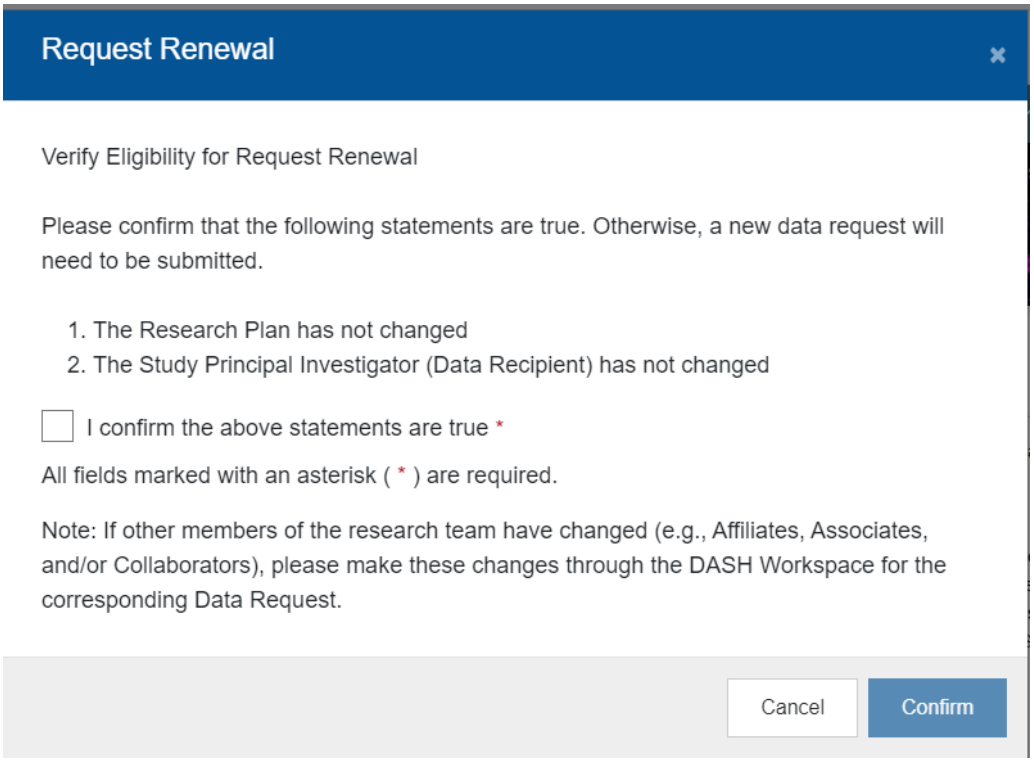
Figure 11: Renew Expiring Request



5.2. System will present the pop-up modal that says "Verify Eligibility for Request Renewal". You will be asked to confirm that Research Plan and Data Recipient have not changed for this request.

5.2.1. If your Research Plan has changed, or if the Data Recipient (Study PI) has changed, then you are required to submit a new data request to DASH.

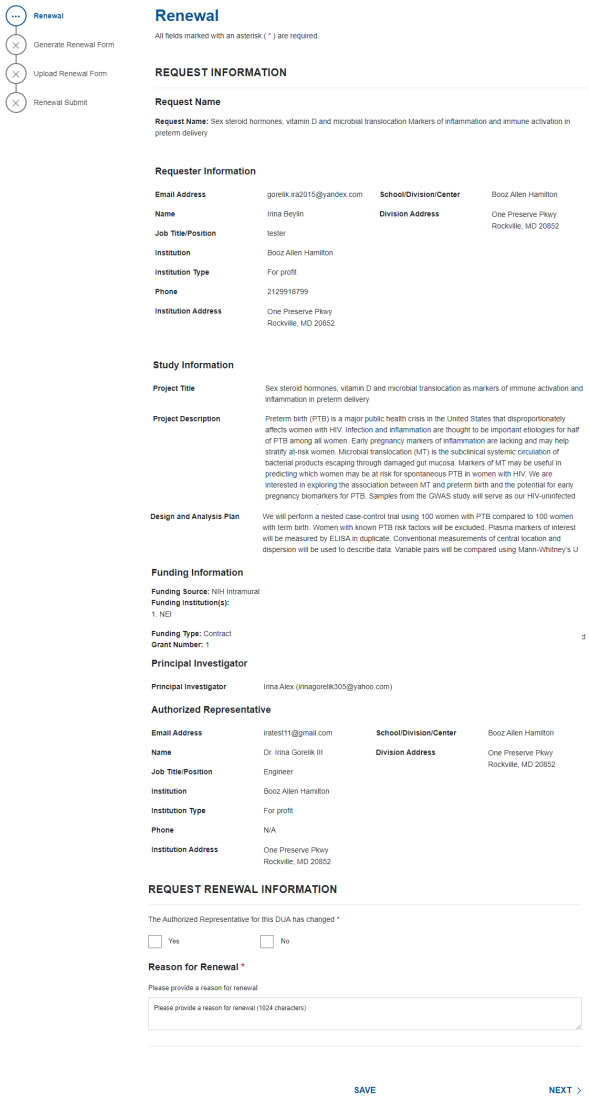
Figure 12: Verify Eligibility for Request Renewal



5.3. System will present the Request Renewal Form prepopulated with information you provided when you submitted the request. The left-hand navigation pane will show you the current stage of the renewal process. All fields marked with an asterisk (*) are required and must be completed to move on to the next page. Fill out the required fields and then click "Next."

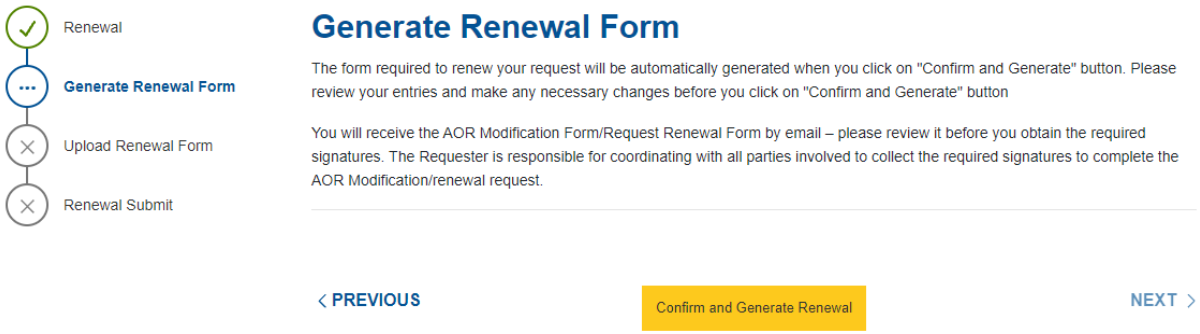
Note: You may start and stop this process at any time. Be sure to click "Save" at the bottom of the window you are working on so your work is available when you return.

Figure 13: Request Renewal Form



5.4. Read the information on the "Generate Renewal Form" page, and then click "Confirm and Generate Renewal." The system will generate the form and send it to you via email.

Figure 14: Generate Renewal Form



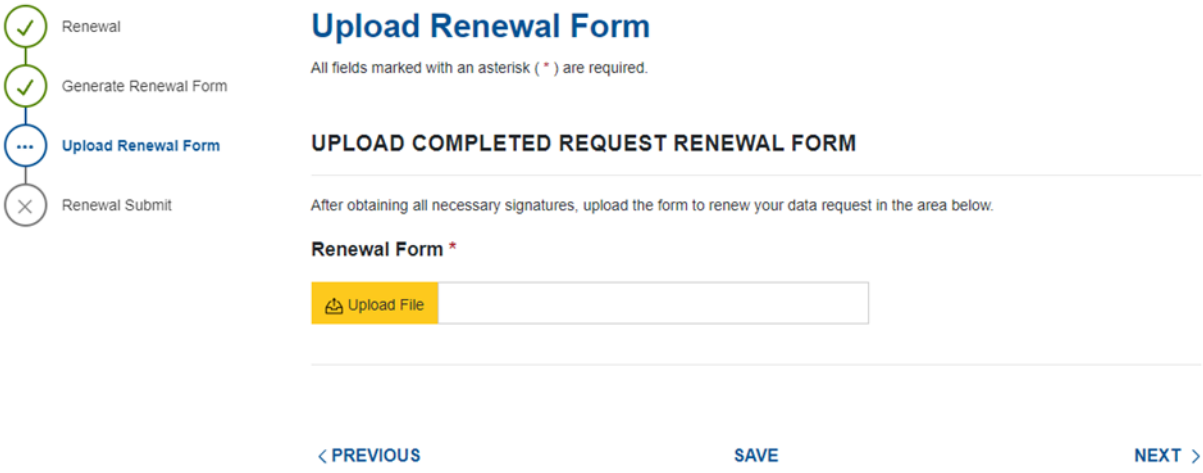
Note: Do not make changes to or add information in the Renewal Form you receive. If you make any changes to your document system has generated, your form will be invalidated, and you will need to generate it again. If there are changes to be made, login to NICHS DASH, make the changes to your Renewal and generate a new document.

5.5. Please review the Renewal Form prior to requesting the AOR's and Data Recipient's signatures.

5.6. To upload the form after obtaining required signatures, scan your documents and log back in to the NICHD DASH system. Click on "Workspace " at the top of the NICHD DASH homepage to begin and select Data Requests tab. Next to the appropriate request, click the "Actions" dropdown and select "Continue Renewal Progress". You will be directed to the "Upload" page.

5.7. Click on the "Upload" button and select the appropriate file saved on your computer. Your document title will appear on the page to verify it has been uploaded.

Figure 15: Upload Request Renewal Form



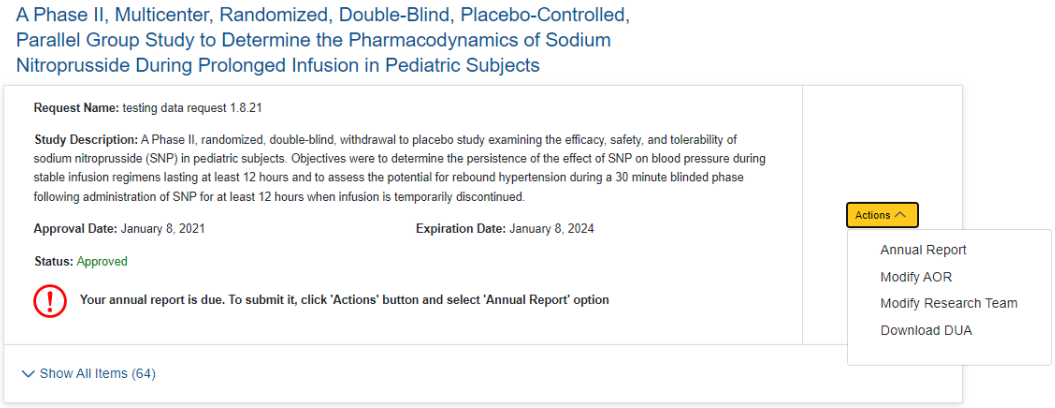
5.8. Once you have uploaded your document, click "Next" to move to the "Renewal Submit" page. This page shows all of the information you have entered; please carefully review this page for accuracy and completeness. Then click the "Submit" button to submit your modification request.

5.9. Your renewal request will be reviewed by the NICHD DASH Data Access Committee. You will be notified via email if any updates or additional information are needed for your request. You will be notified via email with the approval decision.

6. Submit Annual Report

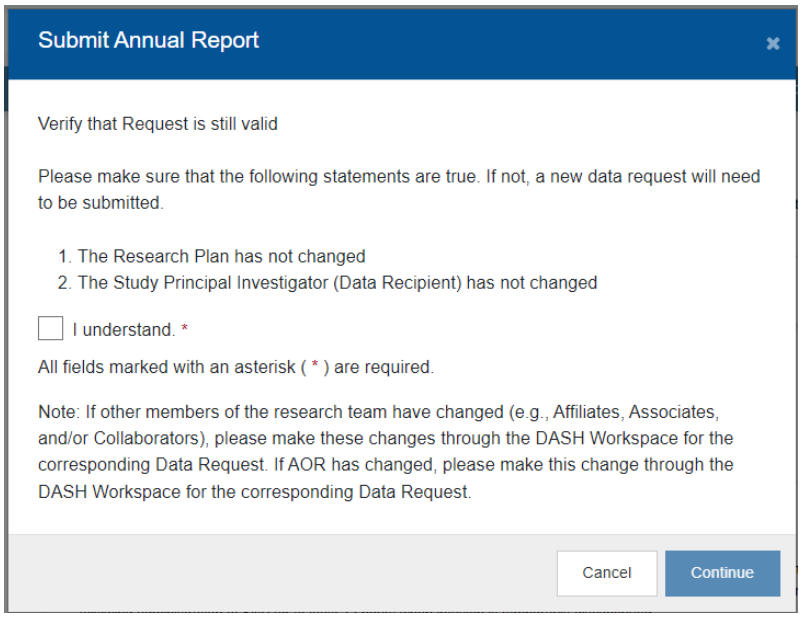
6.1. 30 days prior to the date annual report is due you will see a warning on the Data Requests tab of your Workspace. In order to submit the annual report, click the yellow "Actions" button and then select "Annual Report" option.

Figure 16: Submit Annual Report



6.2. System will present the pop-up modal reminding you that if Research Plan and Data Recipient have changed for this request a new request will have to be submitted. You will be asked to confirm that you understand that a new data request is required if the Research Plan has changed or if the Study Principal Investigator (Data Recipient) has changed.

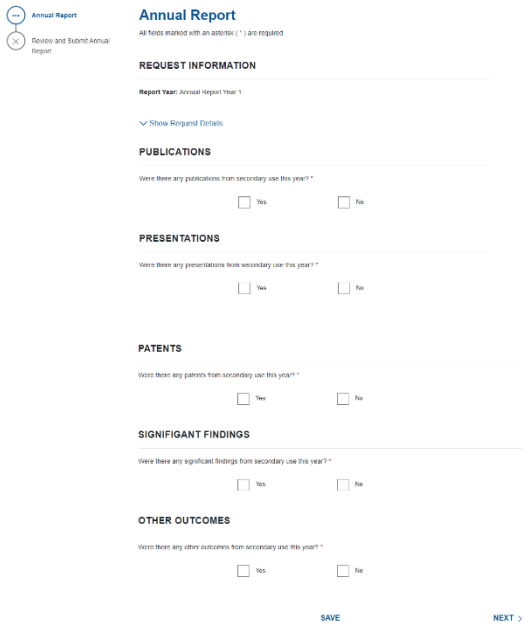
Figure 17: Annual Report Reminder Modal



6.3. System will present the Annual Report Form prepopulated with information you provided when you submitted the request. The left-hand navigation pane will indicate the stage of the Annual Report submission process you are currently at. All fields marked with an asterisk (*) are required and must be completed to move on to the next page. Fill out the required fields for each outcome type and then click "Next."

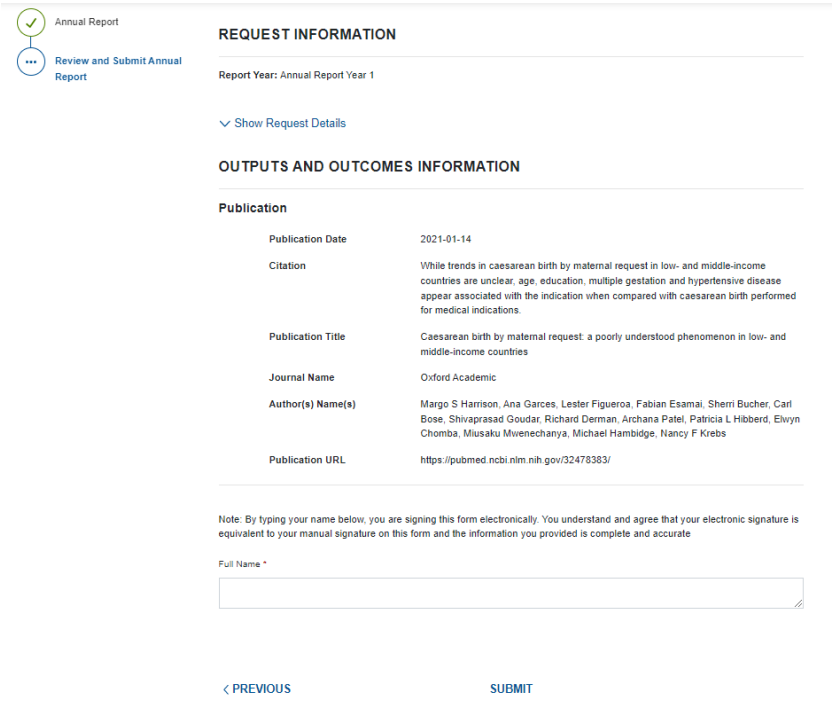
Note: You may start and stop this process at any time. Be sure to click "Save" at the bottom of the window you are working on so your work is available when you return.

Figure 18: Annual Report Form



6.4. System will move you to the Review and Submit Annual Report page, where you will be asked to sign the form electronically by typing your name in the text box at the bottom of the page.

Figure 19: Review and Submit Annual Report



6.5. Please review the Annual Report prior to signing. If you need to make any changes, please return to the Annual Report page by clicking "Previous" button at the bottom of the page or "Annual Report" button on the left-hand navigation pane.

6.6. Once you are satisfied with your entries, please enter your name in the text field and click "Submit".

6.7. Your annual report will be reviewed by the NICHD DASH Administrator. You will be notified via email if any updates or additional information are needed for your annual report. Once your annual report is approved, the information about your outcomes will be added to DASH system for reporting purposes. You will be notified via email with the approval decision.

3. Manage Biospecimen Requests

The "Biospecimen Requests" function lists the requested biospecimens you have been approved to receive and that have been shipped to you by the NICHD Contracted Biorepository. Biospecimens are grouped by request and arranged chronologically.

Figure 20: Manage Biospecimen Requests