



ASSIST (Application Submission System & Interface for Submission Tracking) User Guide

July 27, 2020



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1 ASSIST

The Application Submission System & Interface for Submission Tracking (ASSIST) is a web-based system used to prepare applications using the SF424 Research & Related form set and to submit electronically through Grants.gov to NIH and other participating agencies.

ASSIST allows participants to do the following:

- Leverage current eRA Commons credentials to access ASSIST
- Delegate application preparation responsibilities to multiple users within and outside the applicant organization while maintaining appropriate access control and security
- Populate data from established eRA Commons profiles
- Run validations on federal-wide and agency business rules prior to submission
- Generate Table of Contents, headers, footers, page numbers, etc. automatically
- Print/Preview applications prior to submission in the format used by the agency
- Present to reviewers clear, color PDF images rather than scanned versions of the application
- Avoid the hassle of preparing and shipping multiple paper copies

ASSIST can support both single-project and multi-project (also known as multi-component or complex) applications with features presented differently depending on the type of application, as determined by the entered Funding Opportunity Announcement (FOA).

1.1 Application Format

All electronic single-project applications prepared in ASSIST will include:

- All required forms necessary for the application package
- All optional forms available for the application package

All electronic multi-project applications prepared in ASSIST will include:

- A single Overall Component: The Overall component describes the entire application and how each of the additional components fit together.
- Other Components: Some number of other component types (e.g., Admin Core, Project, Core) with predefined data collection requirements set by the agency when posting the opportunity in Grants.gov

• Summaries: Information compiled from the data provided in the individual components (e.g., component and categorical roll-ups of budget data).

Refer to the help topic titled *Search for an Application* for information on searching for applications.

Refer to the help topic titled *Initiate an Application* for information on initiating an application.

NOTE: Some screens may not display correctly in the Internet Explorer browser with *Compatibility Mode* turned on. To ensure that the screens are correctly displayed, turn off *Compatibility Mode* or use a different browser.

1 Latest Updates

July 25, 2020

The use of ASSIST for the submission of administrative supplements has been expanded and streamlined to support easier initiation and submission of administrative supplements. See *Initiate an Administrative Supplement Application*.

April, 2020

ASSIST now supports the initiation and submission of <u>Administrative Supplements</u>.

March 31, 2020

Updates for Forms-F specifically for; <u>Human Subjects & Clinical Trials Information</u>

Form; PHS398 Cover Page Supplement; <u>Career Development Award Supplement; PHS</u>

Fellowship Supplement; <u>PHS Assignment Request Form; and SBIR/STTR Information</u>

November 25, 2019

ASSIST now permits NIH applicants/awardees to *Upload Human Subjects Data Directly to ClinicalTrials.gov*. This new method allows data to be uploaded to ClinicalTrials.gov directly inside ASSIST in one step. It is simpler than the alternative, which requires exporting the data in ASSIST to an XML file, then logging into ClinicalTrials.gov to upload the contents of the XLM file.

February 27, 2019

Uploading Study Information from ASSIST into ClinicalTrials.gov

To reduce the burden on applicants who have to <u>upload clinical study information</u> to ClinicalTrials.gov as part of registering their clinical trials on CT.gov, ASSIST users can export clinical trial information from the HSCT Information form in ASSIST to CT.gov

January 28, 2019

The Editing Inclusion Counts section of the Inclusion Enrollment Report topic has been updated.

September 12, 2018

ASSIST will now honor <u>delegations made in Commons</u> so that a user who has been delegated the authority, by virtue of these delegations, can perform post award updates to Human Subjects information in ASSIST. These delegated users will need to be granted access within ASSIST to perform post submission actions on behalf of the delegator.

- · Type of Delegations supported:
 - PI Delegation
 - Submit Delegation
 - Support AO: An AO can work on the progress report, and therefore should be able to work and edit an HSS request. However, the AO cannot submit a progress report and should not be allowed to submit an HSS request in ASSIST. The privileges for AO in ASSIST with regards to HSS requests will be the same as the PI.

December 12, 2017

- PD/PIs will now have access to Amendment and Continuation applications that they did not initiate when the status is WIP (Work in Progress).
- Applicants may now use an *Identifier* field and a **Populate** button to import data from ClinicalTrials.gov registration.
- For SAMHSA type 5 applications, the *Primary Project Performance Site* will be pre-populated from the parent application.
- A Competition ID will be added to the Copy Application screen above the Competition Title.

October 12, 2017

Changes for Forms E to support Clinical Trials Initiative — ASSIST has been revamped to accommodate the new integration of PHS Human Subjects and Clinical Trials information and related changes for FORMS-E. Starting in late October, OER will start adding the FORMS-E application packages to existing Funding Opportunity Announcements (FOAs) with due dates on or after January 25, 2018.

March 29, 2017

The Non-Research SF-424 application form has been updated to a new user platform (Spring MVC) to enable a more modern, secure, and flexible environment. Functionality and appearance remain largely the same.

The following have also been updated to the Spring MVC platform:

- ASSIST Welcome Page
- ASSIST search screens
- SF-424B
- SF-424D
- HHS Checklist

- HHS Project Abstract Summary
- SBIR-STTR Information
- PHS Fellowship Supplemental
- PHS398 Cover Page Supplement
- PHS398 Career Dev Award Supplemental
- PHS398 Research Training Program Plan

The Copy Application screen will now provide the FOA # of the application to be copied to avoid the need to refer back to the original application.

Audit validations for null text have been updated to avoid unnecessary audit failures.

Hyperlinks updated to reflect Secure HTTP ("https:" vs "http:").

January 19, 2017

SAMHSA grantees will now use ASSIST for non-competing continuation applications (non-research only). They will initiate the application in eRA Commons and prepare and submit it in ASSIST. Grantees will be able to track the application in eRA Commons through *Status*; they will also be able to manage their entire non-competing continuation process for their grant using a new *Manage Continuations* sub-tab in eRA Commons. Requisite changes will also be made to the Grant Folder.

October 24, 2016

SAMHSA Applicants/Grantees Can Now Submit New Applications and Post-Award Amendments Electronically Using eRA Commons & ASSIST

Submit new applications using ASSIST

You can now prepare your new grant application in ASSIST and submit it via Grants.gov to SAMHSA for funding consideration.

- ASSIST will provide all required and optional forms for the Funding Opportunity Announcement you are applying for (using ASSIST is an alternative to using downloadable forms).
- Log in to ASSIST and initiate your application. You can provide access to the application to individuals on your team.
- Once you fill out the application, you can use the Validate Application action to run the application against SAMHSA's business rules (validations) and see any errors or warnings.
- Once the application is ready for submission, use the Submit button to submit to SAMHSA via Grants.gov.

Once submitted to Grants.gov, you can track the application submission status in Grants.gov and eRA Commons. You are responsible for tracking your application through Grants.gov to a visible application image in eRA Commons. You must address any errors identified in Grants.gov and eRA Commons before the submission deadline.

Detailed steps and screenshots are available in the <u>ASSIST online help</u> (see general help as well as the section on Non-Research Forms)

Submit post-award amendments: Initiate in eRA Commons, Submit through ASSIST

Whether it is a revision to the budget, a carryover request, a change in scope, key personnel, a merger or transfer, a no-cost extension or an organization change, you will be able to fill out and submit these post-amendment applications electronically.

In eRA Commons:

- A new Non-Research tab has been added to the top navigation in eRA Commons
- Clicking that tab and then the Manage Post Award Amendments tab will
 open up a screen that will allow you to search for a list of grants eligible for
 amendments and then initiate a post-amendment application request.

In ASSIST

- Once an amendment request has been initiated in eRA Commons, the system will open ASSIST and the required amendment-specific forms and prepopulate select data fields. You may have to add additional forms manually, as specified by the Funding Opportunity Announcement.
- Upon completion of data entry, ASSIST will run the application through the validations and display any errors or warnings. Once those are corrected, the application can be submitted to Grants.gov.

Back in eRA Commons:

- Grantees can view the status of the submitted application on the Manage Post Award Amendments: View screen in eRA Commons.
- After the post-amendment application is submitted and retrieved by agency, SAMSHA may place a Request for Additional Materials (RAM) after the postamendment application is submitted. In this case, an 'Edit RAM' option will

be displayed in the Action column of the Manage Post Award Amendments: View screen.

The grantee can fill out the fields on the Post-Award Amendment Application: Request for Additional Materials screen and submit the RAM to SAMSHA.

October 20, 2016

- Added Non-Research Amendments section as well as Non-Research Forms list.
 This is initially for SAMHSA use but will be expanded later.
 - Non-Research Amendments
 - Non-Research Forms

April 15, 2016

- Updated to Forms-D incorporated changes to PHS Forms included in Forms-D application packages (for due dates on or after May 25, 2016). See High-level list of FORMS-D form changes for a synopsis. The following topics have been updated:
 - PHS 398 Cover Page Supplement
 - PHS 398 Research Plan
 - PHS 398 Career Development Award Supplemental Form
 - PHS 398 Research Training Program Plan
 - PHS 398 Training Budget
 - PHS 398 Training Subaward Budget Attachment(s) Form
 - PHS 398 Modular Budget
 - PHS Fellowship Supplemental
- Introduced the PHS Inclusion Enrollment form (the new form that combines Planned Enrollment Report and Cumulative Inclusion Enrollment into a single form).
 - See topic PHS Inclusion Enrollment
- Introduced the Assignment Request form, used for capturing assignment requests
 - See topic <u>PHS Assignment Request</u>

2 Using ASSIST

To navigate through the application in ASSIST, select any of the buttons in the **Actions** section, the links in the **Component Type** section of the left-side navigation area (for multi-project applications only), or other links located on the ASSIST pages.



2.1 Actions

The **Actions** section of the left-side navigation provides buttons for accessing the features available for the application (or multi-project component) currently displayed on the page. Some of these buttons remain on the screen at all times. Other buttons are removed or added to this area depending on what is being viewed at the time. For example, for multi-project applications, the available buttons featured in **Actions** when the *Application Information* page is displayed differ from those featured when the *Core Information* page is displayed, because the actions taken against an entire application differ from those taken against an individual component (e.g., **Update Submission Status** vs. **Update Component Status**). The available **Actions** buttons also may change depending on the status of an application or component.

2.2 Component Type

The **Component Type** section of the left-side navigation appears only for multi-project applications and lists the different component types included in the application. Components of the same type are grouped together and displayed under that specific component type heading (e.g., if three different Project components were initiated, all three are listed under the **Project** heading). To view all the components of a certain component type, click the component type heading, which is displayed next to a plus sign (+). To hide the components, select the component type heading when the minus sign (-) is displayed.

The components are listed with numeric identifiers, not the actual component title names; however optional component short names (when added to a component) display beneath the numeric identifier and can aid in keeping track of the different components.



2.3 Breadcrumbs

The breadcrumb links at the top of the ASSIST page may be used to navigate back and forth through pages already visited. The breadcrumbs display a trail indicating how the current page was accessed. To view any of the prior pages, select the page name link within the breadcrumbs.

Home > Search for Applications > Application Search Results > Application Information > Component Information

2.4 Component Form Tabs

A component is a named, agency-defined collection of data elements that may be repeated within an application. When the Component Information is accessed for an Overall or individual component, the included forms for that component are listed across

the page in tabs. Each tab displays the name of the particular form it represents. To navigate among the forms, select the form tab.



NOTE: The image above is a sample of component form tabs and does not reflect the forms available for every application.

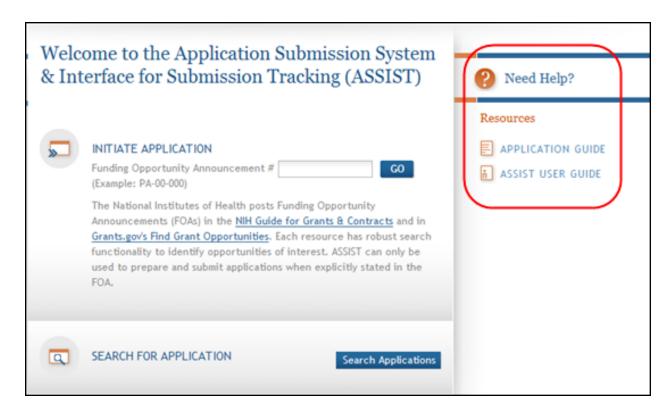
2.5 Navigational Links

Across the top of every ASSIST page, next to the **Logout** link, are the links for accessing the ASSIST Home page (**Home**), for contacting system support (**Contact Us**), and for accessing eRA Service Desk support information (**Help Desk**). Select the appropriate link to access this information.



2.6 Online Help

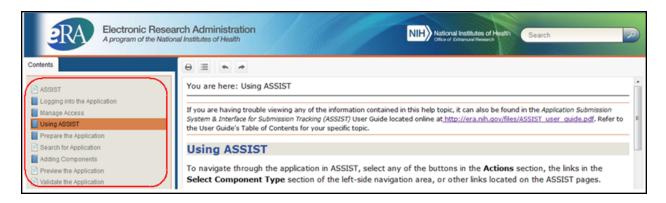
Various sources of help exist for the ASSIST. The *Welcome* page **Resources** section contains links for the **Application Guide** and the **ASSIST User Guide**. In addition, the **Need Help?** icon launches the ASSIST online help feature in a separate browser window.



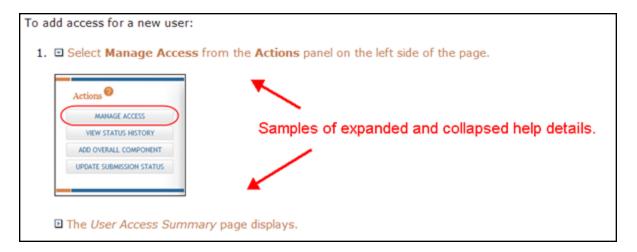
The online help feature is also available for specific topics by selecting the ? icon from the various pages in ASSIST. Selecting the icon from a specific page (rather than from the *Welcome* page) opens the online help for that specific topic.



No matter how online help is accessed, all topics covered in the online help are accessible via the **Contents** list on the left side of the online help window.



Many help topics include figures or additional steps for those who need it. This information is hidden by default with togglers. Click the arrow icons or orange text when available to expand specific hidden text or figures; click again to hide it.



The **Expand All/Collapse All** button located above the breadcrumbs at the top of each help screen expands (or collapses) all hidden text and images within the current topic.



NOTE: Some screens may not display correctly in the Internet Explorer browser with *Compatibility Mode* turned on. To ensure that the screens are correctly displayed, turn off *Compatibility Mode* or use a different browser.

2.7 Logging into the Application

ASSIST uses the same user authorization service as eRA Commons. All ASSIST users must use their existing eRA Commons IDs or work through their organization to obtain them. Anyone with a Commons ID can access ASSIST and initiate an application.

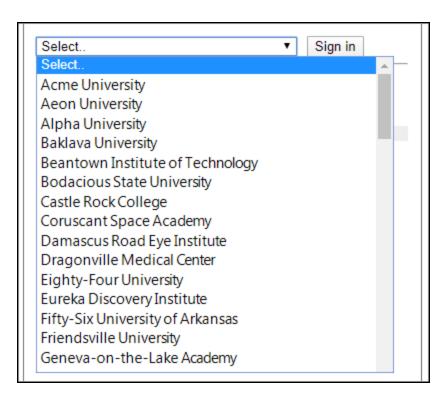
- You can access ASSIST from eRA Commons or by going directly to the ASSIST login page.
 - From eRA Commons, select the **ASSIST** link on the menu bar.



- For this option, log in to eRA Commons first and then click on the ASSIST tab.
- Log in directly using the URL; https://public.era.nih.gov/assist/. This page provides three login options.



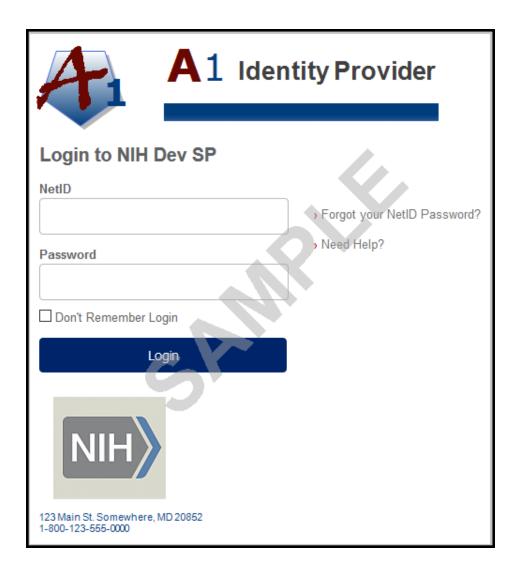
- I. Login with eRA Credentials
 - In the **Username** field, type a valid eRA Commons username and press **Tab** to move to the **Password** field.
 - Type the eRA Commons password and click the **Login** button.
- II. Login with Federated Account
 - Select the appropriate organization from the



• Click the Sign In button



• Your organization's sign in page displays.



• Enter your credential information (e.g., username and password) as appropriate to your organization.

This information - and screen - is managed by your own organization and not by eRA Commons. If you do not know your credentials at your institution or you are having trouble with your institution's log in screen, you will need to contact your institution. eRA cannot help you with this screen.

Validations will occur with your organization to authenticate your credentials. Any failure to authenticate your organization credentials must be addressed with your organization.

If Commons determines that your organization credentials are associated with your Commons ID, you will be successfully logged into Commons and can start using the system. If your accounts are not linked, you will be prompted to do so.

III. Accessing ASSIST with login.gov (two-factor authentication)

Steps for the Initial Setup at login.gov

STEP 1 — Click on the login.gov option

 a. When you click on the login.gov option, you will be redirected to https://login.gov/

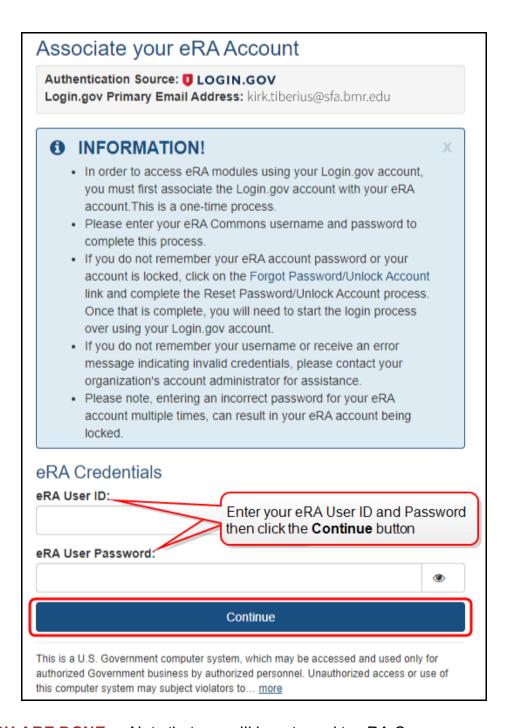


STEP 2 — Create a login.gov account

- a. Enter email address at login.gov
- b. Receive email verification
- c. Verify email address
- d. Create password
- e. Choose a primary authentication method for instance, select phone
 - 1. Enter phone number
 - 2. Enter security code received by text message
 - 3. Set up is confirmed
- f. Set up a secondary authentication method for instance, an authenticator app
 - 1. Scan barcode and enter authenticator code
 - 2. Set up is confirmed
- g. Your account creation at login.gov is confirmed. Click **Continue** to return to eRA Commons.

STEP 3 — Associate your login.gov account with your eRA Commons account (one-time only)

- a. The Associate your eRA Account screen is displayed. Enter your eRA credentials – user name and password – to associate your login.gov account with your eRA Commons account. You will only do this once unless you decide to use a different login.gov account.
- b. Please note, your eRA account must be active. If you do not know your eRA account password or you password is expired, please complete the Forgot Password/Unlock Account process before completing this process.



YOU ARE DONE — Note that you will be returned to eRA Commons rather than ASSIST after associating your account. However, the next time you log into ASSIST using login.gov, you will be automatically

authenticated and re-directed back to ASSIST without having to log in again.

Tip: For screenshots and details, see https://login.gov/help/

2.7.1 Troubleshooting Login Problems with login.gov

If you tried to log in using login.gov, and it did not work, please perform the following before contacting the eRA Service Desk:

- 1. Clear your browser cache/history and then close and restart your browser.
- 2. Make sure you are not using a bookmark that points to an older URL address. Delete your bookmark and go to the main eRA system URL directly. For instance:
 - a. https://public.era.nih.gov/commons/
 - b. https://public.era.nih.gov/assist/
 - c. https://public.era.nih.gov/iar
 - d. http://m.era.nih.gov/cmb
- 3. If it still does not work, please contact the eRA Service Desk at https://grants.nih.gov/support/index.html

NOTE: If this is the first time using your eRA Commons username and password, log into eRA Commons first before attempting to access ASSIST. You can use the provided temporary password to log into eRA Commons for the first time. Once logged in, you will be prompted to change your password.

The system displays the *Home* page with your login information displayed in the upper right corner of the page.

eRA Commons allows up to six unsuccessful attempts to log in. After the 6th attempt the account is locked. You will then be prompted to change your eRA Commons password to gain access to ASSIST.

2.7.2 Changing Your Password

You can change your password for many reasons including if you've forgotten it, if your password has expired, if your account has been locked, etc. When changing your password, remember that all passwords must follow the NIH eRA Password Policy.

2.7.2.1 Forgot Password/Unlock Account

If you have forgotten your password or if your account has been locked, you can submit a request to reset your password. Submitting this request generates a new, temporary

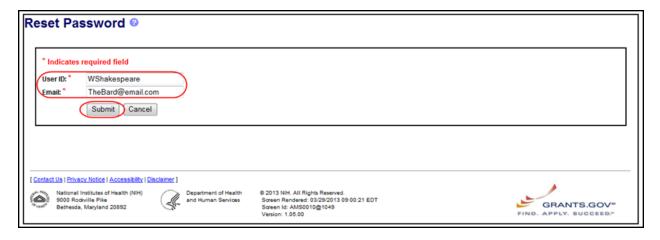
password, which is sent to the email address contained in your Commons personal profile. To reset your password:

1. From the ASSIST login page, select the **Forgot Password/Unlock Account link**.



The Reset Password screen displays.

- 2. Enter your **User ID** (this is the same as your User Name) and **Email** address into the displayed fields. Both fields are required.
- 3. Select the Submit button.



The system returns to the ASSIST login page. Check the email account associated with your profile for the new, temporary password. Once received, log into ASSIST again.

- 4. Use your existing User Name and the temporary password sent to you to log into ASSIST again.
- 5. At the prompt, enter a new password of your choosing for your account. Continue to use this password until it expires.

2.7.2.2 Expired eRA Password

If your eRA Commons password has expired you will be prompted to change their eRA Commons password when attempting to access the ASSIST system. Once the password is changed you will be able to access ASSIST.

Access the following link for more information regarding changing your password https://era.nih.gov/commons/faq_commons.cfm#III3

2.8 Manage Access

Application access is controlled by assigning appropriate access levels or privileges to system users. An access level is a group of privileges. Privileges control the extent to which each person working on an application can view and/or edit application data.

Users from the applicant organization that log in to ASSIST using an eRA Commons ID with an SO role automatically have the *Access Maintainer* privilege needed to manage privileges for other users. Users with the SO role can also assign the *Access Maintainer* privilege to other users within their institution.

Application access can be controlled across three variables:

- 1. Edit vs. View
- 2. Entire application vs. specific component within an application (for multi-project applications)
- 3. Budget data vs. Non-Budget data

It is not necessary for all users who access an application to be affiliated with the applicant organization, although certain functions are only available to affiliated users. For example, only users affiliated with the applicant organization hold the *Access Maintainer* privilege for an application.

Because all users granted access via this screen have the ability to edit the application, it is not necessary to route to PD/PI or route to SO. Routing history is not necessary because you can <u>view status history</u> for the entire application, and you can view access history for an individual user on the User Access Summary screen.

2.8.1 Privileges Automatically Available in ASSIST Based on eRA Commons Role

Some privileges are automatically available based on the organization and roles associated with the eRA Commons ID used to access ASSIST. Since these privileges cannot be individually granted or revoked with ASSIST, the Manage Access interface does not display all users that hold these automatic privileges.

Signing Official (SO) at the lead application organization:

- Initiate application
- Assign, modify, or revoke application access for other users
- Delegate ability to assign, modify, or revoke application access for other users
- Edit entire application
- Submit application (must be SO at lead applicant organization AND have valid Grants.gov Authorized Organization Representative credentials)
- Update the component status from WIP to Final (without setting it to Complete)

Administrative Official (AO) at the lead applicant organization:

- Initiate application
- Edit entire application
- Update the component status from WIP to Final (without setting it to Complete)

Principal Investigator (PI) identified on an application:

- Edit entire application
- Delegate access to another PI on their behalf enabling delegated PI to initiate and work on HSS request.

2.8.2 Delegations from Commons that are supported within ASSIST:

Delegations from Commons

Commons Authority Type	Delegated By	Delegated To	Description
Progress Report	SO, AA, AO (on behalf of PI)	PI	SO, AA, AO are giving this authority on behalf of one PI to another PI, which enables this second PI to initiate and submit a progress report or <i>initiate</i> and submit an HSS request for the first PI. This delegation also gives the delegated PI the authority to submit progress reports for the Institution Note: An AO can work on the progress report, and therefore should be able to work and edit an HSS request. However, the AO cannot submit a progress report and should not be allowed to submit an HSS request in ASSIST. The privileges

Delegations from Commons

			for AO in ASSIST with regards to HSS requests will be the same as the PI.
Progress Report	PI	Any active user within the Organization (this includes the PI, SO, AA or AO or anyone else who has a commons account so that whoever they delegate to can initiate and edit an RPPR or initiate and edit an HSS request on their behalf.)	Enables the authorized user to initiate and edit an RPPR or HSS request
Submit	SO, BO	PI	Enables the PI to submit (progress report or HSS Request)

IMPORTANT: In the case of multi-project applications, once the DUNS number is entered on the SF424 R&R for a component, then similar automatic privileges apply for that specific component. You cannot revoke the automatic access given to the SOs of the component through **Manage Access**. However, when the component is in any status other than *Work In Progress*, the component can only be edited by individuals that are granted edit access to the entire application (the automatic access provided at the component level alone is insufficient). This provides the applicant organization with the ability to limit editing as they are pulling together the application. Access can be restricted to the component lead through **Manage Access** at any time and when the component is in any status.

See Also

- Add Access for a New User
- Modify User Access for an Application
- Revoke Access to an Application

- Manage Access History
- User Access History

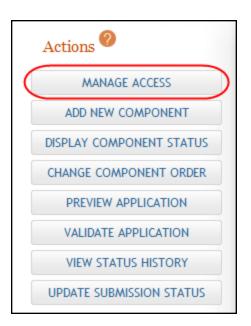
2.8.3 Add Access for a New User

ASSIST users with the appropriate authority can add access rights to new users. Access can be assigned for editing the application or for only viewing it. In addition, users can be restricted from (or allowed to) edit budget information on an application. Users can also be granted authority to maintain access to other users. The Access Maintainer needs to know the eRA Commons ID of a user in order to grant them access to the application.

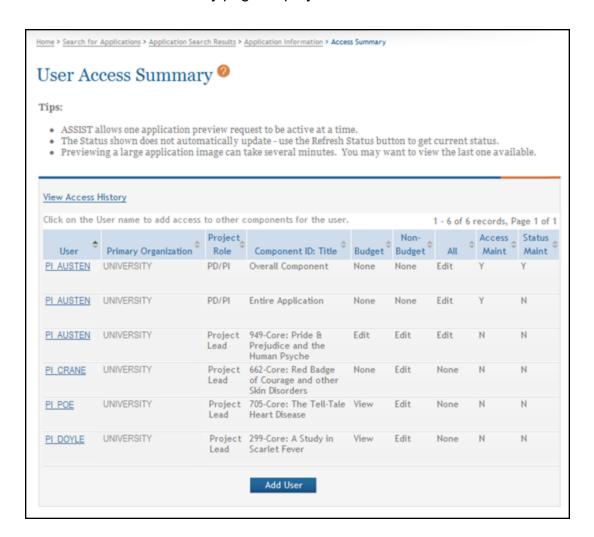
To add access for a new user for single-project or multi-project applications, follow the appropriate steps as listed below.

2.8.3.1 Access for Multi-Project Applications

1. Select Manage Access from the Actions panel on the left side of the page.



2. The User Access Summary page displays.

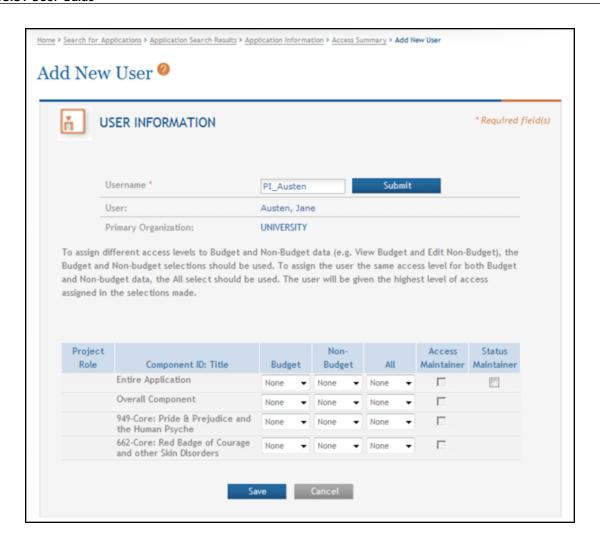


3. Select the **Add User** button at the bottom of the page.

The Add New User page displays.

- 4. Enter the eRA Commons ID into the **Username** field of the **User Information** portion of the page.
- 5. Select the **Submit** button.

The matching User and Primary Organization information populate on the page.



- 6. Select the appropriate access for the Overall Component and/or additional components or the Entire Application. Access is assigned by selecting one of the options None, Edit, or View from the Budget, Non-Budget, and All drop-down lists for the Overall Component, specific component, or Entire Application. If you are assigning different access levels for Budget and Non-Budget information, use the individual drop-down lists for Budget and Non-Budget; however, when you are assigning the same access level for both Budget and Non-Budget data, you should use the All selection.
- 7. Optional: Select the checkbox for **Access Maintainer** if the user is being granted authority to provide and control access to other users. The following rules govern the Access Maintainer privileges:
 - Only an SO/AOR with the Applicant Lead Organization can grant or revoke the Entire Application Access Maintainer access level. This can only be granted to a PI or ASST associated with the institution of the SO/AOR.

- Any user holding the Entire Application Access Maintainer access level has the ability to grant Entire Application Access levels – other than the Entire Application Access Maintainer level – to any AA, AO, ASST, PI, or SO.
- Only an SO/AOR with the Component Lead Organization can grant or revoke the Component Access Maintainer level. This can only be granted to a PI or ASST associated with the institution of the SO/AOR.
- Any user holding the Component Access Maintainer access level has the ability to grant any Component Access levels – other than Component Access Maintainer – to any AA, AO, AST, PI, or SO.
- 8. *Optional*: Select the checkbox for Entire Application **Status Maintainer** if the user is being granted authority to update the status for the entire application.
 - Only an SO or AO from the Applicant Lead Organization can grant or revoke the Status Maintainer access level.
 - By default, the Initiator of the application is given access to this level.
 - Status Maintainer level includes the ability to update the status of an individual component (Complete, Final, Abandoned, WIP) as well as the status of the entire application (All Components Final, Abandoned, Ready for Submission).
 - The Status Maintainer privilege for an entire application cannot be granted to an individual who does not hold the entire application Edit privilege as well (i.e., All column, option Edit). The checkbox for the Status Maintainer privilege is disabled until the Edit privilege is added for that individual.
- 9. Select the **Save** button to save the changes.

After saving the changes, the *User Access Summary* page displays. The added user and corresponding access information are included in the displayed table.

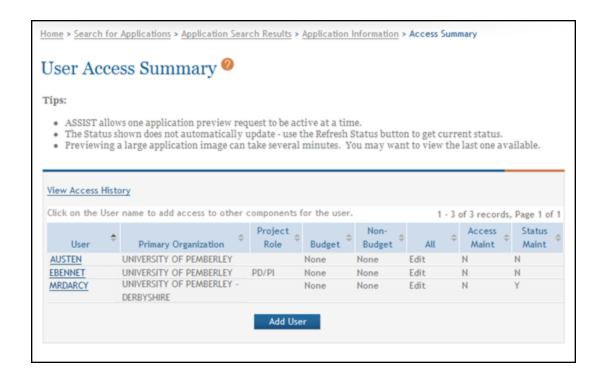
ASSIST automatically sends an email notification to the user assigned the access. The email notification informs the user of the access levels given, to which application or components of that application the access applies, and the user who granted the access.

2.8.3.2 Access for Single-Project Applications

1. Select Manage Access from the Actions panel on the left side of the page.

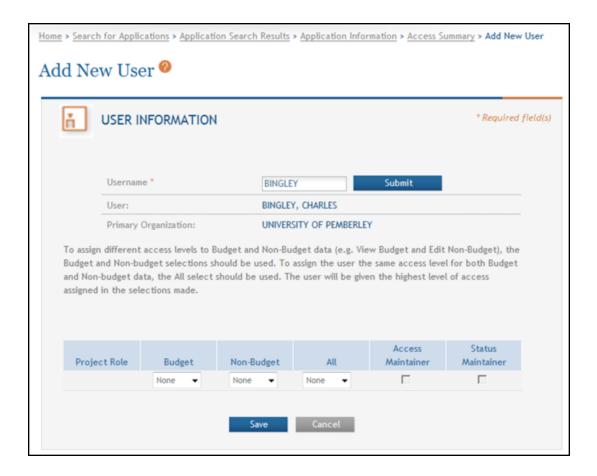


The User Access Summary page displays.



- 2. Select the **Add User** button at the bottom of the page.
- 3. On the displayed *Add New User* page, enter the eRA Commons ID into the **Username** field of the **User Information** portion of the page.
- 4. Select the **Submit** button.

The matching User and Primary Organization information populate on the page.



- 5. Select the appropriate access for the application. Access is assigned by selecting one of the options None, Edit, or View from the Budget, Non-Budget, and All drop-down lists. If you are assigning different access levels for Budget and Non-Budget information, use the individual drop-down lists for Budget and Non-Budget; however, when you are assigning the same access level for both Budget and Non-Budget data, you should use the All selection.
- 6. *Optional*: Select the checkbox for **Access Maintainer** to grant the authority to provide and control access to other users. The following rules govern the Access Maintainer privileges:
 - Only an SO/AOR with the Applicant Lead Organization can grant or revoke the Access Maintainer access level. This can only be granted to a PI or ASST associated with the institution of the SO/AOR.

- Any user holding the Access Maintainer access level has the ability to grant access levels – other than the Access Maintainer level – to any AA, AO, ASST, PI, or SO.
- 7. *Optional*: Select the checkbox for **Status Maintainer** if the user is being granted authority to update the status for the entire application.
 - Only an SO or AO from the Applicant Lead Organization can grant or revoke the Status Maintainer access level.
 - By default, the Initiator of the application is given access to this level.
 - The Status Maintainer privilege for an application cannot be granted to an
 individual who does not hold the entire application Edit privilege as well (i.e.,
 All column, option Edit). The checkbox for the Status Maintainer privilege is
 disabled until the Edit privilege is added for that individual.
- 8. Select the **Save** button to save the changes.

After saving the changes, the *User Access Summary* page displays. The added user and corresponding access information are included in the displayed table.

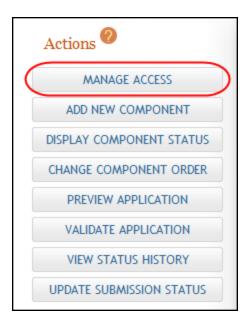
2.8.4 Modify User Access for an Application

ASSIST users with the appropriate authority may view and modify the access of other users. Access can be assigned for editing the application or for only viewing it. In addition, users can be restricted from (or allowed to) edit budget information on an application. Users can also be granted authority to maintain access to other users.

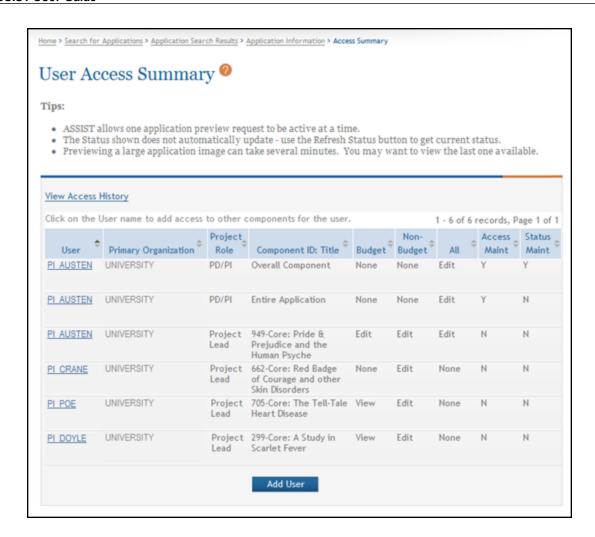
To view and modify access for an existing user for single-project or multi-project applications, follow the appropriate steps as listed below.

2.8.4.1 Modify Privileges for Multi-Project Applications

1. Select the Manage Access button from the Actions panel on the left side of the page.

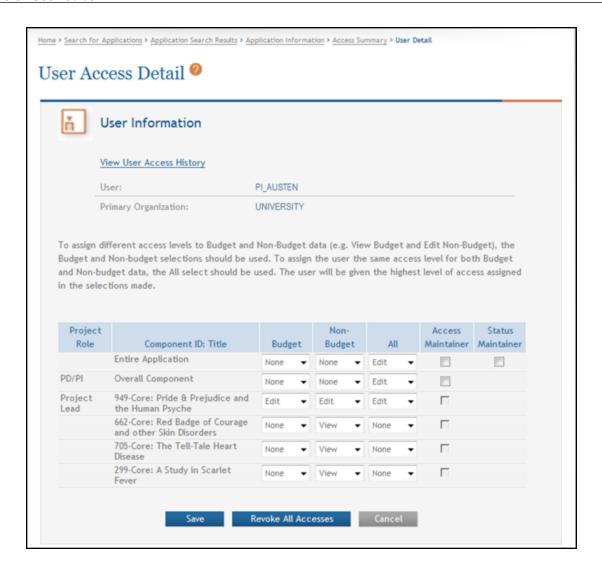


The User Access Summary page displays.



2. The **User** column displays names as hyperlinks. Select the name of the user whose access is being modified.

The User Access Detail page displays.



- 3. Make the appropriate changes by selecting the access for the Overall application, entire application, and/or additional components. Access is assigned by selecting one of the options None, Edit, or View from the Budget, Non-Budget, and All drop-down lists for the Overall Application or specific component.
- 4. *Optional*: Select the checkbox for **Access Maintainer** if you are granting authority to provide and control access to other users. The following rules govern the Access Maintainer privileges:
 - Only an SO/AOR associated with the Applicant Lead Organization can grant or revoke the Entire Application Access Maintainer access level. This can only be granted to a PI or ASST associated with the institution of the SO/AOR.

- Any user holding the Entire Application Access Maintainer access level has the ability to grant Entire Application Access levels – other than the Entire Application Access Maintainer level – to any AA, AO, ASST, PI, or SO.
- Only an SO/AOR associated with the Component Lead Organization can grant or revoke the Component Access Maintainer level. This can only be granted to a PI or ASST associated with the institution of the SO/AOR.
- Any user holding the Component Access Maintainer access level has the ability to grant any Component Access levels – other than Component Access Maintainer – to any AA, AO, AST, PI, or SO.
- 5. *Optional*: Select the checkbox for Entire Application **Status Maintainer** if the user is being granted authority to update the status for the entire application.
 - Only an SO or AO from the Lead Applicant Organization can grant or revoke Status Maintainer access level.
 - By default, the Initiator of the application is given access to this level.
 - Status Maintainer level includes the ability to update the status of an individual component (Complete, Final, Abandoned, WIP) as well as the status of the entire application (All Components Final, Abandoned, Ready for Submission).
- 6. Select the **Save** button to save the changes.

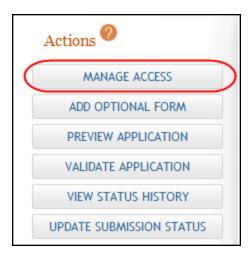
ASSIST automatically sends an email notification to the user whose access has been modified. The email notification informs the user of the changes made to the access levels, to which application or components of that application the access applies, and the user who changed the access.

NOTE: Select the **View User Access History** link on the *User Access Detail* page to view details about the access levels granted and revoked for this specific user. Refer to the help topic titled *User Access History* for more information.

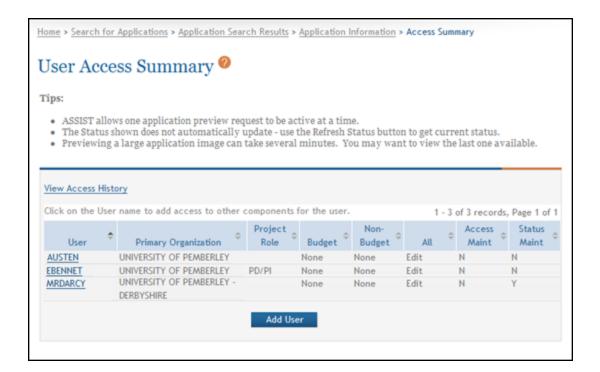
Refer to the help topic titled *Revoke Access to an Application* for information on revoking a user's access to the application and components.

2.8.4.2 Modify Privileges for Single-Project Applications

1. Select the Manage Access button from the Actions panel on the left side of the page.

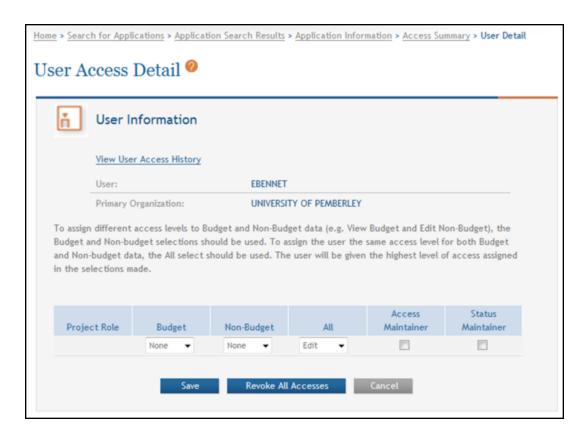


The User Access Summary page displays.



2. The **User** column displays names as hyperlinks. Select the name of the user whose access is being modified.

The User Access Detail page displays.



- 3. Make the appropriate changes by selecting one of the options **None**, **Edit**, or **View** from the **Budget**, **Non-Budget**, and **All** drop-down lists.
- 4. *Optional*: Select the checkbox for **Access Maintainer** if you are granting authority to provide and to control access to other users. The following rules govern the Access Maintainer privileges:
 - Only an SO/AOR associated with the Applicant Lead Organization can grant or revoke the Access Maintainer access level. This can only be granted to a PI or ASST associated with the institution of the SO/AOR.
 - Any user holding the Access Maintainer access level has the ability to grant Application Access levels – other than the Access Maintainer level – to any AA, AO, ASST, PI, or SO.
- 5. *Optional*: Select the checkbox for **Status Maintainer** if the user is being granted authority to update the status for the entire application.
 - Only an SO or AO from the Lead Applicant Organization can grant or revoke Status Maintainer access level.
 - By default, the Initiator of the application is given access to this level.

- The Status Maintainer privilege for an application cannot be granted to an
 individual who does not hold the entire application Edit privilege as well (i.e.,
 All column, option Edit). The checkbox for the Status Maintainer privilege is
 disabled until the Edit privilege is added for that individual.
- 6. Select the **Save** button to save the changes.

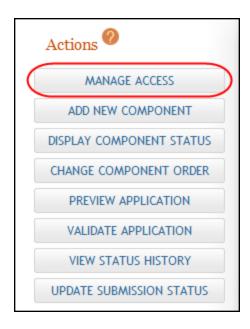
2.8.5 Revoke Access to an Application

ASSIST users with the appropriate authority may view and modify the access of other users, including revoking access to components or the entire application.

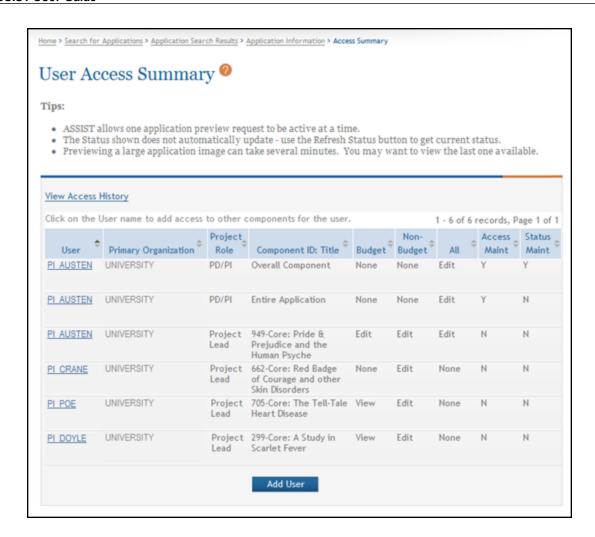
NOTE: There are sample figures in this topic for both single-project and multi-project applications. When referencing a figure, please verify it is the appropriate image for your type of application.

To revoke access for an existing user:

1. Select the Manage Access button from the Actions panel on the left side of the page.

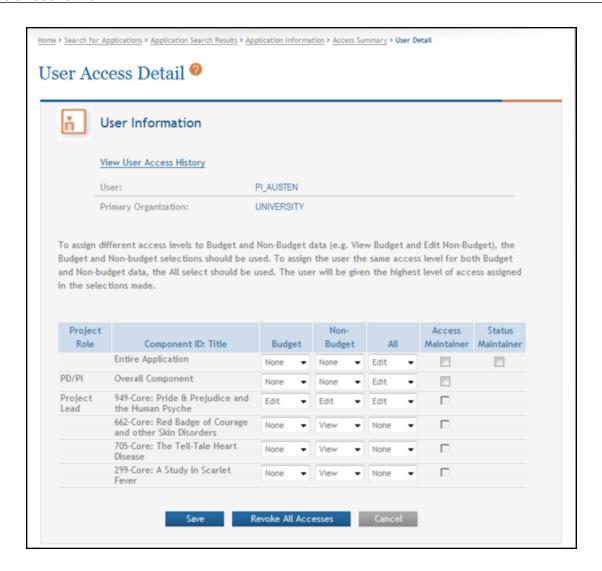


The User Access Summary page displays.



2. The **User** column displays names as hyperlinks. Select the name of the user whose access is being revoked.

The User Access Detail page displays.



3. Revoke access in one of the following manners:

To revoke specific access: Update the **Budget**, **Non-Budget**, and/or **All** access by selecting **None** from the corresponding drop-down list and click the **Save** button to save the changes.

-OR-

To revoke access maintainer. Unselect the checkbox for **Access Maintainer** to remove this ability from a user and click the **Save** button to save the changes.

-OR-

To revoke status maintainer. Unselect the checkbox for **Status Maintainer** to remove this ability from a user. Click the **Save** button to save the changes.

-OR-

To revoke all set access levels: Select the **Revoke All Accesses** button. At the confirmation message *Are you sure you want to revoke access to the application from this user?* select the **Continue** button.

The Status Maintainer privilege for an entire application cannot be granted to an individual who does not hold the entire application Edit privilege as well (i.e., **All** column, option **Edit**). For this reason, revoking an individual's Edit privilege for the entire application also removes that individual's Status Maintainer privilege (where applicable).

Users whose access has been revoked receive email notifications informing of the changes. The email includes the application, the person who revoked the access, and the access level revoked.

IMPORTANT: Some access levels cannot be revoked. The institution-based privileges automatically granted to SOs and AOs cannot be revoked. The PD/PIs for the application must have at least Entire Application Viewer access level, and the Project Lead must have at least the Component (All) Viewer access level.

2.8.6 Manage Access History

ASSIST users with the appropriate privileges may view the access history of the entire application (including Overall and additional components for multi-project applications). Refer to the steps below for single-project or multi-project applications as appropriate.

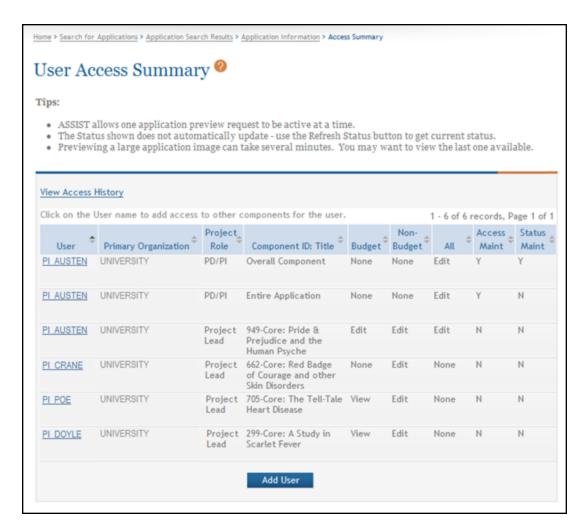
2.8.6.1 Manage Access History for Multi-Project Applications

The access history provides details about the access granted or revoked for an application and its components. This detail includes such information as the username and organization, the action taken against the account, the access level granted, the component to which access was granted, username of the person who granted the access, and the date on which the action occurred. This information displays for each user/component combination.

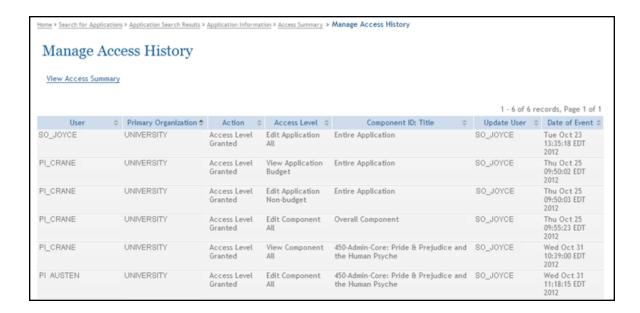
To view the application and component access history for all users:

- 1. Select the **Return to Application Info** button on the **Actions** panel to return to the *Application Information* page.
- 2. From the *Application Information* page, select the **Manage Access** button from the **Action** panel.

The User Access Summary displays details of all users holding access to the application components.



- 3. Select View Access History link.
- 4. The Manage Access History displays. This page provides a summary of the access granted and/or revoked to all users for the application. The information on this page includes:
 - User
 - Primary Organization
 - Action taken (e.g., access granted or access revoked)
 - Access Level
 - Component ID: Title
 - Update User
 - Date of Event



5. Select the **View Access Summary** link to return to the *User Access Summary* page.

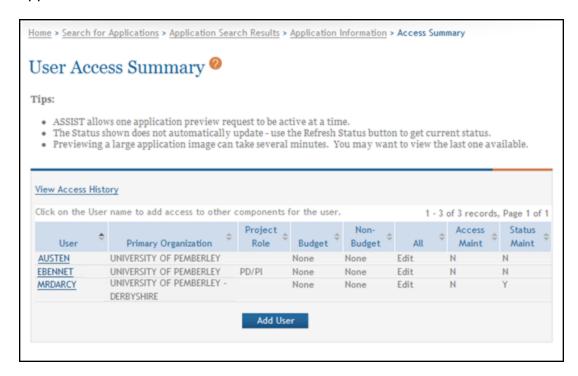
2.8.6.2 Manage Access History for Single-Project Applications

The access history provides details about the access granted or revoked for an application. This detail includes such information as the username and organization, the action taken against the account, the access level granted, username of the person who granted the access, and the date on which the action occurred.

To view the application access history for all users:

- 1. Select the **Return to Application** button on the **Actions** panel to return to the *Application Information* page.
- 2. From the *Application Information* page, select the **Manage Access** button from the **Action** panel.
- 3. The User Access Summary displays details of all users holding access to the

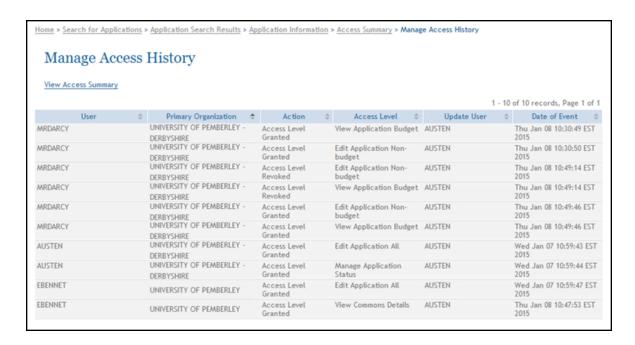
application.



4. Select View Access History link.

The Manage Access History displays. This page provides a summary of the access granted and/or revoked to all users for the application. The information on this page includes:

- User
- Primary Organization
- Action taken (e.g., access granted or access revoked)
- Access Level
- Update User
- Date of Event



5. Select the **View Access Summary** link to return to the *User Access Summary* page.

2.8.7 User Access History

ASSIST users with the appropriate privileges may view a specific user's access history. Refer to the steps below for single-project or multi-project applications as appropriate. The access history provides details such as the person's name and organization, the action taken against the account, the access level granted, the component to which access was granted, username of the person who granted the access, and the date on which the action occurred.

2.8.7.1 Use Access History for Multi-Project Applications

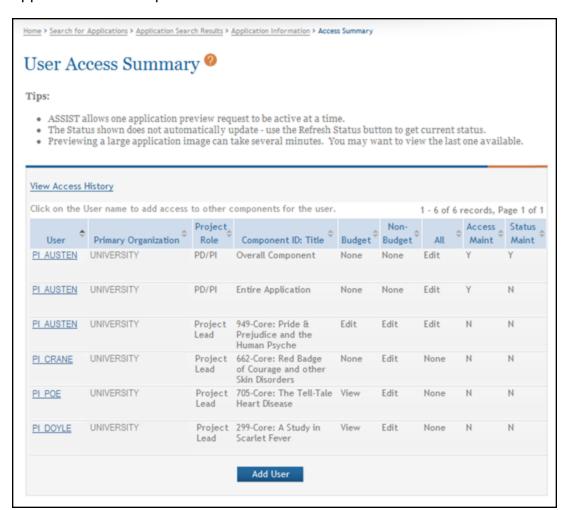
The access history provides details such as the person's name and organization, the action taken against the account, the access level granted, the component to which access was granted, username of the person who granted the access, and the date on which the action occurred.

To view the access history for a specific user:

- 1. Select the **Return to Application Info** button on the **Actions** panel to return to the *Application Information* page.
- 2. From the *Application Information* page, select the **Manage Access** button from the **Actions** panel.

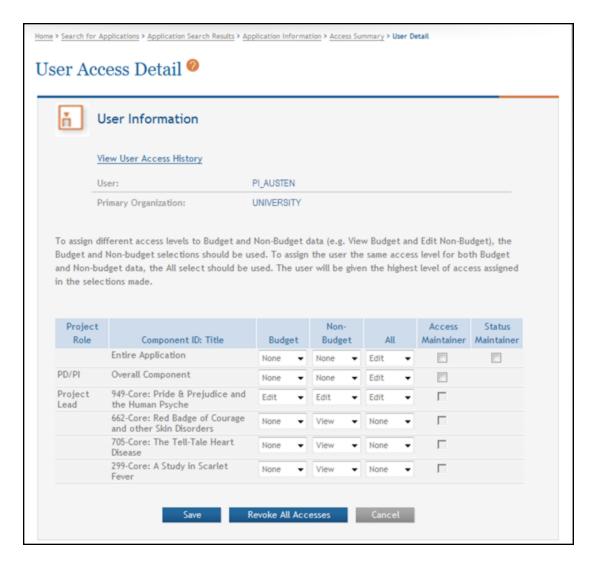
The User Access Summary displays details of all users who have access to the

application and components.



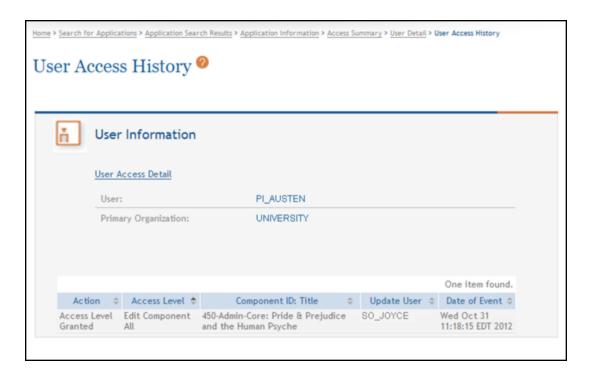
3. The **User** column displays names as hyperlinks. Select the name of the user whose access is being modified.

The User Access Detail page displays.



4. Select the View User Access History link.

The User Access History page displays for the selected user. Information regarding this user's access is included for the Overall Application and all additional components, regardless of which was selected from the *User Access Summary* in the steps above.



The information on this page includes:

- User
- Primary Organization
- Action taken (e.g., access granted or access revoked)
- Access Level
- Component ID: Title
- Update User
- Date of Event
- 5. To return to the *User Access Detail* page, select the **User Access Detail** link, or use the breadcrumbs at the top of the page or the **Actions** on the side of the page to navigate away.

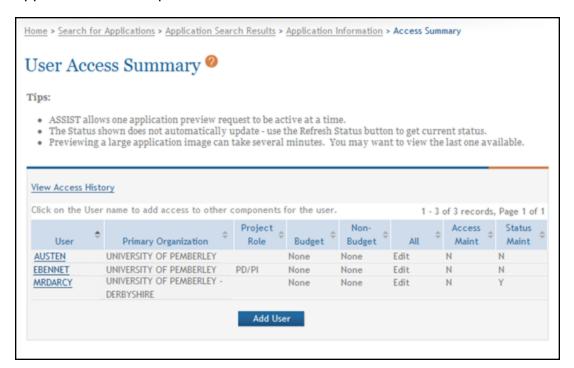
2.8.7.2 Use Access History for Single-Project Applications

The access history provides details such as the person's name and organization, the action taken against the account, the access level granted, the component to which access was granted, username of the person who granted the access, and the date on which the action occurred.

To view the access history for a specific user:

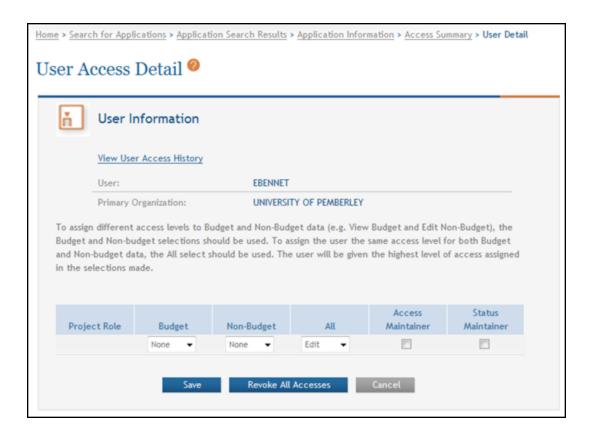
- 1. Select the **Return to Application Info** button on the **Actions** panel to return to the *Application Information* page.
- 2. From the *Application Information* page, select the **Manage Access** button from the **Actions** panel.

The User Access Summary displays details of all users who have access to the application and components.



3. The **User** column displays names as hyperlinks. Select the name of the user whose access is being modified.

The User Access Detail page displays.



4. Select the View User Access History link.

The User Access History page displays for the selected user.



The information on this page includes:

- User
- Primary Organization
- Action taken (e.g., access granted or access revoked)
- Access Level
- Update User
- Date of Event
- 5. To return to the *User Access Detail* page, select the **User Access Detail** link, or use the breadcrumbs at the top of the page or the **Actions** on the side of the page to navigate away.

2.9 Actions

The **Actions** section of the left-side navigation provides buttons for accessing the features available for the application (or multi-project component) currently displayed on the page. The buttons available to an individual ASSIST user vary depending on such conditions as the privileges granted to the user, the stage in the work flow, the status of the application, whether a single- or multi-project application, the part of the application being worked on, etc.

This help topic lists the potential **Actions** buttons available to an ASSIST user. Click on the links below for information on the specific button, keeping in mind that not all are applicable to your application.

- Add New Component
- Add Optional Form
- Change Component Order
- Copy Application
- Delete Application
- Delete Component
- Display Component Status
- Manage Access
- Preview Application
- Preview Current Component
- Preview Current Form
- Return to Application Information
- Submit Application
- Update Component Status

- Update Submission Status
- Validate Application
- Validate Component
- View Status History (for the application)
- View Status History (for a component of a multi-project application)

2.10 Manage Attachments

Some form fields allow or call for attachments, which must be in the form of a PDF. Please review the NIH eRA PDF guidelines for further details and tips on successfully attaching documents.

https://grants.nih.gov/grants/ElectronicReceipt/pdf guidelines.htm

Refer to the appropriate Application Guide for information on PDF creation:

Creating PDFs for Text Attachments

- General
- SBIR/STTR
- Individual Fellowship

Format Specifications for Text (PDF) Attachments

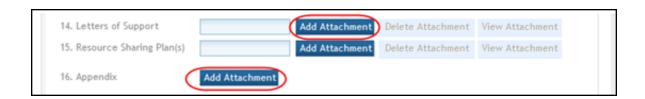
- General
- SBIR/STTR
- Individual Fellowship

IMPORTANT: You must use unique file names for multiple attachments within the same form. Duplicate file names can exist across multiple forms.

2.10.1 Add Attachment

To add an attachment:

 From any area on a form with an attachment field, select the Add Attachment button.



A pop-up window opens providing the ability to search for the file.

- 2. Use the **Browse** button within the pop-up window to search for the PDF file.
- 3. With the file selected, click the Submit button.



For fields allowing a single attachment, the **Add Attachment** button on the form field is replaced by the **Replace Attachment**, **Delete Attachment**, and **View Attachment** buttons. The attached file name displays within the field.

Fields allowing multiple attachments display the files in a table. **Update** and **View** buttons display for each attached file.

2.10.2 Replace Attachment

File attachments display differently depending on whether the field allows for one attachment or multiple attachments.

To replace an attachment from a field allowing only one attachment:

1. From any form field with an added attachment, select the **Replace Attachment** button.



A pop-up window opens providing the ability to search for the file.

- 2. Use the **Browse** button within the pop-up window to search for the PDF file.
- 3. With the file selected, click the **Submit** button.

The form field displays with the replaced attachment

To replace an attachment from a field allowing multiple attachments:

 Select the **Update** button in the **Update Attachment** column for the specific file. (click to view)



A pop-up window opens for providing the ability to search for the file.

- 2. Use the **Browse** button within the pop-up window to search for the PDF file.
- 3. With the file selected, click the **Submit** button.

The table is updated with the new file.

2.10.3 Delete Attachment

File attachments display differently depending on whether the field allows for one attachment or multiple attachments.

To delete an attachment from a field allowing only one attachment:

From any form field with an attachment, select the Delete Attachment button.



A delete confirmation window displays.

2. Confirm the deletion by selecting the **Continue** button.

To delete an attachment from a field allowing multiple attachments:

- 1. Click the checkbox in the **Delete on Save** column for the specific file.
- 2. Select the Save and release Lock button.



The attachment is removed from the table.

2.10.4 View Attachment

File attachments display differently depending on whether the field allows for one attachment or multiple attachments.

1. For fields allowing only one attachment: From any area on a form with an attachment added, select the **View Attachment** button.



-OR-

From fields allowing multiple attachments: Select the **View** button in the **View Attachment** column for the specific file.



2.	Select the Open button to view the attached file or the Save button to save the file
	locally.

3 Prepare an Application

The process for preparing an application include the following:

- 1. Initiate the application
- 2. Update Overall component (for multi-project applications only)
- 3. Add additional components and enter data (for multi-project applications only)
- 4. Manage access
- 5. Prepare applications for submission
- 6. Search for the application

3.1 Initiate an Application

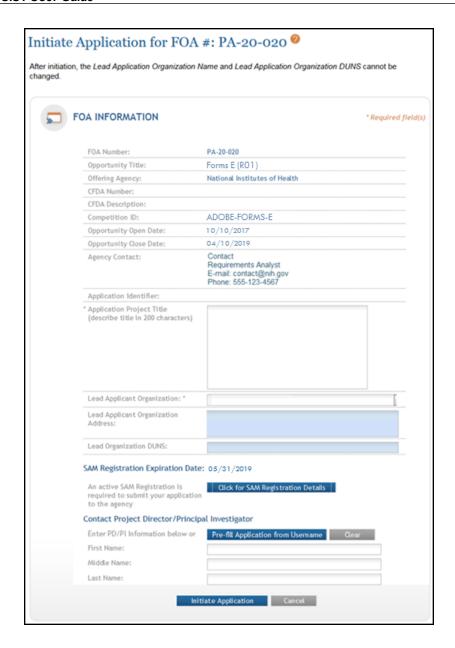
Prior to initiating an application using ASSIST, applicants must identify a Funding Opportunity Announcement (FOA) to which they would like to apply. FOAs are posted in the NIH Guide for Grants & Contracts and in Grants.gov Find Grant Opportunities link, each of which has robust search capabilities. The FOA text indicates whether ASSIST can be used to apply to that opportunity. The FOA number (e.g., PA-12-987) is required to initiate an application.

NOTE: Anyone with an eRA Commons ID can initiate an application.

To initiate the application:

- 1. Log into the ASSIST system.
- 2. From the Welcome page, enter the FOA in the **Funding Opportunity Announcement #** field.
- 3. Select the **Go** button.

The Initiation Application page displays.



Fill in the required fields:

1. Enter a title for the application in the **Application Project Title** field.

NOTE: This populates the **Descriptive Title of Applicant's Project** field on the SF424 RR Cover. The maximum number of characters for the **Application Project Title** is 200.

After initiating your application, you can update your project title by editing the **Descriptive Title of Applicant's Project** field.

2. Make a selection from the drop-down menu **Lead Applicant Organization Name**.

NOTE: The list reflects the organizations affiliated with the user's eRA Commons ID. Selecting the appropriate organization populates the **Lead Applicant Organization** fields and the appropriate fields in the SF424 RR.

- 3. Review the **Lead Applicant Organization Address**.
- 4. Review the **Lead Applicant Organization DUNS** number.

SAM Registration Expiration Date: The SAM registration requires a yearly renewal. ASSIST will display the expiration date of the organization's SAM registration if it has expired, or will expire within 14 days.

1. Select the Click for SAM Registration Details button.

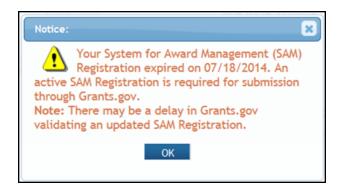
The *Initiate SAM Registration Details* pop up appears.



NOTE: In addition to the pop-up message window, a new status button will be added to the initiation page for all new applications. Users will be able to confirm the status of their institution's SAM registration by clicking this button.

- a. Once **OK** is selected, you will be returned to the *Initiate Application* screen.
- b. If this is the first time that registration has been made, upon **OK** being selected a confirmation notice displays containing **Submit**and **Cancel** buttons. Submit forwards the application to *Grants.gov*; Cancel returns
- c. the screen to the lottiste Application screen.

 and their



Optional: Enter the fields for Contact Project Director/Principal Investigator.

Tip: If the Contact PD/PI's username is known, click the **Pre-fill Application from Username** button, enter the username in the presented pop-up, and select **Submit**. This will automatically populate the contact's name. This pre-fill button will not become enabled until a Lead Applicant Organization is added.

4. Select the **Initiate Application** button to continue.

NOTE: Selecting the **Cancel** button at any time cancels the initiation. A warning message, *Are you sure you want to cancel*, confirms the action. Select **Continue** to cancel the initiation or **Go Back** to return to the *Initiate Application* page.

The Application Information page displays as read-only with the status of the application as Work in Progress. The informational message Application saved appears at the top of the page.

NOTE: For multi-project applications, the Overall component is created at the time of initiation and can be accessed from the **Component Type** section of the navigation panel.

After initiating the application the user has the ability to access:

Manage Access

Edit Forms

Add New Component (applies to multi-project applications only)

3.2 Initiate an Administrative Supplement Application

ASSIST supports the initiation and submission of administrative supplements. Applicants should follow instructions in the application guide, as well as the Funding Opportunity Announcement (FOA) and/or Notice of Special Interest (NOSI) for any additional submission instructions.

In ASSIST, both the PI (any PD/PI) and the SO can initiate administrative supplements and use the prepopulate features if their organization ID matches the organization ID on the parent grant.

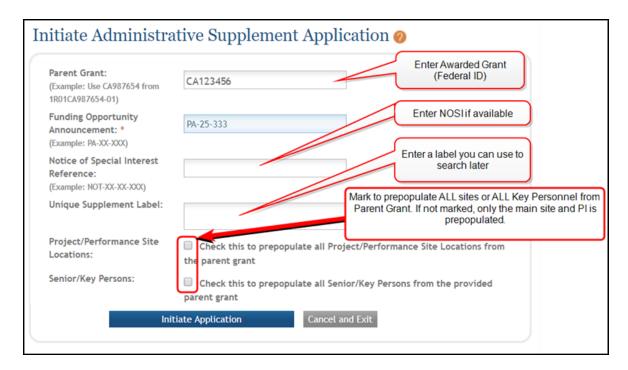
NOTE: Administrative supplement requests can also be initiated, although not filled out or submitted, from the eRA Commons Administrative Supplement module. If initiated from eRA Commons, the administrative supplement has the parent grant number prepopulated.

Initiating an Administrative Supplement Application from ASSIST:

 Log into ASSIST and enter an Administrative Supplement FOA. Click the Go button.



- 2. The *Initiate Administrative Supplement Application* screen displays. At this point, the FOA that you entered on the previous screen is non-editable.
- 3. Optionally, enter the federal ID of the awarded grant (Parent Grant), and ASSIST will use information on the parent award to pre-populate specific data fields on the administrative supplement application.
- 4. A Notice of Special Interest (NOSI) is not required but, if one is entered, the format needs to be valid. The Notice of Special Interest reference must be in the form NOT-XX-XXXX, e.g. NOT-CA-19-001.
- 5. Enter a title or descriptor in the *Unique Supplement Label* field. This label is for your own purposes so that you can readily identify and search for the administrative supplement after it is initiated. Enter text that will help you search for the application in progress at a later date.

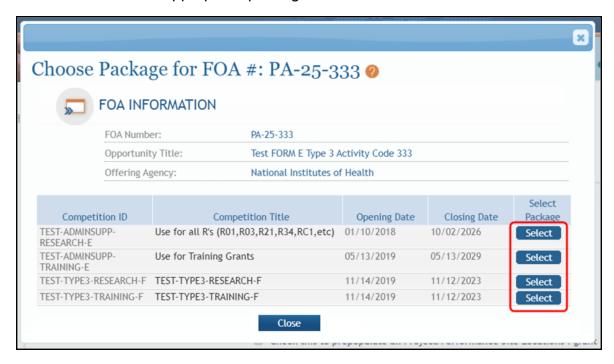


- 6. Mark checkboxes if you want prepopulation of forms to occur from the parent grant. This means that information already recorded from the parent grant will populate appropriate corresponding forms and fields in ASSIST. **Attachments** such as specific aims, research strategy, and biosketches, for example, are not copied over since the FOA or NOSI may request that specific information be added in these sections. Available prepopulation checkboxes are:
 - a. Project/Performance Site Location checkbox. If marked, ASSIST will prepopulate all of the sites from the Parent Grant into the Supplement Application "Performance Site" form. If not marked, only the Primary Site from the Parent Grant will be pre-populated.
 - b. Senior/Key Persons checkbox. If marked, ASSIST will pre-populate all Senior/Key persons from the Parent Grant into the Supplement Application "Senior Key Persons" form. If not marked, only the Contact PD/PI will be pre-populated.
- 7. When you click **Initiate Application**, the federal ID will be validated and, if it exists, you will be taken to the ASSIST summary screen to complete the application.

NOTE: The forms will not be pre-populated if no parent grant federal ID was entered on the *Initiate Administrative Supplement Application* screen.

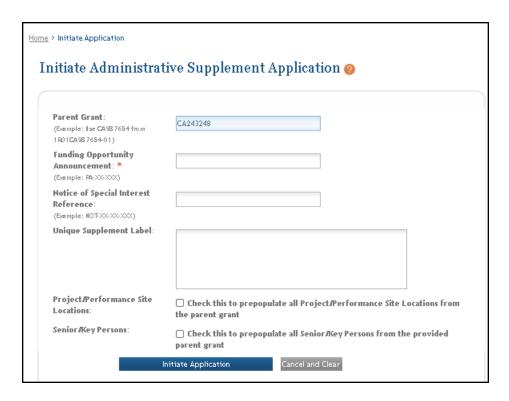
8. If there are multiple packages associated with the funding opportunity, the available packages window opens before the ASSIST summary screen. Click the

Select button for the appropriate package.



Initiating an Administrative Supplement Application from eRA Commons:

- 1. Log into eRA Commons.
- 2. Navigate to the **Administrative Supp** module in eRA Commons.
- 3. Search for a grant and click the three-dot ellipsis menu and select the **Start Application** option.
- 4. You are redirected to the ASSIST application, and the Initiate Administrative Supplement Application screen appears.
 - The **Parent Grant** (federal ID) field is filled in based on the grant that you were working on in the Administrative Supplement module of eRA Commons. It cannot be changed.



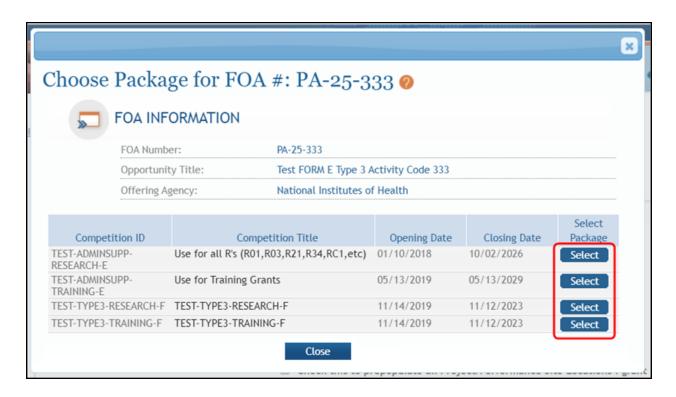
- 5. Enter the number of a FOA under which you want to apply for the administration supplement.
- 6. A Notice of Special Interest (NOSI) is not required but, if one is entered, the format needs to be valid. The Notice of Special Interest reference must be in the form NOT-XX-XXXX, e.g. NOT-CA-19-001.
- 7. Enter a title or descriptor in the *Unique Supplement Label* field to readily identify the administrative supplement. Enter text that will help you search for the application in progress at a later date.
- 8. Mark checkboxes if you want prepopulation of forms to occur from the parent grant (if parent grant specified). This means that information already recorded from the parent grant will populate appropriate corresponding forms in ASSIST. Available prepopulation checkboxes are:
 - a. Project/Performance Site Location checkbox. If marked, ASSIST will prepopulate all of the sites from the Parent Grant into the Supplement Application "Performance Site" form. If not marked, only the Primary Site from the Parent Grant will be pre-populated.
 - b. Senior/Key Persons checkbox. If marked, ASSIST will pre-populate all Senior/Key persons from the Parent Grant into the Supplement Application "Senior Key Persons" form. If not marked, only the Contact PD/PI will be pre-populated.

NOTE: Attachments such as specific aims, research strategy, and biosketches, for example, are not copied over since the FOA or NOSI may request that specific information be added in these sections.

9. When you click **Initiate Application**, the federal ID will be validated and, if it exists, you will be taken to the ASSIST summary screen to complete the application.

NOTE: The forms will not be pre-populated if no parent grant federal ID was entered on the *Initiate Administrative Supplement Application* screen.

10. If there are multiple packages, the available packages window opens before the ASSIST summary screen. Click the **Select** button for the appropriate package.



NOTE: While working in an administrative supplement application initiated from eRA Commons, the **Copy Application** button is not available from the left side navigation buttons.

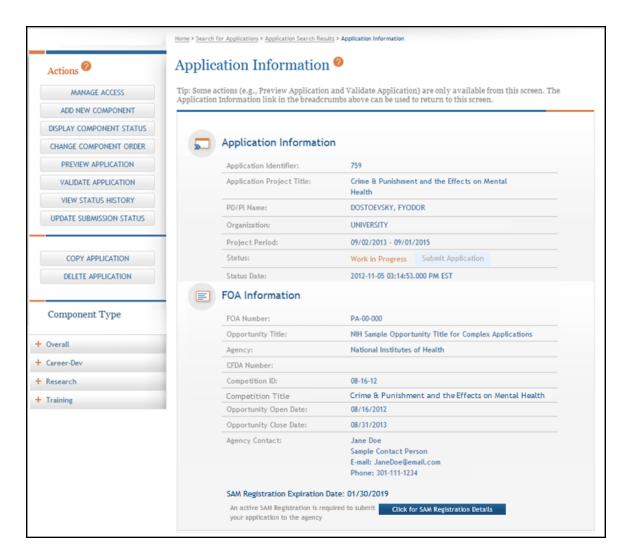
For information on filling out forms, see *Forms Data Entry*.

3.3 Application Information

The Application Information page is the ASSIST landing page for the entire application. This page is the first page seen when selecting a searched application or initiating a new application.

IMPORTANT: You can access *Application Information* any time by selecting the **Return to Application Info** button on the **Actions** panel.

The *Application Information* page includes two sections: **Application Information** and **FOA Information**.



3.3.1 Application Information Section

The **Application Information** section reflects the information entered during the initiation process and is read-only.

Application Identifier

Unique, system-generated number assigned to the application in ASSIST.

Application Project Title

Title of the application/project as entered by the person who initiated the application.

PD/PI Name

Contact PI for the entire application.

Organization

The lead applicant organization name of the submitting institution.

Project Period

The start and end dates of the project.

Status

The current status of the entire application. The **Submit Application** button is also located here. It is disabled until the application is ready to be submitted. For information on submitting the application refer to the topic titled <u>Submit the Application</u>.

Tip: Hover over the status with your mouse for a short description of the status.

Status Date

The date and time of the last status update.

When an application is in *Submitted* status, the **View Submission Status Details** link displays next to the status. Selecting this link displays the submission details for ASSIST, Grants.gov, and Agency when available.

3.3.2 FOA Information Section

The FOA Information section displays read-only summary information concerning the funding opportunity against which the application will be submitted. The following information is displayed:

FOA Number

The Funding Opportunity Announcement number.

Opportunity Title

The name of the announcement.

Agency

The Agency offering the grant opportunity (e.g., NIH).

3.3.3 Delete the Application

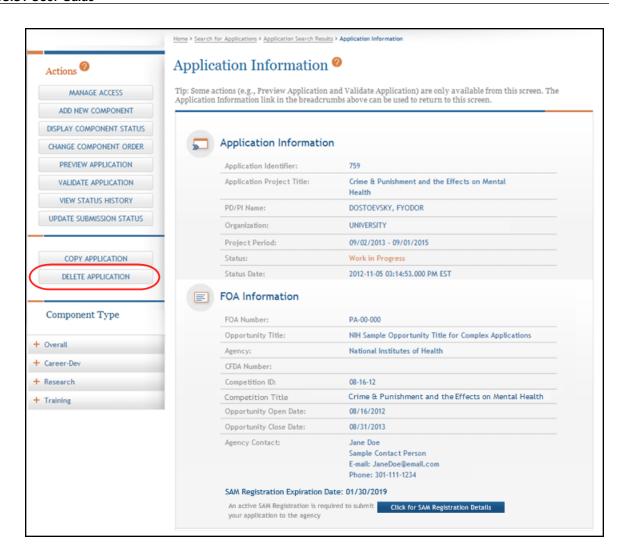
If you are the Signing Official you have access to the Delete Application feature in ASSIST. The Delete Application feature allows you to permanently delete an entire application in any status.

IMPORTANT: Deleting an application is a permanent action. Once deleted, the application cannot be accessed, re-instated, or viewed. There is no way to recover a deleted application.

NOTE: ASSIST also has a Delete Component feature for deleting individual components of a multi-project application. Refer to the topic titled <u>Delete a Component</u> for steps on deleting individual components.

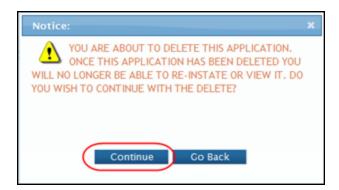
To delete the entire application:

- 1. Open the Application Information page of the application you wish to delete.
- 2. From the Actions panel, select the Delete Application button.



A confirmation message displays as follows: You are about to delete this application. Once this application has been deleted you will no longer be able to re-instate or view it. Do you wish to continue with the delete?

July 27, 2020



3. Select the appropriate action:

You may cancel the action at this point by selecting the **Go Back** button. If you choose **Go Back**, the delete process ends, you return to the summary tab from which you began, and the following steps are no longer applicable.

-OR-

To continue with the deletion, select the Continue button.

Upon continuing, a second confirmation displays as follows: Selecting Continue will delete this application permanently.



4. This warning provides a final means of aborting the deletion. Carefully select the appropriate action:

To stop the deletion process, select the **Go Back** button. If you choose **Go Back**, the delete process ends, you return to the summary tab from which you began, and the following steps are no longer applicable.

-OR-

To confirm the action and permanently delete the application, select the Continue button. Remember that this action is irreversible. Once the application is deleted, you cannot re-instate it.

You cannot delete an application if one or more of the forms are locked by yourself or another ASSIST user. If a form is locked, you will see the following error on your screen after continuing from the second confirmation screen:

The application cannot be deleted as the following form(s) are currently locked by <User ID> in: <application ID>: <locked form>

Once you've successfully deleted the application, the ASSIST log in page displays with the message *Application successfully deleted*.

See Also

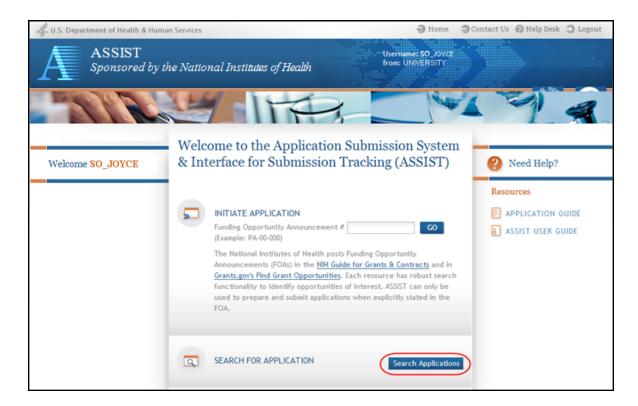
Component Information

3.4 Search for an Application

Applications initiated in ASSIST are saved online and are accessible by multiple users who have been given access to the application. In order for a previously initiated application to be accessed, a search for that application must be performed on the *Search for Application* page. Only those users granted permission to view or edit the application can locate it via the search function. eRA Commons users with the Signing Official (SO) role can search and find any application within their own organization.

To search for an application:

- 1. Log into the ASSIST system.
- 2. From the welcome page, select the Search Applications button.



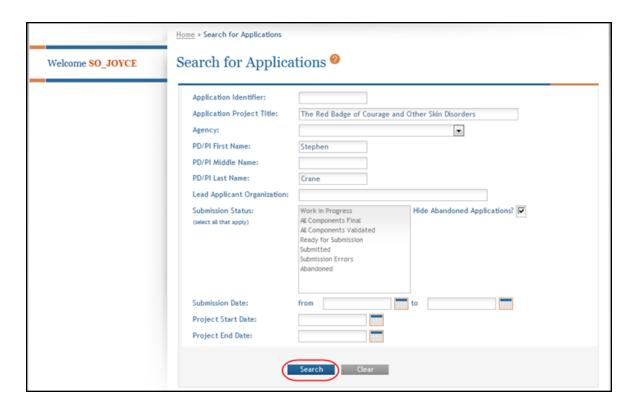
3. Enter any combination of optional search criteria on the Search for Applications page to locate the application.

When entering search parameters, it is important to note that all parameters are

case insensitive and punctuation is ignored.

Entering search parameters is an optional step. When a search is performed without search parameters entered, ASSIST returns all applications for which the user has the privileges to access. If the number of records found exceeds the allowable limit, an error message displays. In this instance, use the parameters to narrow the search.

4. Select the Search button to display the closest matched applications.



Depending on the search parameters entered, multiple matching records may be found. These results can be sorted, by selecting the arrow in the appropriate column heading.

NOTE: Selecting the **Clear** button at any time will clear the fields.

5. From the results listed on the *Search for Application Results* page, click the Select button in the **Action** column next to the appropriate application.



The Application Information page displays for the selected application.

Refer to the help topic titled *Prepare an Application* for details on completing an application.

3.5 Copy Application

If you are the Signing Official or Administrative Official of the lead organization and/or hold the Entire Application Editor privilege, you have access to the Copy Application feature in ASSIST.

The *Copy Application* screen is used to copy the components (multi-projects) and data from the application currently opened in ASSIST to another application for a requested FOA. The feature allows you to copy the application's structure and data to be used for another application. For multi-project applications, the feature copies over the Overall component, component identifiers, any existing component short names, assigned access levels, data, and attachments.

When you copy an application in ASSIST, you are granted Entire Application Editor privileges for the new application. The submission status of the new application is set to *Work in Progress*, as is the component status of all included components (for multi-project applications).

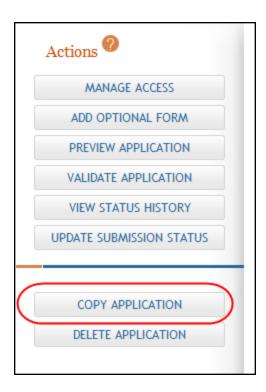
NOTE: While working in an administrative supplement application initiated from eRA Commons, the **Copy Application** button is not available from the left side navigation buttons.

IMPORTANT: The forms used in a copied application may not match the forms used for the FOA of the new application. In these cases, ASSIST will perform a best-effort match in which the system will copy fields within the form(s) that have matching names

in the new form. Fields that do not exist in the new form will not be copied from the copied application.

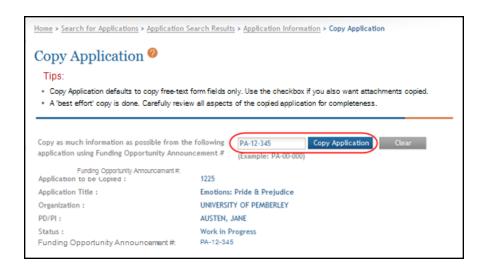
NOTE: Submission date, certification, and Authorized Representative signature from submitted applications are never copied over to new applications. Application and component history also are not copied.

- 1. Use ASSIST to search for and open the application you are copying.
- 2. Select the Copy Application button on the Actions panel.



The Copy Application screen opens.

3. Enter the FOA for the new application into the Copy to Funding Opportunity Announcement # field and select the **Copy Application** button.



Before copying the application, ASSIST performs certain validations against the entered FOA, including checks to determine if the FOA is valid and is for a multiproject or single-project submissions as appropriate. A single-project application cannot be copied over to a multi-project FOA and vice versa. Error messages will appear if these validations do not meet business and system rules.

Follow the steps below for copying a multi-project or single-project application.

3.5.1 Copying a Multi-project Application

After validating the FOA, the screen displays the components in the current application that can be copied to the new application. This information includes:

Copy from Component

The unique identifier and short name (if existing) of the components in the copied application.

Project Title

The project title of the components in the copied application.

Status

The status of the components in the copied application. Although this provides you the status of the components in the copied application, remember that the components in the new application will have a status of Work in Progress.

Project Lead

Individual responsible for the scientific and technical direction of the component project in the as indicated in the copied application.

Copy to Component options

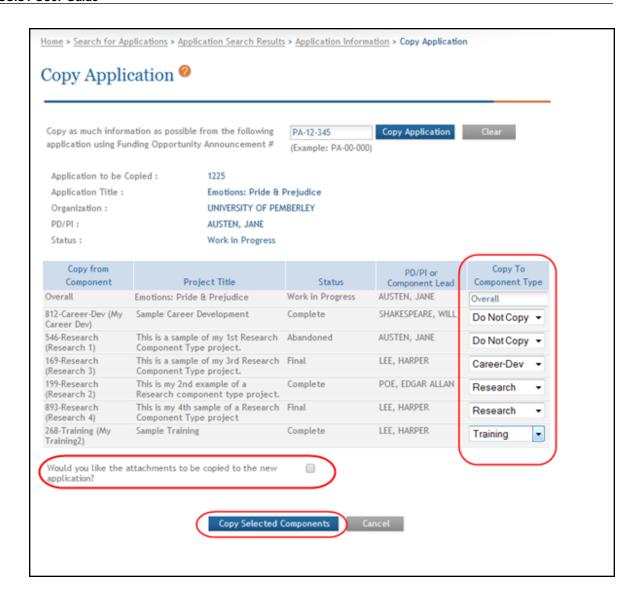
A drop-down list of component types available in the new application based on the indicated FOA of the new application. It is possible to copy a component of a specific type in the original application to a different component type in the new application.

IMPORTANT: You must copy the Overall component and it must be copied to the Overall component of the new application. For this reason, the **Copy To Component Type** field for the Overall component is not editable.

Not all FOAs require or allow the same component types. When copying an application, ASSIST determines which component types are allowed in the FOA you provided for the new application. The options available in the **Copy to Component Type** drop-down list reflect this.

- 1. Select an option from the **Copy to Component Type** drop-down list for all components being copied to the new application.
- 2. Optional: To copy attachments, select the checkbox next to the question **Would** you like the attachments to be copied to the new application?
- 3. Click the Copy Selected Components button.

The default value of this field is *Do Not Copy*. Any components left with a value of *Do Not Copy* will not be copied to the new application. The Overall component will always be copied to the new application's Overall component.



A confirmation message displays as a pop-up box. Please make sure you thoroughly understand the warning before continuing.

The copy feature will do a **best effort** copy of form field data. Data loss is possible when copying from one announcement to another due to potential form differences. Application attachments will not be retained. Be sure to carefully check the new copy of the application for completeness.



- 4. Select the **OK** button to confirm the copy. Selecting **Cancel** will return you to the *Copy Application* screen without completing the copy.
- 5. After confirming the copy, another pop-up box prompts you to choose which application you wold like to display in ASSIST. The following prompt displays: *Please select OK to remain in the current application. To open the new application, select Continue.*



Select the **OK** button to remain in the original application.

-OR-

Select the **Continue** button to display the newly created application.

3.5.2 Copying a Single-project Application

After validating the FOA, the screen displays the information for the current application being copied to the new application. This information includes:

Project Title

The project title of the components in the copied application.

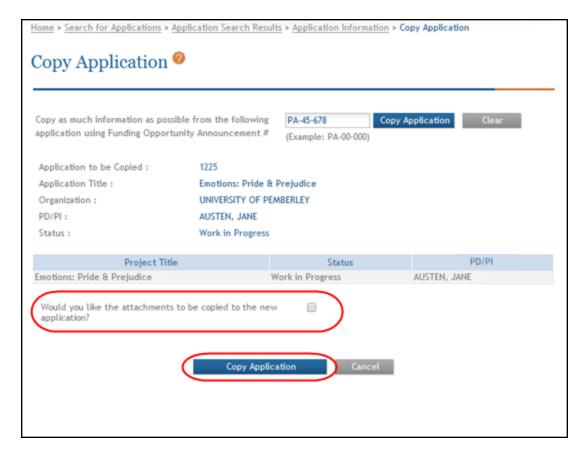
Status

The status of the components in the copied application. Although this provides you the status of the components in the copied application, remember that the components in the new application will have a status of Work in Progress.

PD/PI

Individual responsible for the scientific and technical direction of the component project in the as indicated in the copied application.

- 1. Optional: To copy attachments, select the checkbox next to the question **Would** you like the attachments to be copied to the new application?
- 2. Select the Copy Application button.



A confirmation message displays as a pop-up box. Please make sure you thoroughly understand the warning before continuing.

The copy feature will do a **best effort** copy of form field data. Data loss is possible when copying from one announcement to another due to potential form differences. Application attachments will not be retained. Be sure to carefully check the new copy of the application for completeness.



- 3. Select the **OK** button to confirm the copy. Selecting **Cancel** will return you to the *Copy Application* screen without completing the copy.
- 4. After confirming the copy, another pop-up box prompts you to choose which application you wold like to display in ASSIST. The following prompt displays: *Please select OK to remain in the current application. To open the new application, select Continue.*



Select the **OK** button to remain in the original application.

-OR-

Select the **Continue** button to display the newly created application.

3.6 Delete the Application

If you are the Signing Official you have access to the Delete Application feature in ASSIST. The Delete Application feature allows you to permanently delete an entire

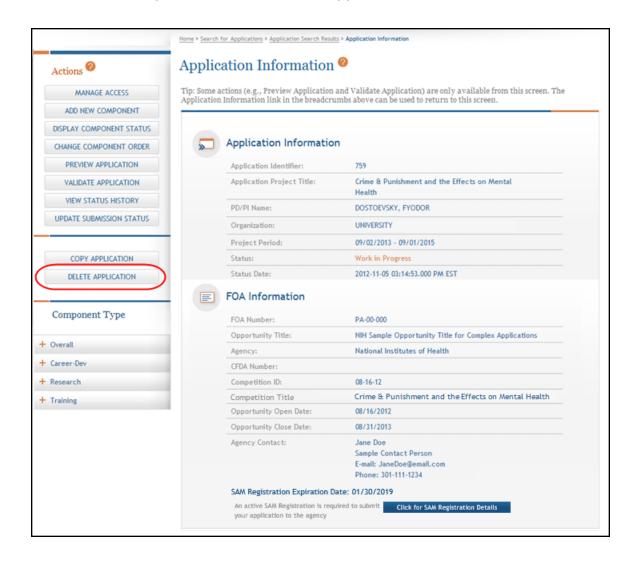
application in any status.

IMPORTANT: Deleting an application is a permanent action. Once deleted, the application cannot be accessed, re-instated, or viewed. There is no way to recover a deleted application.

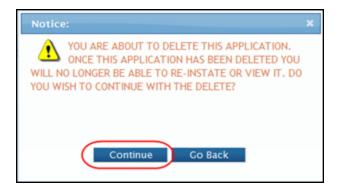
NOTE: ASSIST also has a Delete Component feature for deleting individual components of a multi-project application. Refer to the topic titled <u>Delete a Component</u> for steps on deleting individual components.

To delete the entire application:

- 1. Open the Application Information page of the application you wish to delete.
- 2. From the Actions panel, select the Delete Application button.



A confirmation message displays as follows: You are about to delete this application. Once this application has been deleted you will no longer be able to re-instate or view it. Do you wish to continue with the delete?



3. Select the appropriate action:

You may cancel the action at this point by selecting the **Go Back** button. If you choose **Go Back**, the delete process ends, you return to the summary tab from which you began, and the following steps are no longer applicable.

-OR-

To continue with the deletion, select the Continue button.

Upon continuing, a second confirmation displays as follows: Selecting Continue will delete this application permanently.



4. This warning provides a final means of aborting the deletion. Carefully select the appropriate action:

To stop the deletion process, select the **Go Back** button. If you choose **Go Back**, the delete process ends, you return to the summary tab from which you began, and the following steps are no longer applicable.

-OR-

To confirm the action and permanently delete the application, select the Continue button. Remember that this action is irreversible. Once the application is deleted, you cannot re-instate it.

You cannot delete an application if one or more of the forms are locked by yourself or another ASSIST user. If a form is locked, you will see the following error on your screen after continuing from the second confirmation screen:

The application cannot be deleted as the following form(s) are currently locked by <User ID> in: <application ID>: <locked form>

Once you've successfully deleted the application, the ASSIST log in page displays with the message *Application successfully deleted*.

3.7 Add Optional Forms

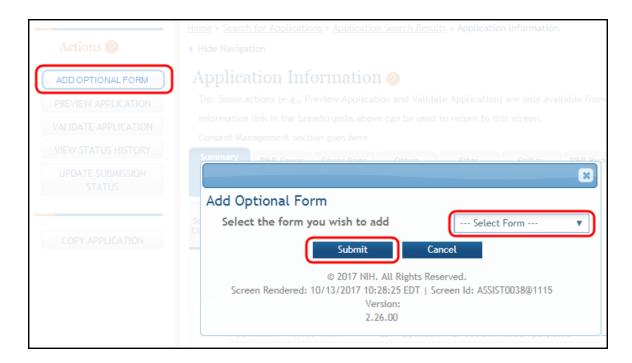
Depending on the funding opportunity, optional forms may exist for both single- and multi-project applications. You can add optional forms using the **Add Optional Form** feature. Only the optional forms available for the specific funding opportunity can be added.

3.7.1 Optional Forms for Single Project Applications

To add optional forms to a single-project application:

1. Select the **Add Optional Form** button from the **Actions** navigation panel.

A pop-up window opens for selecting the form to be added.



2. Choose a form from the drop-down list and select the **Submit** button to add the form to the component.

NOTE: Selecting the **Cancel** button closes the window without added the form to the component.

3. Select the tab of the corresponding form to enter information on the form.

3.7.2 Optional Forms For Multi-Project Applications

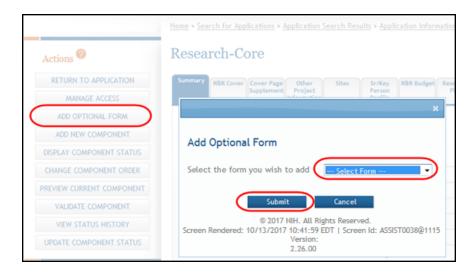
To add optional forms to a multi-project application:

- 1. Select the **Return to Application Info** button on the **Actions** panel to return to the *Application Information* page.
- 2. From the *Application Information* page expand the appropriate component from the **Component Type** section.
- 3. Select a component type to display the Component Information.

The Component Information page opens for the component.

4. Select the **Add Optional Form** button from the **Actions** navigation panel.

A pop-up window opens for selecting the form to be added.



- 5. Choose a form from the drop-down list.
- 6. Select the **Submit** button to add the form to the component.

NOTE: Selecting the **Cancel** button closes the window without added the form to the component.

7. Select the tab of the corresponding form to enter information on the form.

See Also

- Edit Overall Component Forms
- Edit Additional Component Type Forms

3.8 Other Components of Multi-Project Applications

Multiple-project opportunities often require additional component types with pre-defined data collection requirements. Examples of these additional components include Admin Core, Core, Project, Construction, Career Development, and Training. The component types required for a multiple-project application differ depending on the Funding Opportunity Announcement (FOA).

The required component types for the FOA can be selected from ASSIST and added to the application. ASSIST *only* allows the required component types specific to the opportunity to be added to the application. Adding a component also adds its corresponding forms (e.g., Cover Page, Checklist).

Please refer to the FOA for details on the application and component type requirements.

Refer to the Application Guide for more information on components.

https://grants.nih.gov/grants/how-to-apply-application-guide.html

See Also

- Edit Additional Component Type Forms
- Add Additional Component Types

3.8.1 Overall Component

The Overall component provides overview information for the application. The Overall component describes the entire application and explains how each of the additional components fit together. It is a special component type with a single occurrence in every complex application. The PD/PI and multi-PD/PIs for the entire application are captured in the Overall component. It is the only component that includes full SF424 R&R cover data collection. It does not include a budget.

The Overall component with corresponding forms (e.g., *Cover Page*, *Checklist*) is automatically created when you initiate your application.

If additional components are available, they can be added using the **Add New Component** button in the **Actions** section. Refer to the topic titled <u>Other Components of Multi-Project Applications</u> for more information.

IMPORTANT: The figures provided in these topics serve as examples only. They may not reflect what you see in your own applications and may not always represent valid data.

If you have specific questions about the forms available for your application, please refer to the Application Guide.

See Also

Edit Overall Component Forms

3.8.2 Add Additional Component Types

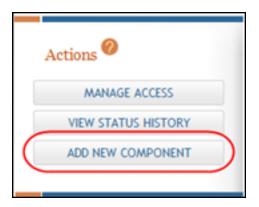
The additional component types available in ASSIST will vary by opportunity.

Users should add components for a specific component type in the order in which they should appear within the final application image used by the agency for funding consideration.

NOTE: The order of component types cannot be rearranged once they are added to the application.

To add additional component types:

- 1. Select the **Return to Application Info** button on the **Actions** panel to return to the *Application Information* page.
- 2. From the *Application Information* page or the *Component Information* page, select the Add New Component button in the Actions panel.



The Add Component page displays.

3. Select a **Component Type** from the drop-down list.

NOTE: Only component types available for the application's FOA display in the drop-down list.

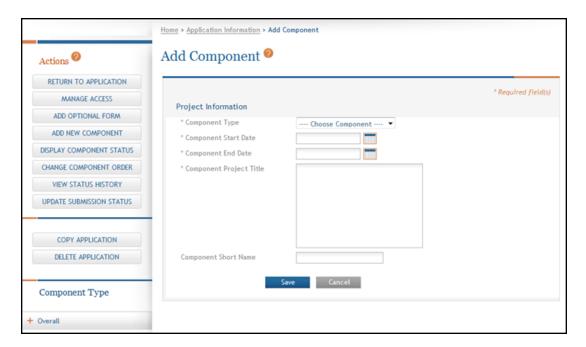
- 4. Enter a **Component Start Date** or select one from the calendar tool. This field defaults to the project start date entered on the Overall component.
- 5. Enter a **Component End Date** or select one from the calendar tool. This field defaults to the project end date entered on the Overall component.
- 6. Enter a Component Project Title
- 7. *Optional*: Enter a **Component Short Name** (up to 20 characters) to help identify the component. This is not a required field.

Component short names -when existing- appear on the *Component Information* page as well as under the component identifier on the left-side **Component Type** navigation panel. Component short names must be unique to the project and can be updated from the *Component Information* page. Component short names are available only for your convenience in ASSIST and do not carry over to Grants.gov at the time of submission.



8. Select the **Save** button to add the component to the application and display the forms associated with the component type selected.

NOTE: Selecting the **Cancel** button cancels the action without saving any information.



The Component Information page displays the Component Information (as well as **Application Information**) as read-only with the status of the component as Work in Progress. Tabs across the top of the page provide access to the applicable component forms.

Tip: Check the Funding Opportunity Announcement text for component-specific instructions for preparing additional components.

After adding the component you have the ability to access:

Update Component Forms

Manage Access

Add New Component

View Status History

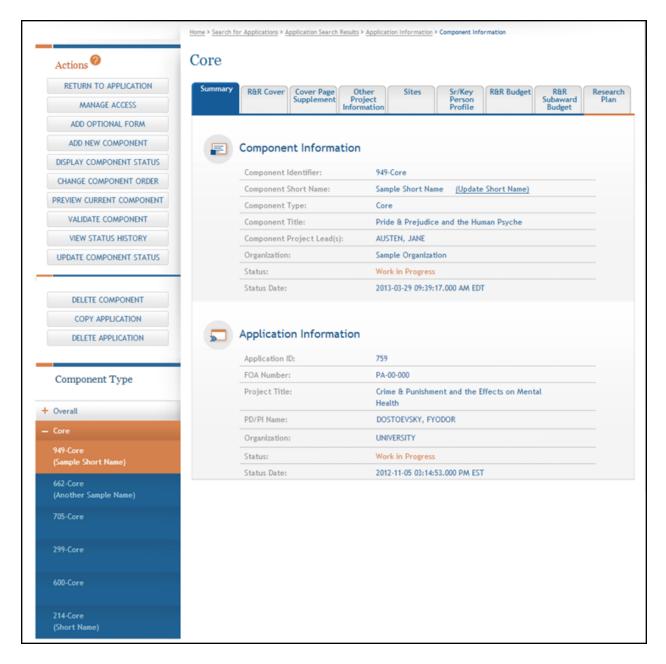
Add Optional Form

Preview Current Component

Update Component Status

3.8.3 Component Information

The Component Information page is the ASSIST landing page for a specific component of a multi-project application. This page is the first page seen when selecting a component from the **Component Type** navigation panel. This page is also displayed when the **Summary** tab is selected for a component. The *Component Information* page includes two sections: **Component Information** and **Application Information**.



3.8.3.1 Component Information Section

The **Component Information** section reflects the information entered when the component of a multi-project application was added to the application and is read-only. The information includes the following:

Component Identifier

Unique, system-generated number assigned to the component in ASSIST.

• Component Short Name (not for Overall components)

The short name entered at the time the component was added. Select the **Update Short Name** link in this field to change the short name for this component.

Component Type

The type (e.g., Core) selected from the list of component types when the component was added to the application.

Component Title

The title given to the component when added to the application.

Component Project Lead

The component lead(s) as entered on the **Sr/Key Person Profile** tab for the component.

Organization

The organization name as added in the **R&R Cover** tab for the component.

Status

The current status (e.g., Work in Progress, Complete) for the component.

Tip: Hover over the status with your mouse for a short description of the status.

Status Date

The date and time of the last status change for the component.

3.8.3.2 Application Information Section

The **Application Information** section reflects the information entered during the initiation process and is read-only.

Application ID

Unique, system-generated number assigned to the application in ASSIST.

FOA Number

The Funding Opportunity Announcement number associated with the application.

Project Title

Title of the application/project as entered by the person who initiated the application.

PD/PI Name

Contact PI for the entire application.

Organization

The lead applicant organization name of the submitting institution.

Status

The current status of the entire application.

Tip: Hover over the status with your mouse for a short description of the status.

Status Date

The date and time of the last status update.

3.8.3.3 Delete a Component

IMPORTANT: This topic is applicable only to multi-project applications.

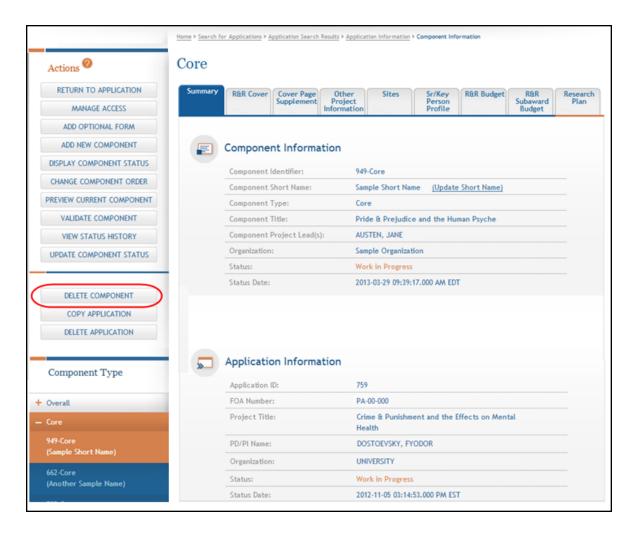
If you are the Signing Official, Administrative Official, or the PI of the lead organization - and/or- you have Entire Application Editor privilege, you have access to the Delete Component feature in ASSIST. The Delete Component features allows you to permanently delete individual components of any status from the application.

IMPORTANT: Deleting components is a permanent action. Once deleted, a component cannot be accessed, retrieved, or viewed. There is no way to recover the component.

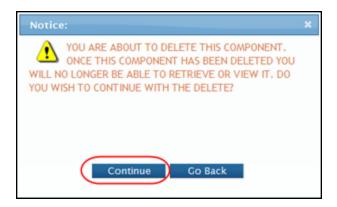
NOTE: ASSIST also has a Delete Application feature for deleting an entire application. Individual components do not need to be deleted first when deleting the entire application. Refer to the topic titled <u>Delete the Application</u> for steps on deleting entire applications.

To delete a component:

- 1. Open the *Summary* tab of the component you wish to delete.
- 2. From the Actions panel, select the Delete Component button.



A confirmation message displays as follows: You are about to delete this component. Once this component has been deleted you will no longer be able to retrieve or view it. Do you wish to continue with the delete?



3. Select the appropriate action:

You may cancel the action at this point by selecting the **Go Back** button. If you choose **Go Back**, the delete process ends, you return to the summary tab from which you began, and the following steps are no longer applicable.

-OR-

To continue with the deletion, select the Continue button.

Upon continuing, a second confirmation displays as follows: Selecting Continue will remove this component permanently from the application.



4. This warning provides a final means of aborting the deletion. Carefully select the appropriate action:

To stop the deletion process, select the **Go Back** button. If you choose **Go Back**, the delete process ends, you return to the summary tab from which you began, and the following steps are no longer applicable.

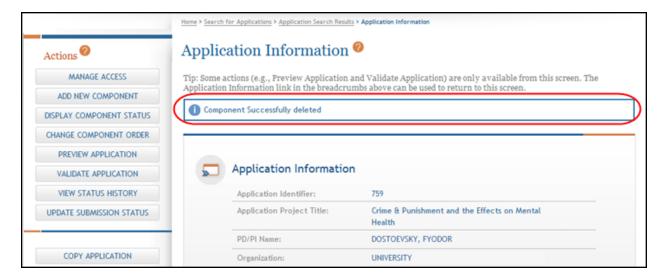
-OR-

To confirm the action and permanently delete the component from the application, select the Continue button. Remember that this action is irreversible. Once the component is deleted, you cannot retrieve it.

NOTE: You cannot delete a component if one or more of its forms are locked by yourself or another ASSIST user. If a form is locked, you will see the following error on your screen after continuing from the second confirmation screen:

The component cannot be deleted as the following form(s) are currently locked by <User ID> in: <application ID>: <locked form>

The Application Information screen displays with the message *Component successfully deleted*. You will also notice that the component has been removed from the left-side panel of Component Types.



When a component is deleted from an application, the Application Status History reflects this action. The **Status** in the history show as *Abandoned*. The **Status Comment** will indicate that the component was deleted by displaying the following *Component ID: <ID number> Deleted*, along with the name of the ASSIST user who performed the deletion.



See Also

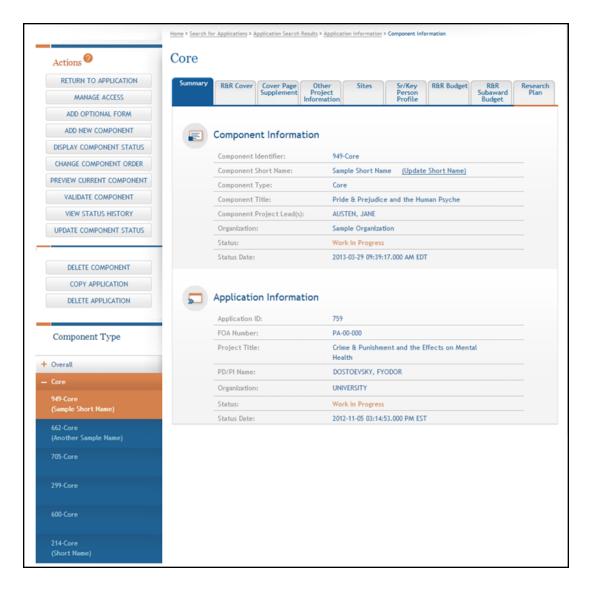
- Updating the Component Short Name
- Application Information

3.8.3.4 Updating the Component Short Name

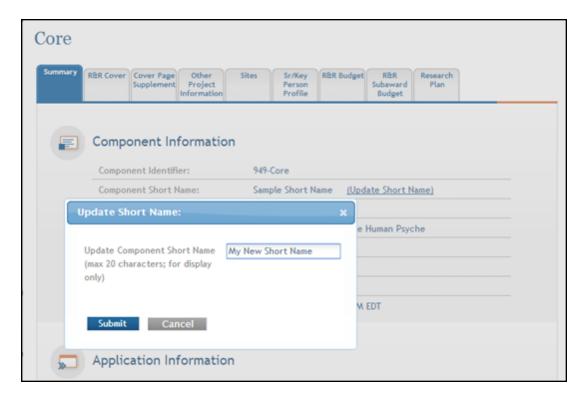
The **Component Short Name** is an optional field which can be entered when a component is added to an application. The short name provides an alternative means for identifying the component in case the system-generated component identifier is not known. The short name is provided as a convenience and is used only in ASSIST. The **Component Short Name** field also can be entered for the first time or updated from the *Component Information* page.

To update the component short name:

1. Access the Component Information page by selecting the Summary tab for the component or by selecting the component from the Component Type navigational panel.



- 2. Click the Update Short Name link located in the Component Short Name field.
- 3. From the Update Short Name pop-up window, enter a new name 20 characters or less. The name must be unique, not used as the short name of another component on the application.



4. Select the **Submit** button.

The Component Information updates with the new component short name.

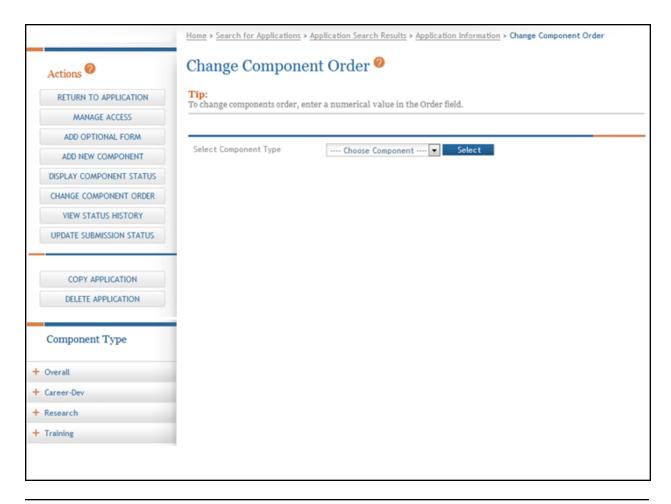
See Also

Component Information

3.8.4 Change Component Order

IMPORTANT: This topic is applicable only to multi-project applications.

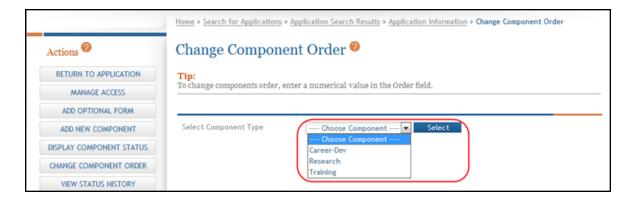
The Change Component Order screen is used to set the order in which your components appear in the submitted application (i.e., the PDF version) for each particular component type. For example, if your application contains four components of the component type *Research*, you can re-arrange those four components into any order you wish. The component order can be changed for components in the status of *Work in Progress*, *Complete*, or *Final*.



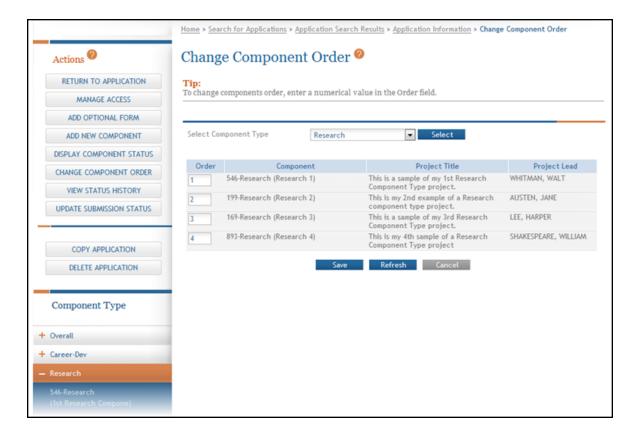
NOTE: Although components *within* a particular component type can be re-ordered, you cannot re-arrange the order of component types.

Access the *Change Component Order* screen by selecting the **Change Component Order** button on the **Actions** panel. Once the screen is opened, follow the steps below to update the order of components of a particular component type:

 Select a component type from the Select Component Type drop-down list and click the Select button. The component types displayed in the list depend on your application's FOA.



The screen updates to display the current Order, Component, Project Title, and Project Lead for each component of the selected component type. Components display in the order in which they were added to the application until they are reordered using this feature. Once components have been re-ordered, they will display in the current (i.e., updated) order.

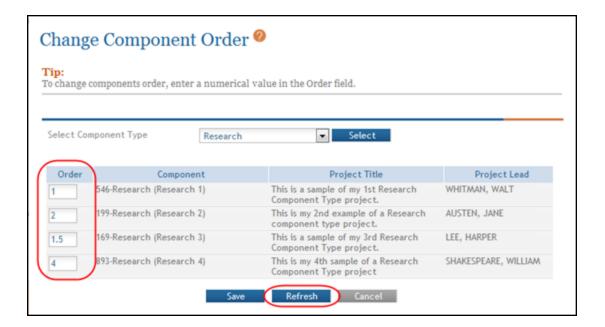


2. Use the text box in the Order column for each component being re-ordered to enter an order value. Make sure to enter a unique value in each **Order** field. You will receive an error if you attempt to save the order of components with duplicate order

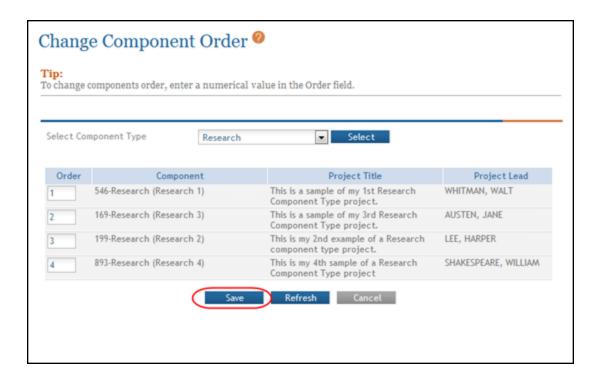
values.

You may use decimal numbers (up to 2 places) and negative numbers to avoid renumbering <u>every</u> component. For example, to re-order a particular component to appear between the first and second components, enter that component **Order** as 1.5.

After updating the values, you can use the **Refresh** button to display the components in the updated order. Refreshing the displayed order <u>does not save</u> the order and you can always use the **Cancel** button to abort the action, even after refreshing the screen.



3. When satisfied with the component order, select the Save button to save your results and return to the Application Information screen.



You can see your changes reflected in the Component Type panel.



See Also

- Actions
- Application Information
- Component Information

3.8.5 Add Optional Forms

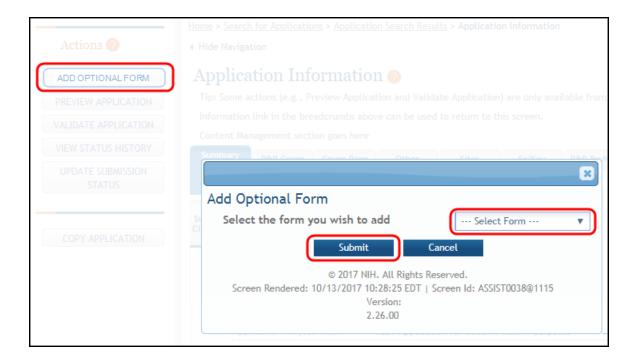
Depending on the funding opportunity, optional forms may exist for both single- and multi-project applications. You can add optional forms using the **Add Optional Form** feature. Only the optional forms available for the specific funding opportunity can be added.

3.8.5.1 Optional Forms for Single Project Applications

To add optional forms to a single-project application:

1. Select the **Add Optional Form** button from the **Actions** navigation panel.

A pop-up window opens for selecting the form to be added.



2. Choose a form from the drop-down list and select the **Submit** button to add the form to the component.

NOTE: Selecting the **Cancel** button closes the window without added the form to the component.

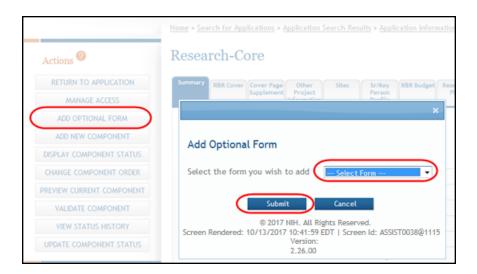
3. Select the tab of the corresponding form to enter information on the form.

3.8.5.2 Optional Forms For Multi-Project Applications

To add optional forms to a multi-project application:

- 1. Select the **Return to Application Info** button on the **Actions** panel to return to the *Application Information* page.
- 2. From the *Application Information* page expand the appropriate component from the **Component Type** section.
- 3. Select a component type to display the *Component Information*.
 - The Component Information page opens for the component.
- 4. Select the **Add Optional Form** button from the **Actions** navigation panel.

A pop-up window opens for selecting the form to be added.



- 5. Choose a form from the drop-down list.
- 6. Select the **Submit** button to add the form to the component.

NOTE: Selecting the **Cancel** button closes the window without added the form to the component.

7. Select the tab of the corresponding form to enter information on the form.

See Also

- Edit Overall Component Forms
- Edit Additional Component Type Forms

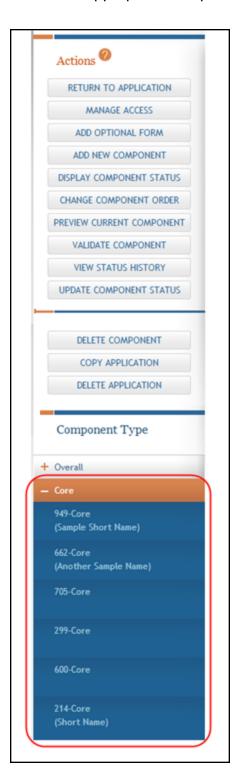
3.8.6 Edit Additional Component Type Forms

The forms of the component may be edited when the status is *Work in Progress*. The following lists the basic steps for navigating and enabling forms for editing.

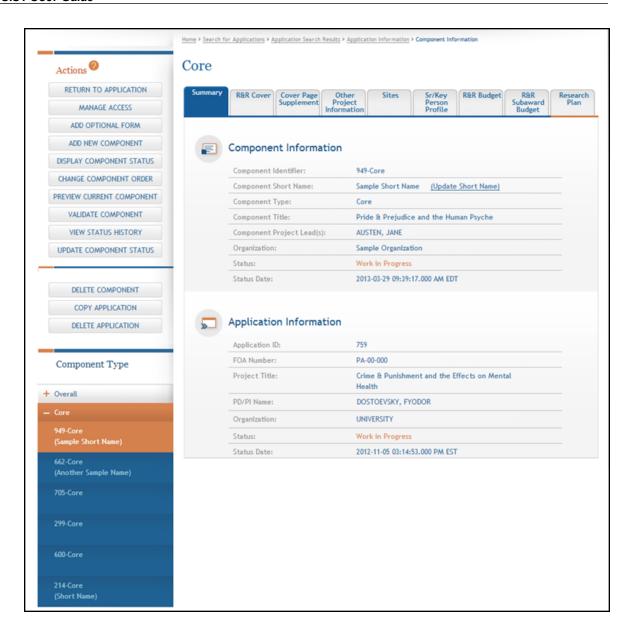
To edit component forms:

- 1. Select the **Return to Application Info** button on the **Actions** panel to return to the *Application Information* page.
- 2. From the *Application Information* page expand the appropriate component from the **Component Type** section.
- 3. Expand the component type to display the components.

4. Select the appropriate component.



The Component Information page displays for the selected component.



- 5. Select the tab for the appropriate form.
- 6. Select the **Edit** button at the top of the form to open the fields for editing. Selecting this button reserves the form, enables it for editing, and prevents others from editing it simultaneously.
- 7. For forms with grouped sections, all editable data fields are expanded by default as shown by the selected **Expand All** checkbox. Unselect the checkbox to collapse the fields on the form.

NOTE: Individual fields can be expanded (when applicable) by selecting the down arrow on the right side of the field and collapsed by selecting the up arrow.

8. Complete the forms as necessary, paying attention to the validation warnings. These validations exist to ensure that the proper and required information is entered correctly. Refer to the help topic titled Form and Field Level Validations for more information.

For assistance with the information required on this form, please refer to the appropriate Application Guide.

https://grants.nih.gov/grants/how-to-apply-application-guide.html

For system help with entering data into form fields, refer to the specific form help topic located in <u>Overall Component Forms</u> and/or <u>Other Components</u> section of the online help or User Guide.

- 9. Select one of the save options at the bottom of the form to save the data:
 - a. To save the information and keep the form open for further editing, select the **Save and Keep Lock** button.
 - To save the information and close the form, select the Save and Release
 Lock button
 - c. For multi-page forms only: To save the data on the current page of the form and to display a new page for entry, select the **Save and Add** button. The **Save and Add** button is not available on all forms.

NOTE: Selecting the **Cancel and Release Lock** button - followed by the **Continue** button on the confirmation - returns the form to read-only and does not save any of the entered information onto the form.

- 10. Navigate to the other forms by selecting the corresponding tabs.
- 11. When unsaved data exists: When navigating from tab to tab without saving the data, a warning message displays as follows:

Exiting without saving will result in losing the data entered. Do you wish to save before exiting?

Return to the form to save the data.

-OR-

Continue to next form without saving.

For security reasons, ASSIST employs a session time-out feature which logs you out of ASSIST when the system determines that there has been no activity for a specific amount of time. Before doing so, ASSIST displays a warning message indicating the

remaining amount of time until the automatic logout occurs. To prevent the automatic time-out, select the **Continue Working** button from the warning screen.

3.8.7 Delete a Component

IMPORTANT: This topic is applicable only to multi-project applications.

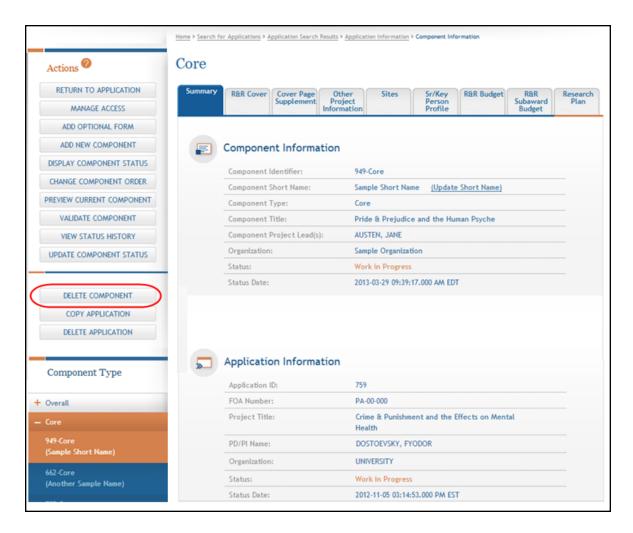
If you are the Signing Official, Administrative Official, or the PI of the lead organization - and/or- you have Entire Application Editor privilege, you have access to the Delete Component feature in ASSIST. The Delete Component features allows you to permanently delete individual components of any status from the application.

IMPORTANT: Deleting components is a permanent action. Once deleted, a component cannot be accessed, retrieved, or viewed. There is no way to recover the component.

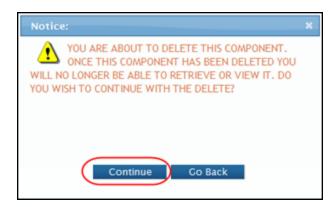
NOTE: ASSIST also has a Delete Application feature for deleting an entire application. Individual components do not need to be deleted first when deleting the entire application. Refer to the topic titled <u>Delete the Application</u> for steps on deleting entire applications.

To delete a component:

- 1. Open the Summary tab of the component you wish to delete.
- 2. From the Actions panel, select the Delete Component button.



A confirmation message displays as follows: You are about to delete this component. Once this component has been deleted you will no longer be able to retrieve or view it. Do you wish to continue with the delete?



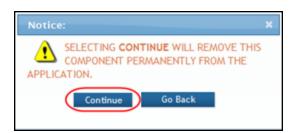
3. Select the appropriate action:

You may cancel the action at this point by selecting the **Go Back** button. If you choose **Go Back**, the delete process ends, you return to the summary tab from which you began, and the following steps are no longer applicable.

-OR-

To continue with the deletion, select the Continue button.

Upon continuing, a second confirmation displays as follows: Selecting Continue will remove this component permanently from the application.



4. This warning provides a final means of aborting the deletion. Carefully select the appropriate action:

To stop the deletion process, select the **Go Back** button. If you choose **Go Back**, the delete process ends, you return to the summary tab from which you began, and the following steps are no longer applicable.

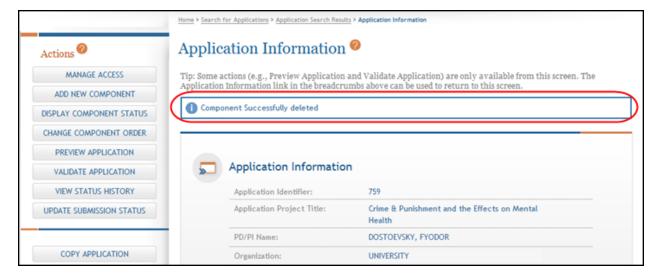
-OR-

To confirm the action and permanently delete the component from the application, select the Continue button. Remember that this action is irreversible. Once the component is deleted, you cannot retrieve it.

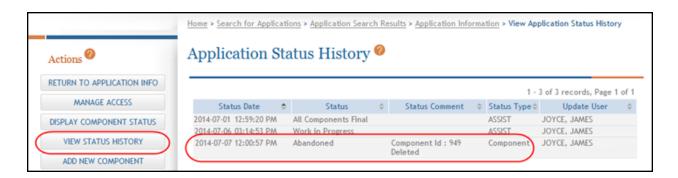
NOTE: You cannot delete a component if one or more of its forms are locked by yourself or another ASSIST user. If a form is locked, you will see the following error on your screen after continuing from the second confirmation screen:

The component cannot be deleted as the following form(s) are currently locked by <User ID> in: <application ID>: <locked form>

The Application Information screen displays with the message *Component successfully deleted*. You will also notice that the component has been removed from the left-side panel of Component Types.



When a component is deleted from an application, the Application Status History reflects this action. The **Status** in the history show as *Abandoned*. The **Status Comment** will indicate that the component was deleted by displaying the following *Component ID: <ID number> Deleted*, along with the name of the ASSIST user who performed the deletion.



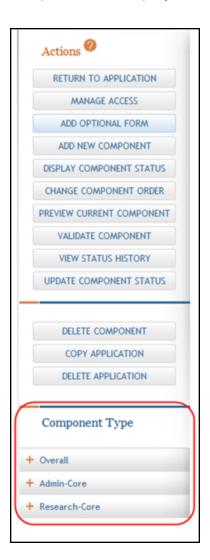
4 Forms Data Entry

The forms of an application can be edited when the status of the application (or of a multi-project component) is *Work in Progress*. This topic lists the basic steps for navigating and enabling forms for editing. Before starting to enter data on a form, be prepared to enter data marked with an asterisk (*) as these data elements are required to save the form.

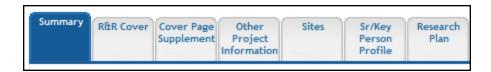
To edit application forms:

- 1. Select the **Return to Application** button on the **Actions** panel to return to the *Application Information* page.
- 2. If you are working on a single-project application, refer to Step 3. For multi-project applications:
 - a. From the Application Information screen expand and select the appropriate component from the Component Type section. After being selected, the





3. Select the tab for the appropriate form.



4. Select the **Edit** button at the top of the form to open the fields for editing. Selecting this button reserves the form, enables it for editing, and prevents others from editing it simultaneously.

5. For forms with grouped sections, all editable data fields are expanded by default, as shown by the selected **Expand All** check box. Unselect the check box to collapse the fields on the form.

NOTE: Individual fields can be expanded (when applicable) by selecting the down arrow on the right side of the field and collapsed by selecting the up arrow.

Complete the forms as necessary, paying attention to the validation warnings.
 These validations exist to ensure that the proper and required information is entered correctly. Refer to the help topic titled Form and Field Level Validations for more information.

For assistance with the information required on this form, please refer to the appropriate Application Guide.

https://grants.nih.gov/grants/how-to-apply-application-guide.html

- 7. Select one of the save options at the bottom of the form to save the data:
 - a. To save the information and keep the form open for further editing, select the **Save and Keep Lock** button.
 - b. To save the information and close the form, select the **Save and Release Lock** button.
 - c. For multi-page forms only: To save the data on the current page of the form and to display a new page for entry, select the **Save and Add** button. The **Save and Add** button is not available on all forms.

NOTE: Selecting the **Cancel and Release Lock** button - followed by the **Continue** button on the confirmation - returns the form to read-only and does not save any of the entered information onto the form.

- 8. Navigate to and complete the other forms by selecting the corresponding tabs and following the same steps.
- 9. When unsaved data exists: When navigating from tab to tab without saving the data, a warning message displays as follows:

Exiting without saving will result in losing the data entered. Do you wish to save before exiting?

Return to the form to save the data.

- a. Select the **Go Back** button to return to the unsaved form.
- b. Select the button for a save option at the bottom of the form.

c. Navigate to the next form again.

-OR-

Continue to next form without saving.

- a. Select the **Continue** button to move to the selected form without saving the changes entered onto the current form.
- b. Complete the new form as appropriate.
- c. Repeat steps for navigating to other forms.

For security reasons, ASSIST employs a session time-out feature which logs you out of ASSIST when the system determines that there has been no activity for a specific amount of time. Before doing so, ASSIST displays a warning message indicating the remaining amount of time until the automatic logout occurs. To prevent the automatic time-out, select the **Continue Working** button from the warning screen.

4.1 Human Subjects & Clinical Trials Information Form

4.1.1 Research & Related Other Project Information

For assistance with the information required on this form, please refer to the appropriate application guide on the <u>How to Apply</u> page. For a full list of significant FORMS-F changes, see the <u>High-level Grant Application Form Change Summary</u>: FORMS-F PDF.

NOTE: The forms in these topics reflect FORMS-F, which must be used for applications with due dates on or after May 25, 2020 (see the most recent <u>NIH FORMS-F notice NOT-OD-20-026</u>, <u>NIH FORMS-F notice NOT-OD-20-047</u>, and <u>annotated form set</u> for Forms-F.) For due dates on or before May 24, 2020, use FORMS-E.

4.1.1.1 New in Forms-F

- The Summary page now asks the question, "Does any of the proposed research in the application involve human specimens and/or data?"
- The explanation attachment is now always available.
- Question 1.4.a "Does the study involve human participants?" now defaults to
 "Yes" and cannot be changed unless the user changes the response to the
 question "Are Human Subjects Involved?" on the Other Projects Information form.
 Because a study record should be completed only for research involving human
 participants, the "No" option is no longer available for this question.
- In study record Section 2 Study Population Characteristics:
 - The inclusion of children is now covered in a new "Inclusion of Individuals Across the Lifespan" attachment. (2.3.a)

- The "Women, Minorities, and Children" attachment was relabeled the "Inclusion of Women and Minorities." (2.4)
- The "Enrollment of First Subject" field (2.8) has been renamed to "Enrollment of First Participant" to be consistent with the language used in the Clinical Trial Questionnaire in Section 1. Also, for post-submission, you do not enter any information for question 2.8; instead, form instructions direct you to enter the information in question 6.3.
- A field number, 2.9, has been added to the *Inclusion Enrollments Report(s)* field for usability and instruction clarity.
- In the Inclusion Enrollment Report, available from Section 2 of the Study Record, there is a new Inclusion Enrollment Report Title field. The human subjects study title appears by default for all existing studies and can be changed by the user. For new users and those with a work in progress study, the title is blank and must be filled out by the grantee.
- In Section 4 Protocol Synopsis:
 - The Brief Summary attachment was removed and the Narrative Study Description was renamed to Detailed Description. Information in Brief Summary prior to June 13, 2020 will continue to be available in the PDF images of applications and Research Performance Progress Reports (RPPRs) submitted prior to this change.
 - Also in Section 4, the question was added, "Is this an applicable clinical trial under FDAAA?"

4.1.2 Steps for Filling out the Form

This page walks you through the *PHS Human Subjects and Clinical Trials Information* form, which consolidates human subjects, inclusion enrollment, and clinical trial information previously collected across multiple agency forms.

The human subjects section of the Research & Related Other Product Information form will need to be completed before opening the Human Subjects and Clinical Trials form. The first few answers in the R&R Other Product Information form will populate the first three questions in the Human Subjects and Clinical Trials Information form.

Summary	R&R Cover	Cover Page Supplement	Other Project Information		Sites	Pe	/Key rson ofile	R&R B	udget	Research Plan	
	ch & Relat therProje	formation							MB Number: 4040 tion Date: 12/31/		
Edit	t										* Required field
1. * Are	Human Subje	ects Involved		o Yes	o No						
1.a	If YES to Hum Is the project regulations?	nan Subjects t exempt from	Federal	o Yes	o No						
	If yes, check exemption n	the appropriat	te	1	_ 2	3	4	5	6	7	8
	If no, is the I	RB review Pen	ding?	o Yes	o No						
	IRB Approval	Date									
	Human Subje	ects Assurance	Number								
2. * Are	Vertebrate A	nimals Used?		o Yes	o No						
2.a	If YES to Vert	ebrate Animal	s								
	Is the IACUC	review Pendin	g?	o Yes	o No						
	IACUC Appro	val Date									
	Animal Welfa	are Assurance I	Number								
info	proprietary/pri prmation inclu plication?	_		o Yes	o No						
p n	otential impac egative - on th	ct have an actu ct - positive or he environmen		o Yes	o No						
	. If yes, please										
	potential im environment been authori environment or environment	t, has an exemptized or an cal assessment ental impact	otion (EA)	o Yes	o No						
des	ignated, or el	erformance site igible to be historic place?		o Yes	o No						

The top of the *Human Subjects & Clinical Trials* form has a reminder to complete the *R&R Other Project Information* form first.

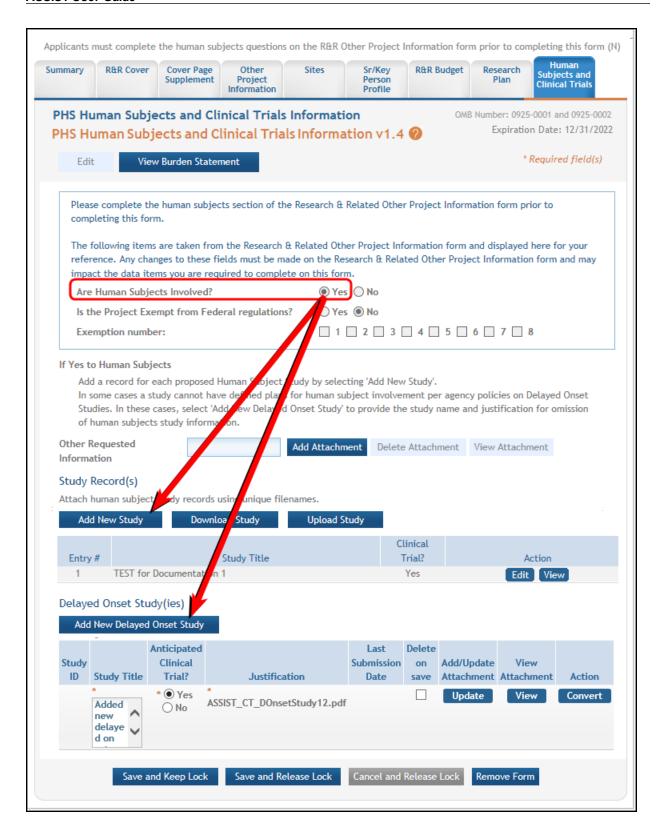


The Summary page will be the first page of the Human Subjects and Clinical Trials form. This is where you will see the pre-populated answers from the R&R Other Project Information form regarding Human Subjects. Those pre-populated answers will determine the content and mandatory actions in the next section of the form.

The first question asks if the proposed research involves human specimens and/or data.

cants must co	omplete ti	he human subj	ects questions o	n the R&R C	ther Proj	ect Info	rmation f	orm p
nmary R&	R Cover	Cover Page Supplement	Other Project Information	Sites	Sr/K Pers Prof	on	R&R Budg	get
	_		inical Trials Clinical Tri			n v2.0	0	
Edit	View	/ Burden Stater	nent					
Use of Hun	nan Spec	imens and/o	or Data					
Does any	of the pro	oposed researc	h in the applic	ation involv	e human	specin	nens and/	or da
human sub	ojects res	search.	se of human sp					
Please com this form.	nplete the	human subjec	ts section of the	e Research 8	Related	Other P	roject Info	orma
reference.	Any char	nges to these fi	n the Research ields must be m uired to comple	ade on the F	Research 8			
Are Hum	an Subje	cts Involved?		• Y	es o No			
Is the Pro	oject Exe	empt from Fed	eral regulation	s? o Y	es • No			
Exemption	on numbe	er:		_ 1	2	3	4	
If Yes to Hu	uman Su	bjects						
In some Studies.	cases a st In these o	udy cannot hav	Human Subject ve defined plans Id New Delayed Ition.	for human	subject in	volveme	ent per ag	
Other Requ	uested Ir	nformation						

• If specimens and/or data *are* involved, select "Yes" and add a Study Record or Delayed Onset Study for each proposed Human Subjects study and any *Other Requested Information* indicated in the FOA.



 An additional functionality available in ASSIST is to download a study to your local environment to provide to other collaborators to complete and then the completed study can be uploaded. The buttons for these functions are to the right of the **Add New Study** button.

• For *Other Requested Information* follow instructions in the funding opportunity (FOA) regarding the inclusion of other information or attachments. Additionally, for multi-core applications that share studies, use this area in the affected cores to reference the study in the *Overall* core.

IMPORTANT: Studies must only be added once for each application regardless of how many times they are used by other cores.

NOTE: With regard to Project Exemptions from Federal regulations, those applicable to NIH are 1, 2, and 4. See this NIH infographic for more detail. A summary is listed below.

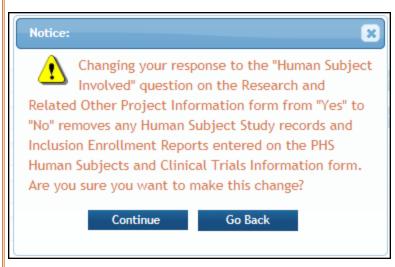
- * **Exemption 1** research conducted in an educational setting involving normal educational practices.
- * **Exemption 2** research using educational tests, surveys, interviews, or observations of public behavior unless identifiable and pose risks. (not collecting sensitive information). See the infographic for limits on involving children.
- * **Exemption 4** secondary research using identifiable information or biospecimens if publicly available, or recorded such that subjects cannot be reidentified.
- Add one or more Study Records or Delayed Onset Studies. All study titles must be
 unique to your organization. For multi-component applications with shared
 protocols, the study should be included in the Overall and the study referred to
 using this box.

NOTE: A Delayed Onset Study, marked as an anticipated clinical trial, can fulfill FOA requirements

Tip: You will not be able to add a regular or delayed study if you answered "No" to the human subjects question in the *R&R Other Project Information* form.

 For Delayed Onset Studies, provide a Justification regarding the reasons why the study cannot be described at the time of submission. **Tip**: For *Delayed Onset Studies*, multiple studies may be grouped in a single record.

IMPORTANT: If you change your answer to the "Are Human Subjects Involved" question on the *R&R Other Project Information Form* after you have started entering information into the *PHS Human Subjects and Clinical Trials Information* form, your data in the *PHS Human Subjects and Clinical Trials Information* form may be lost. A warning pop-up will display:



4.1.3 Study Record

4.1.3.1 The Study Record consists of five sections:

- Section 1 Basic Information: Title, exemptions, and Clinical Trial information
- Section 2 Study Population Characteristics: Focus, Demographics, IERs, etc.
- <u>Section 3 Protection and Monitoring Plans:</u> Information regarding PHS issues, data and safety monitoring, and team structure.
- <u>Section 4 Protocol Synopsis:</u> Study design, purpose, interventions, metric parameters, etc.
- <u>Section 5 Other Clinical Trial-related Attachments:</u> Area used for any additional attachments that do not fit the other sections.
- <u>Section 6 Clinical Milestone Plan:</u> Used to record milestone dates and whether study is an applicable clinical trial under FDAAA.

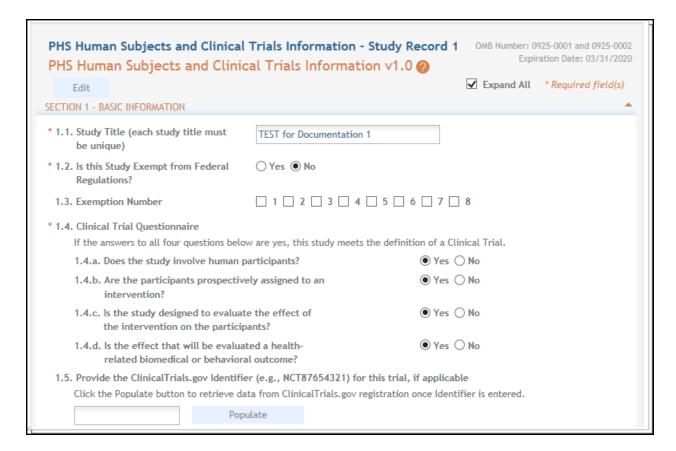
The bottom of the Study Record includes five buttons:

- Save and Keep Lock. Save your changes and keep the form locked from further changes
- Save and Release Lock. Save your changes and release the form to be edited by others
- Save and Add.
- Cancel and Release Lock. Cancel any changes made and release the form to be edited by others.
- Remove Study. Removes the current study and saves the deletion.



4.1.3.2 Study Record - Section 1 Basic Information

Section 1 includes basic information and must be completed for all human study records, both those with or without clinical trials.



This section includes:

- A **Study Title** up to 600 characters, which must be unique within your organization.
- Exemption question. This is a required question and is system enforced.
- Exemption code information. Where the exemption code information provided on the *Other Project Information* form was for the application as a whole, this field asks about exemption code information at the study level.
- A clinical trial questionnaire. If you answered Yes to Are Human Subjects Involved? question on the Other Project Information form, then question 1.4.a Does the study involve human participants? defaults to Yes and is non-editable. If you answer Yes to all four questions, the study will be considered a clinical trial and section 5 appears on the form, requiring you to provide trial-specific data. Refer to more comprehensive instructions in the How to Apply guides located here; https://grants.nih.gov/grants/how-to-apply-application-guide.html.
- A ClinicalTrials.gov Identifier (NCT number) if available. To populate information
 from a trial registered at ClinicalTrials.gov, enter the NCT number in the specified
 format and select the **Populate** button. This feature will do a best effort copy of
 form field data as well as attachments. When the copy is done, you should check
 the form for completeness.

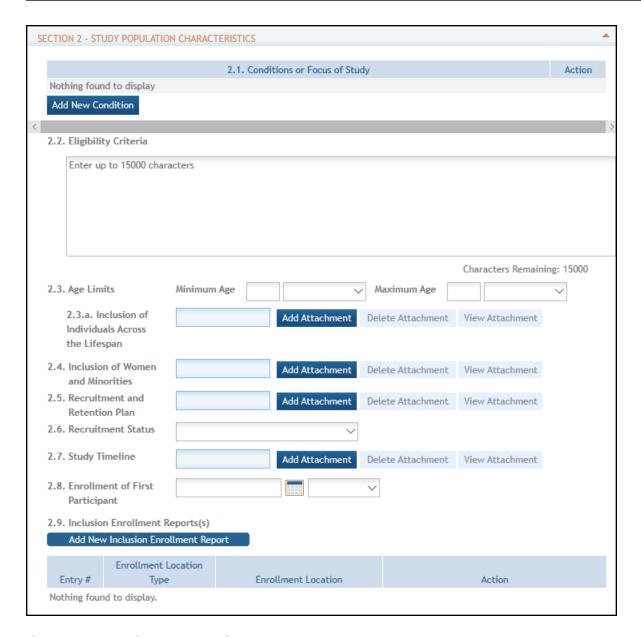
NOTE: The *Human Subjects and Clinical Trials* forms in ASSIST and the ClinicalTrials.gov forms have many fields in common. Collecting the NCT number in ASSIST positions us for a future exchange data with ClinicalTrials.gov to reduce data entry and provide more consistent information between systems.

4.1.3.3 Study Record - Section 2 Study Population Characteristics

Section 2 is used to capture conditions and eligibility criteria as well as demographic information.

This section is required for all human subject studies, unless exemption 4 applies.

For Conditions or Focus of Study, use the **Add New Condition** button in Section 2 to enter up to 20 conditions or areas of focus, each of which is limited to 255 characters.



If you view this form in Post Submission, then question 2.8 directs you to answer the Enrollment of First Participant question in section 6.3, which appears only in Post Submission.

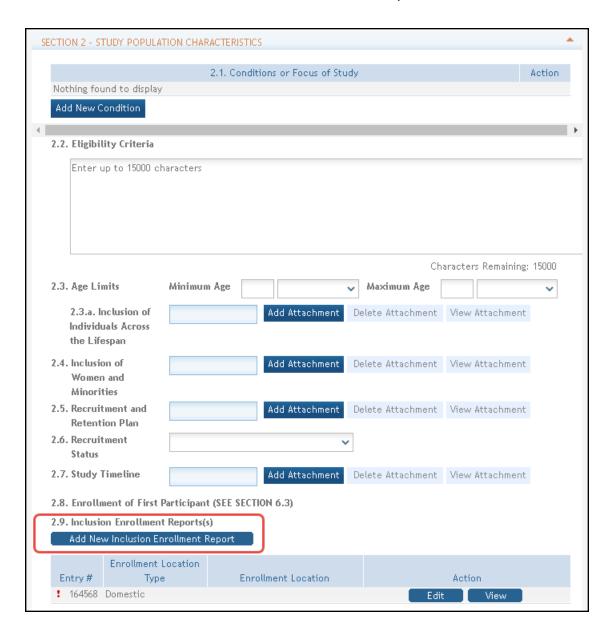
The last item in this section is for inclusion reporting. When you click the **Add New Inclusion Enrollment Report** button, the intake form for the inclusion enrollment report opens. See the IER page for more detail.

4.1.3.4 Inclusion Enrollment Report

Standalone PHS Inclusion Enrollment Report forms are no longer used. Instead, data collection for up to 20 *Inclusion Enrollment Reports* has been folded into each *Study Record*.

For specific information, please see the <u>Inclusion Enrollment Reports section of the SF424 (R&R) application guide.</u>

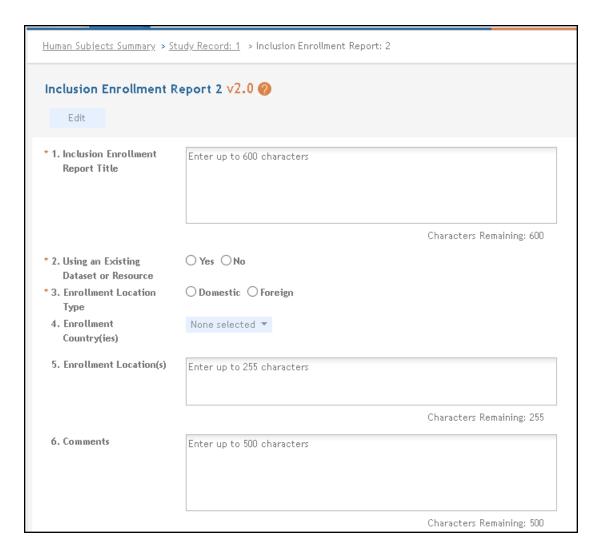
Click on the Add New Inclusion Enrollment Report button in Section 2 of the *Study Record* screen to initiate the Inclusion Enrollment Report.



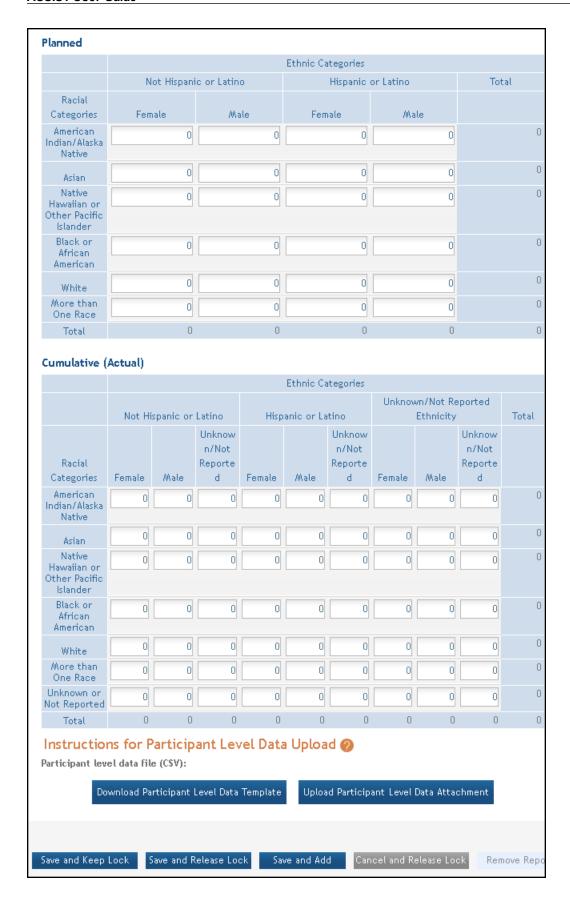
For each *Inclusion Enrollment Report*, applicants must indicate whether an existing dataset or resource will be used and whether the enrollment location type is domestic or foreign.

There are also a few optional fields in the report, including a text entry *Comments* field. The *Inclusion Enrollment Report Title* field should be unique to help you identify the report. The human subjects study title appears by default for all existing studies but can

be changed. For new users and those with a work in progress study, the title is blank and must be filled out.



Planned and Cumulative enrollment data is entered into two separate tables.



Editing Cumulative (Actual) Inclusion counts

There are two ways to edit the existing Inclusion Enrollment Report (IER) data for Cumulative (Actual) counts:

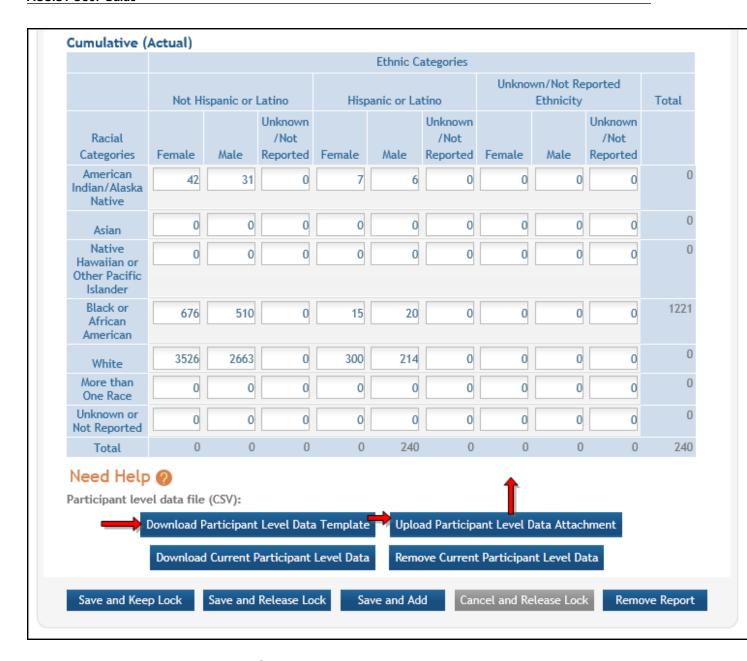
- 1. You can update the cells online in the existing report in the web form.
- 2. You can upload participant-level data using the **Upload Participant Level Data Attachment** button. This is required for some applications (see **Notes**).

Notes:

- If you plan to upload the data, you must use the provided template by clicking the Download Participant Level Data Template button. This downloads a CSV file that can be updated with new totals.
- Individual-level participant data on sex/gender, race, ethnicity and age at enrollment are *required* in progress reports for competitive applications submitted for due dates on or after January 25, 2019 (See NIH Guide Notice <u>NOT-OD-18-116</u>).

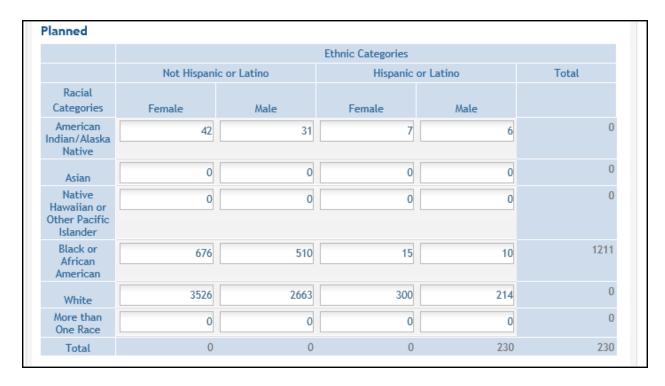
To use the template:

- Download the spreadsheet template for entering participant-level data by clicking the **Download Participant Level Data Template** button below the Cumulative (Actual) table. Fill the template with data for the study.
 - The columns in the template should not be altered; altering the format or category titles will result in an error during the uploading process.
 - Data may be copied/transferred into the template from another source or entered directly into the template.
- Once the new totals have been entered into the template and the file has been saved, use the Upload Participant Level Data Attachment button to upload the file which will update the Cumulative (Actual) counts in the online web form.



You can click on the **Download Current Participant Level Data** button to download the file containing the data for your own records.

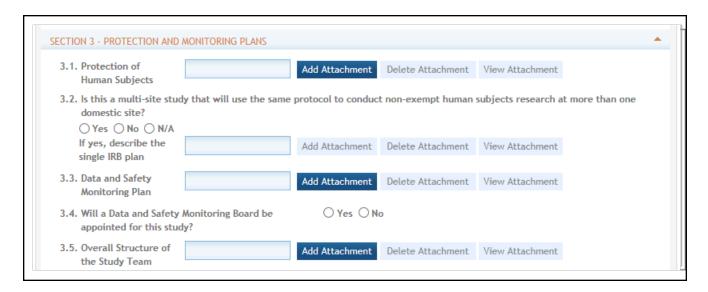
For Planned counts, the cells must be updated online in the report itself.



4.1.3.5 Study Record - Section 3 Protection and Monitoring Plans

This section includes the *Protection of Human Subjects* attachment. Before filling the attachment out, read through the application guide instructions for the *Protection of Human Subjects* attachment.

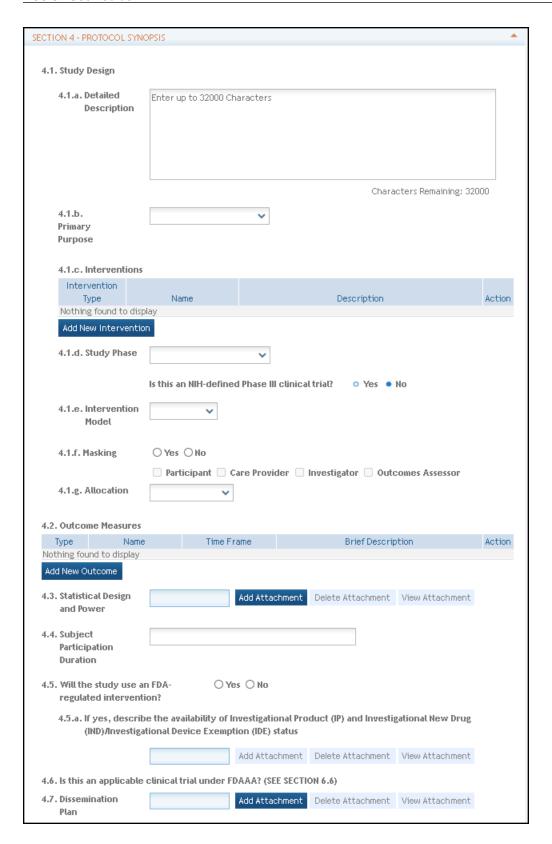
All human subjects studies must provide a *Protection of Human Subjects* attachment and answer the question regarding multi-site studies. If applicants propose a multi-site study that will use the same protocol to conduct non-exempt *Human Subject* research at more than one domestic site, they need to attach your plan describing how they will comply with the NIH policy on the use of single-IRB for multi-site research. Note that the IRB Plan attachment is not required for Forms F version 2.0 and later.



The remaining fields in this section – the *Data and Safety Monitoring Plan* attachment, question about the use of a Data Safety Monitoring Board, and the *Overall Structure of the Study Team* attachment – only apply to studies involving clinical trials, though other studies can include them if needed.

4.1.3.6 Study Record - Section 4 Protocol Synopsis

Section 4 is the Protocol Synopsis and is only required for study records involving independent clinical trials.



The protocol synopsis includes:

- Study Design fields related to:
 - A Narrative Study Description, up to 32,000 characters
 - A drop-down selection for *Primary Purpose*
 - The type, name and description for up to 20 *Interventions*
 - A drop-down selection for Study Phase
 - A drop-down selection for Intervention Model
 - Check boxes for *Masking Information*. If "Yes" is selected, at least one of the related boxes must be checked.
 - A drop-down selection for Allocation
- The ability to provide the name, type, time frame and description for at least one, but up to 50 *Outcome Measures*. Character limits for the *Name* and *Time Frame* are 255 characters and the limit for the *Brief Description* is 999 characters.
- A Statistical Design and Power attachment.
- A **Subject Participation Duration** attachment with a 255 character limit.
- Question 4.6, Is this an applicable clinical trial under FDAAA, is new. If in presubmission, enter the answer to this question in Section 4. If in post-submission, enter this question in section 6.6. FDAAA refers to the Food and Drug Administration Amendments Act (FDAAA) of 2007. To learn more, see the Identifying an Applicable Clinical Trial under FDAAA flowchart.
- A Dissemination Plan attachment used to describe an applicant's plan for the
 dissemination of NIH-funded clinical trial information and how they plan to meet
 the expectations of NIH's new policies including the requirement to register and
 report results in ClinicalTrials.gov. Usually, one plan per application is sufficient
 and the plan may be attached in multiple studies.

NOTE: If you previously entered information in the Brief Summary field, which was removed from the form as part of FORMS F changes, that information will be preserved in the PDF of the form.

The *Description*, *Study Design*, and *Outcome Measures* fields all directly map to fields in ClinicalTrials.gov.

4.1.3.7 Study Record - Section 5 Other Clinical Trial-Related Attachments

The final section, Section 5, is for *Other Clinical Trial-related Attachments*. It appears only for clinical trial study records and only when an attachment is specifically requested in the funding opportunity announcement (FOA) to which you are applying. If the

answers to questions 1.4.a through 1.4.d are all **Yes**, then section 5 appears, as those questions indicate a clinical trial.

If attachments are required, follow the directions in the FOA and/or contact the indicated program staff listed in the FOA for further guidance.



4.1.3.8 Study Record - Section 6 Clinical Milestone Plan

Section 6 appears only in post-submission in the form HSCT Post Submission to record key milestone dates. .

Summary HSCT Post Submission			
~~~~~	·····	~~~~~	~~~~~
~~~~~~	~~~~	~~~~	^^^
SECTION 6 - Clinical Trial I	Milestone Plan		
6.1. Study Primary		─ O Anticipated	○ Actual
Completion Date			~
6.2. Study Final Completion Date		Anticipated	○ Actual
6.3. Enrollment and randomization			
Enrollment		── Anticipated	○ Actual
of the first participant			
(Study Start			
Date)			
25% of		── Anticipated	○ Actual
planned enrollment	-		
recruited			
by			
50% of		── Anticipated	○ Actual
planned			
enrollment recruited			
by			
75% of		── O Anticipated	○ Actual
planned	L		
enrollment recruited			
by			
100% of		Anticipated	○ Actual
planned	l	01	Oncom
enrollment			
recruited by			
6.4. Completion of		■ O Anticipated	∩ Actual
primary		O Milliospaced	○ MCtuat
endpoint data			
analyses		_	A
6.5. Reporting of results in		Anticipated	○ Actual
ClinicalTrials.gov			
6.6. Is this an applicable			

In question 6.6, FDAAA refers to the Food and Drug Administration Amendments Act (FDAAA) of 2007. To learn more, see the <u>Identifying an Applicable Clinical Trial under FDAA</u> flowchart.

4.1.3.9 Participant Level Data Collection

Participant Level Data rules (including Age):

- 1. Participant level data collection will include one or more entries with 5 fields: Race, Ethnicity, Gender, Age, and Age Unit. Data can be uploaded as a CSV file through ASSIST UI, or submitted as XML through S2S.
 - Race, Ethnicity, Sex/Gender must contain valid values per OMB standards (consistent with Grants.gov form). For S2S these should be enforced in the XML schema. - (DAT attached)
 - Race values are:
 - American Indian
 - Asian
 - Black
 - Hawaiian
 - More than one race
 - Unknown
 - White
- 2. Age must be a whole number between 0 and 9999 (four digits). Valid Age Units are Minutes, Hours, Days, Weeks, Months, Years, Ninety Plus, and Unknown. If the Age Units are any value other than Ninety Plus or Unknown, an Age number is required. If Ninety Plus or Unknown is specified as the Age Unit, the Age number must be blank.

4.2 Export and Upload Data to ClinicalTrials.gov

Once clinical trial data has been entered, ASSIST provides options to export the data and/or to upload it to the ClinicalTrials.gov site. Clink a link below for further information and instructions.

- Export Human Subjects Data to an XML File to your local drive
- Upload an XML File to ClinicalTrials.gov from your local drive
- Upload Human Subjects Data Directly to ClinicalTrials.gov (without having to export an XML file)

4.2.1 Upload Human Subjects Data Directly to ClinicalTrials.gov

NIH applicants/awardees can upload study record data available in the Human Subjects System (HSS) directly to ClinicalTrials.gov, thereby avoiding the need to re-key those clinical study fields at that site.

NOTE: In order to upload study data to ClinicalTrials.gov, the study's sponsoring organization must first have a Protocol Registration and Results System (PRS) account. If necessary, follow the steps to apply for a PRS account.

 Log in to eRA Commons and identify the application/award containing the study record, and then click the **Human Subjects** link to go to ASSIST.



NOTE: The **Export XML** appears only for study records that propose a clinical trial where the user has entered "yes" responses to questions 1.4a through 1.4d on the Study Record.

2. Click the **Export XML** button. The *CT Gov Export Info* window displays.



IMPORTANT: The **Upload** check box only appears for clinical trial study records that have a study ID, but that do not have an NCT# (the ClinicalTrials.gov identifier), and that have not been uploaded previously to ClinicalTrials.gov.

 Check the Upload directly to ClinicalTrials.gov box. Additional upload fields are displayed and the Export button changes to the Upload to ClinicalTrials.gov button.



NOTE: The **Organization Name** is the one-word name assigned when your Protocol Registration and Results System (PRS) account was created. The **Unique Protocol ID** is a unique identifier up to 30 characters that you chose.

Enter the username and password for PRS, and then click the **Upload to** ClinicalTrials.gov button. Note that ClinicalTrials.gov requires additional information to register a trial. This information, as well as any edits must be done in the PRS system.

If your upload was successful, the following message displays:

You have successfully uploaded your protocol complete the registration of your clinical trial, you must log into the Protocol Registration and Results System (PRS) at ClinicalTrials.gov (https://register.clinicaltrials.gov/) and complete the required information.

If your upload was unsuccessful, the following message displays:

The ClinicalTrials.gov upload capability for this study is disabled because an NCT number is already associated with the study record or the study record has already been uploaded to ClinicalTrials.gov. If you need to update the ClinicalTrials.gov information for this study, you need to login into the Protocol Registration and Results System (PRS) at ClinicalTrials.gov.

4.2.1.1 Check Uploaded Data on ClinicalTrials.gov

1. Log into <u>ClinicalTrials.gov PRS</u> with your assigned *Organization*, *Username*, and *Password*. The *Protocol Registration and Results System* page displays.



2. Review the uploaded data and add or modify as necessary.

Tip: Tip: For detailed instructions on how to view and modify clinical data on ClinicalTrials.gov, refer to the PRS help system's page on Modifying a Record in PRS.

4.2.2 Export Human Subjects Data to an XML File

Use this process to create an XML file on your local disk that contains a copy of the study's Human Subjects Study (HSS) data.

NOTE: If you are the ClinicalTrials.gov "responsible party" user, you have the option to upload your study's HSS data directly, without having to create an XML file yourself. To do so, follow the instructions at Upload XML Data to ClinicalTrials.gov. Note that the PRS account is granted to an organization by ClinicalTrials.gov. Each organization decides who can use the account to upload studies to CTG. Thus, the "responsible party" could be the signing official or some other official from the organization. If necessary, apply for a PRS account and then proceed with the steps below.

Tip: If you are the ClinicalTrials.gov "responsible party" user, you have the option to upload your study's HSS data directly, without having to create an XML file yourself. To do so, follow the instructions at Upload Study Data Directly to ClinicalTrials.gov.

1. Log in to eRA Commons and identify the application/award containing the study record. Click the **Human Subjects** link to go to ASSIST.



2. Click the **Export XML** button to display the CT Gov Export Info window.

NOTE: The **Export XML** button is displayed only for Clinical Trial Studies, which are studies that have "yes" responses to all four of questions 1.4a through 1.4d on the Study Record.



NOTE: The **Organization Name** is the one-word name assigned when your Protocol Registration and Results System (PRS) account was created. The **Unique Protocol Identification Number** can be any unique identifier that you chose up to 30 characters in length.

3. Complete the *Organization Name* and the *Unique Protocol ID Number* fields, and then click the **Export** button. (Leave the **Upload** check box blank)

The XML file is saved to your computer's default download folder.

4.2.3 Upload an XML File to ClinicalTrials.gov

A signing official (SO) can use an XML file with Human Subjects Study (HSS) data to populate corresponding data fields at ClinicalTrials.gov. (Refer to Export Human Subjects Data to XML for instructions on creating the XML file.) Once you have the XML file, follow the steps below to upload its data to ClinicalTrial.gov.

Tip: Signing officials also have the option to use a simplified upload process that uploads HSS data directly to ClinicalTrials.gov without having to create a separate XML file. To use this simplified method, follow the instructions at Upload Human Subjects
Data Directly to ClinicalTrials.gov.

NOTE: In order to perform an upload to ClinicalTrials.gov, the sponsoring organization must have a PRS account. If necessary, follow the steps to apply for a PRS account. Once this account exists, follow the steps below upload the data in the XML file to ClinicalTrials.gov.

For more detailed instructions on how to upload data to ClinicalTrials.gov, refer to the PRS User Guide.

1. Log into <u>ClinicalTrials.gov PRS</u> with your assigned *Organization*, *Username*, and *Password*. The *Protocol Registration and Results System* page displays.



- 2. Click on **Records** and select *Upload Record XML* from drop-down list. The *Upload XML* screen displays.
- 3. Click the **Upload** button.

If your upload was successful, the following message displays:

You have successfully uploaded your protocol
protocol ID> to
ClinicalTrials.gov. To complete the registration of your clinical trial, you must
log into the Protocol Registration and Results System (PRS) at
ClinicalTrials.gov (https://register.clinicaltrials.gov/)

If your upload was unsuccessful, the following message displays:

The ClinicalTrials.gov upload capability for this study is disabled because an NCT number is already associated with the study record or the study record has already been uploaded to ClinicalTrials.gov. If you need to update the ClinicalTrials.gov information for this study, you need to login into the Protocol Registration and Results System (PRS) at ClinicalTrials.gov.

NOTE: This process populates data fields at ClinicalTrials.gov that correspond with data fields in HSS. Since the data imported from the NIH HSS is only a subset of the information required by ClinicalTrials.gov, you will see warnings that PRS requires additional information.

4.3 Non-Research Forms

Applications for non-research funding opportunities may require additional forms or the existing forms may be used differently. This section details the forms and processes used for each in conjunction with non-research applications.

4.3.1 SF424 (Application for Federal Assistance)

This form must be completed by applicants for all non-research grants.

This is part of the application package and is accessed from the FOA.

4.3.2 SF424-A (Budget Information – Non-Construction Programs)

This form is designed so that an application can be made for funds from one or more grant programs. Fill out Sections B, C, and E of the SF-424A. It is highly recommended that you use the sample budget format in Appendix J. This will expedite review of your application.

In preparing the budget, adhere to any existing federal grantor agency guidelines which prescribe how and whether budgeted amounts should be separately shown for different functions or activities within the program.

Instructions for the form are found here: https://grants.nih.gov/grants/how-to-apply-application-guide.html

Source: Grants.gov Application Kit Package

4.3.3 SF424-B (Assurances for Non-Construction)

You must read the list of assurances provided on the SAMHSA website and check the box marked 'I Agree' before signing the first page (SF-424) of the application.

The instructions for his form are found here: https://grants.nih.gov/grants/how-to-apply-application-guide.html

Source: SAMHSA Website; https://www.samhsa.gov/grants/applying/forms-resources

4.3.4 SF424-C (Budget Information for Construction Programs)

Instructions may be found here: https://grants.nih.gov/grants/how-to-apply-application-guide.htm

4.3.5 SF424-D (Assurances for Construction Programs)

Instructions are located here: https://grants.nih.gov/grants/how-to-apply-application-guide.htm

4.3.6 HHS Checklist

The HHS Checklist ensures that you have obtained the proper signatures, assurances, and certifications. You must complete the entire form, including the top portion ("Type of Application") indicating if this is a new, noncompeting continuation, competing continuation, or supplemental application. The BO and PD/PI contact information (Part C), and your organization's nonprofit status (Part D, if applicable) must be completed as well.

4.3.7 Project Abstract Summary

Your total abstract must not be longer than 30 lines. It should include the project name, population(s) to be served (demographics and clinical characteristics), strategies/interventions, project goals and measurable objectives, including the number of people to be served annually and throughout the lifetime of the project, etc. In the first five lines or less of your abstract, write a summary of your project that can be used, if your project is funded, in publications, reports to Congress, or press releases.

4.3.8 Budget Narrative

Applicants must include a detailed Budget Narrative in addition to the Budget Form SF-424A.

- In order to determine whether costs are allowable, allocable, and reasonable, please explain how each of the budgeted amounts was determined.
- Personnel -describe the role and responsibilities of each position.
- Fringe Benefits -list all components of the fringe benefit rate.
- Travel -provide (if applicable) the following information: Airfare per staff, # of staff attending ea. meeting, lodging per staff, # of days, per diem rate, mileage, etc.
- Supplies -generally self-explanatory; however, if not, describe need.
- Contractual explain the need for each contractual arrangement and how these components relate to the overall project.
- Other -each category must be listed.

4.3.9 Project/Performance Site Location(s)

The purpose of this form is to collect location information on the site(s) where work funded under this grant announcement will be performed.

4.3.10 Project Narrative

The application must address how the applicant will implement and meet the goals and objectives of the program. Applicants must attach their project narrative file (Adobe PDF format only) inside the Project Narrative Attachment Form. See the FOA: Part I for specific guidance.

4.3.11 SF-LLL (Disclosure of Lobbying Activities)

Federal law prohibits the use of appropriated funds for publicity or propaganda purposes or for the preparation, distribution, or use of the information designed to support or defeat legislation pending before Congress or state legislatures. You must sign and submit this form, if applicable.

4.3.12 Other Attachments

The specific Funding Opportunity Announcement (FOA) will specify if additional forms, available on SAMHSA's website, will be required for an application. Additional form links and details can be found here: https://www.samhsa.gov/grants/applying/forms-resources.

Forms may include:

Biographical Sketches and Job Descriptions

Biographical Sketches

Existing curricula vitae of project staff members may be used if they are updated and contain all items of information requested below. You may add any information items listed below to complete existing documents. For development of new curricula vitae include items below in the most suitable format:

- 1. Name of staff member
- 2. Educational background: school(s), location, dates attended, degrees earned (specify year), major field of study
- 3. Professional experience
- 4. Honors received and dates
- 5. Recent relevant publications
- 6. Other sources of support [Other support is defined as all funds or resources, whether federal, non-federal, or institutional, available to the Project Director/Program Director (and other key personnel named in the application) in direct support of their activities through grants, cooperative agreements, contracts, fellowships, gifts, prizes, and other means.]

Job Description

- 1. Title of position
- 2. Description of duties and responsibilities
- 3. Qualifications for position
- 4. Supervisory relationships
- 5. Skills and knowledge required
- 6. Personal qualities
- 7. Amount of travel and any other special conditions or requirements
- 8. Salary range
- 9. Hours per day or week

Confidentiality and SAMHSA Participant Protection/Human Subjects

In Section F of your application, you must describe procedures relating to Confidentiality, Participant Protection, and the Protection of Human Subjects Regulations.

HHS 690

Every grant applicant must have a completed <u>HHS 690 form (PDF)</u> on file with the Department of Health and Human Services.

Charitable Choice Form - SMA 170

Delete this if not applicable to your program. This form is required only for programs offering substance abuse prevention or treatment services: Applicants for this program are required to complete the <u>Assurance of Compliance with SAMHSA Charitable Choice</u> Statutes and Regulations Form SMA 170.

SAMHSA Assurances for Non-Construction Programs

Form SF-424B located here; https://www.samhsa.gov/sites/default/files/samhsa-assurances-sf424b-v1.1.pdf

SAMHSA List of Certifications

This list pertains to Lobbying, Program Fraud Civil Remedies Act (PFCRA), and Environment Tobacco Smoke. The form is located here; https://www.samhsa.gov/sites/default/files/listofcertifications.pdf

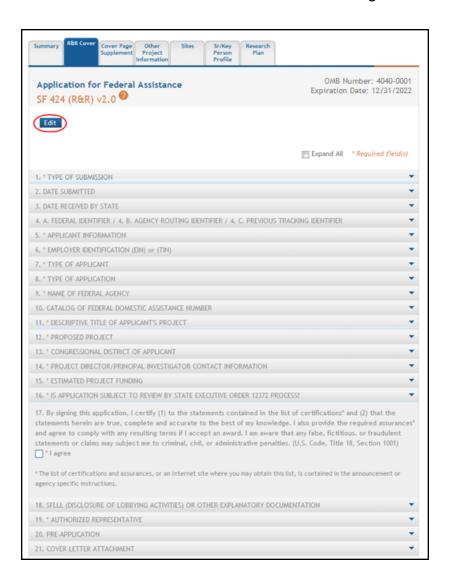
4.4 SF 424 R&R Cover

For assistance with the information required on this form, please refer to the appropriate application guide on the How to Apply page.

NOTE: The forms in these topics reflect FORMS-F, which must be used for applications with due dates on or after May 25, 2020 (see the most recent <u>NIH FORMS-F notice NOT-OD-20-026</u>, <u>NIH FORMS-F notice NOT-OD-20-047</u>, and <u>annotated form set</u> for Forms-F.) For due dates on or before May 24, 2020, use FORMS-E.

For guidance on completing the form in the ASSIST system, refer to the steps below:

1. Select the Edit button to enable the form for editing.



2. Complete the required fields for each section. Required fields are marked with asterisks (*).

Some information, including the organization details in the **Applicant Information** section and the fields within the **Project Director/Principal Investigator Contact Information** section, is carried over from the application initiation. These fields are disabled for editing and are read-only.

The **Descriptive Title of Applicant's Project** is also carried over from the **Application Project Title** provided on the *Initiate Application* page; however, this field may be edited if necessary.

Tip: For components in multi-project applications, you can use the **Populate from Overall component's R&R cover** button to auto-populate the fields in **Section 5** with information entered on the Overall component R&R Cover form.

3. To save the entered information, select the **Save and Keep Lock** button to keep the form open for further editing -or- select the **Save and Release Lock** button to close the form after saving.

NOTE: Selecting the **Cancel and Release Lock** button - followed by the **Continue** button on the confirmation - returns the form to read-only and does not save any of the entered information onto the form.

4.5 PHS 398 Cover Page Supplement

For assistance with the information required on this form, please refer to the appropriate application guide on the <u>How to Apply</u> page.

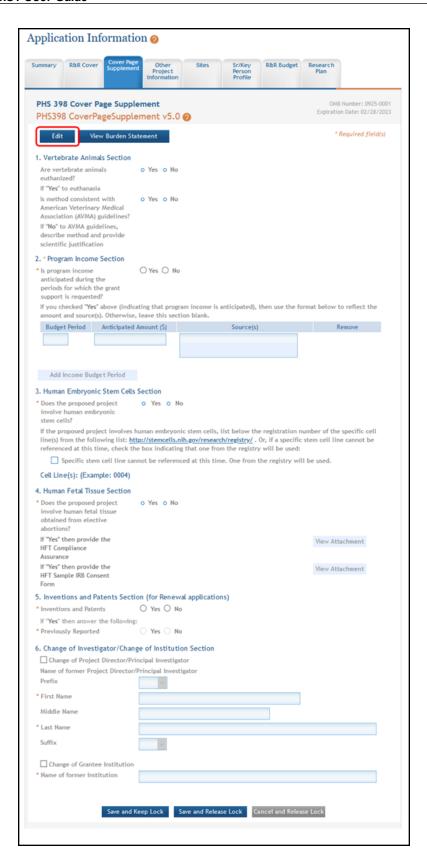
NOTE: The forms in these topics reflect FORMS-F, which must be used for applications with due dates on or after May 25, 2020 (see the most recent <u>NIH FORMS-F notice NOT-OD-20-026</u>, <u>NIH FORMS-F notice NOT-OD-20-047</u>, and <u>annotated form set</u> for Forms-F.) For due dates on or before May 24, 2020, use FORMS-E.

4.5.1 New in Forms F

- A new Human Fetal Tissue section has been added to the PHS 398 Cover Page Supplement form.
- You must answer the question, "Does the proposed project involve human fetal tissue obtained from elective abortions?"
- If yes, provide two attachments:
 - The HFT Compliance Assurance and the HFT Sample IRB Consent forms.
 These changes allow NIH to accurately identify applications proposing the use of human fetal tissue and help applicants provide the required information.

4.5.1.1 For guidance on completing the form in the ASSIST system, refer to the steps below:

- 1. Select the **Edit** button to enable the form for editing.
- 2. Complete the required fields for each section. Required fields are marked with asterisks (*).



Some information, including the **Project Director/Principal Investigator** section and the contact name within the **Applicant Organization Contact** section, is carried over from the application initiation. These fields are disabled for editing and are read-only.

3. To save the entered information, select the **Save and Keep Lock** button to keep the form open for further editing -or- select the **Save and Release Lock** button to close the form after saving.

NOTE: Selecting the **Cancel and Release Lock** button - followed by the **Continue** button on the confirmation - returns the form to read-only and does not save any of the entered information onto the form.

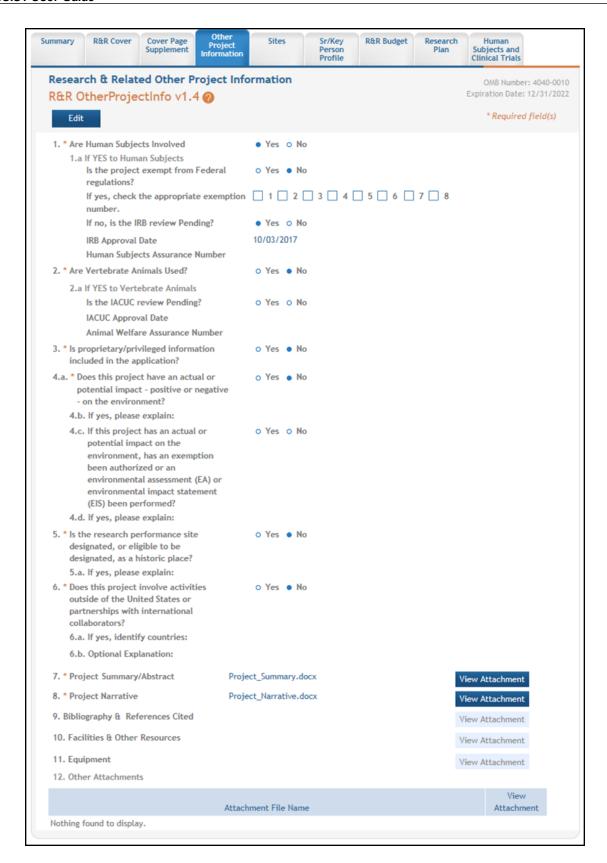
4.6 Research & Related Other Project Information

For assistance with the information required on this form, please refer to the appropriate application guide on the How to Apply page.

NOTE: The forms in these topics reflect FORMS-F, which must be used for applications with due dates on or after May 25, 2020 (see the most recent <u>NIH FORMS-F notice NOT-OD-20-026</u>, <u>NIH FORMS-F notice NOT-OD-20-047</u>, and <u>annotated form set</u> for Forms-F.) For due dates on or before May 24, 2020, use FORMS-E.

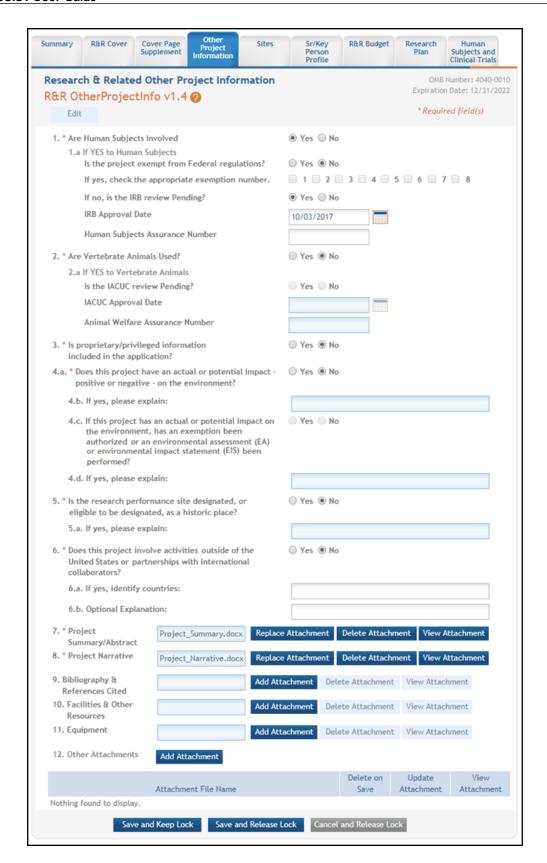
For guidance on completing the form in the ASSIST system, refer to the steps below:

1. Select the Edit button to enable the form for editing.



- 2. Complete the required fields for each section. Required fields are marked with asterisks (*).
- 3. To save the entered information, select the **Save and Keep Lock** button to keep the form open for further editing -or- select the **Save and Release Lock** button to close the form after saving.

NOTE: Selecting the **Cancel and Release Lock** button - followed by the **Continue** button on the confirmation - returns the form to read-only and does not save any of the entered information onto the form.



4.7 Project/Performance Sites

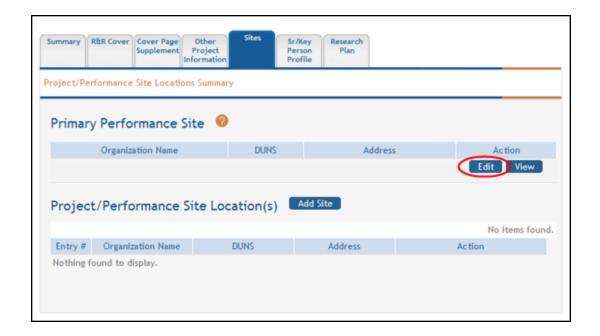
For assistance with the information required on this form, please refer to the appropriate application guide on the <u>How to Apply</u> page.

NOTE: The forms in these topics reflect FORMS-F, which must be used for applications with due dates on or after May 25, 2020 (see the most recent <u>NIH FORMS-F notice NOT-OD-20-026</u>, <u>NIH FORMS-F notice NOT-OD-20-047</u>, and <u>annotated form set</u> for Forms-F.) For due dates on or before May 24, 2020, use FORMS-E.

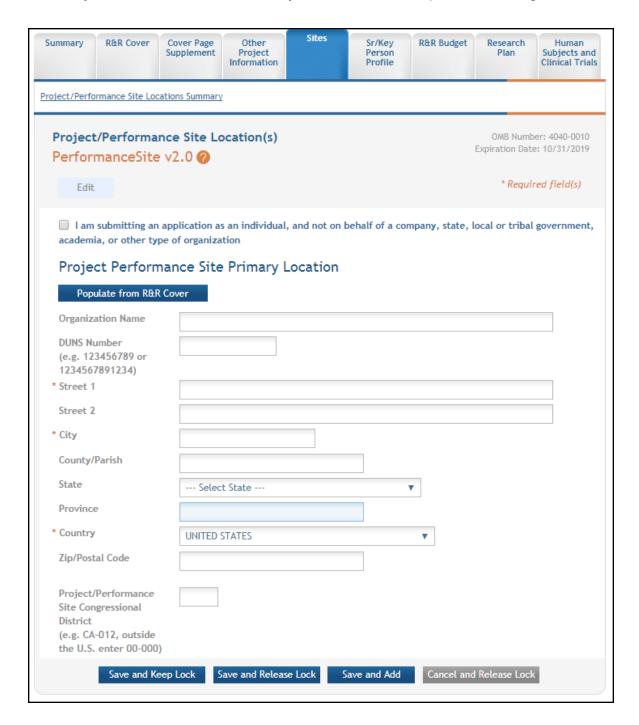
For guidance on completing the form in the ASSIST system, refer to the steps below.

4.7.1 Primary Performance Site

1. Select the Edit button in the Primary Performance Site section of the page.



The Project Performance Site Primary Location section opens for editing.



- 2. *Optional*: Select the **Populate from this component's R&R Cover** button to populate the fields with the Applicant Information entry from the application's R&R Cover.
- 3. Complete the required fields and any other appropriate information. Required fields are marked with asterisks (*).

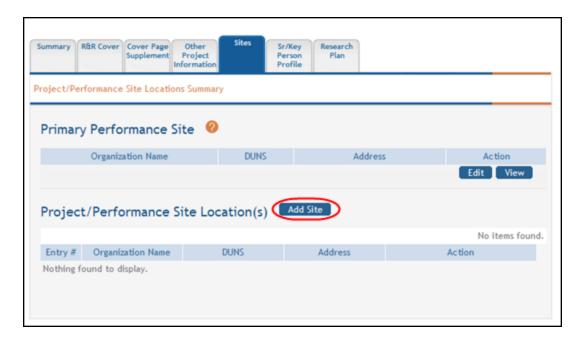
- 4. Select one of the save options at the bottom of the form to save the data:
 - a. To save the information and keep the form open for further editing, select the **Save and Keep** button.
 - b. To save the information and close the form, select the **Save and Release** Lock button.
 - c. To save the data on the current page of the form and to display a new page for entry, select the **Save and Add** button.

NOTE: Selecting the **Cancel and Release Lock** button - followed by the **Continue** button on the confirmation - returns the form to read-only and does not save any of the entered information onto the form.

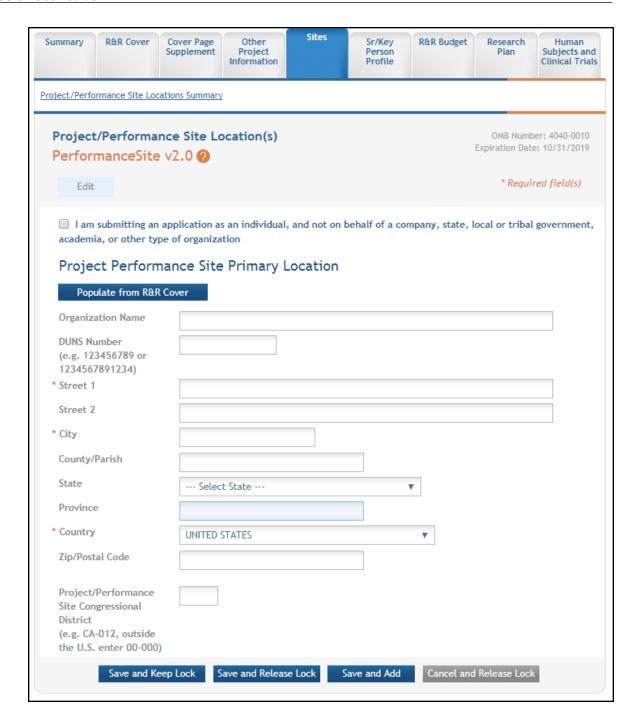
The **Edit** and **View** buttons can be used to edit or view the added Primary Performance Site information.

4.7.2 Project/Performance Site Location(s)

1. Select the Add Site button in the Project/Performance Site Location(s) section to add additional sites.



The Project Performance Site Location section opens for editing.

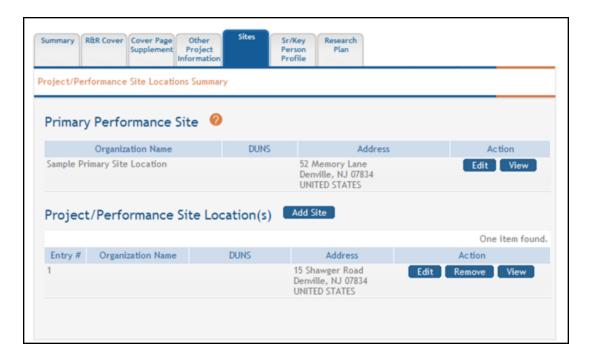


- 2. *Optional*: Select the **Populate from this component's R&R Cover** button to populate the fields with the Application Information entry from the component's R&R Cover.
- 3. Enter the required fields and any other appropriate information.

- 4. Select one of the save options at the bottom of the form to save the data:
 - a. To save the information and keep the form open for further editing, select the **Save and Keep** button.
 - b. To save the information and close the form, select the **Save and Release** Lock button.
 - c. To save the data on the current page of the form and to display a new page for entry, select the **Save and Add** button.

NOTE: Selecting the **Cancel and Release Lock** button - followed by the **Continue** button on the confirmation - returns the form to read-only and does not save any of the entered information onto the form.

The **Edit**, **Remove**, and **View** buttons can be used to edit, remove, or view a Project/Performance Site Location.



4.8 Senior/Key Person Profile

For assistance with the information required on this form, please refer to the appropriate application guide on the <u>How to Apply</u> page.

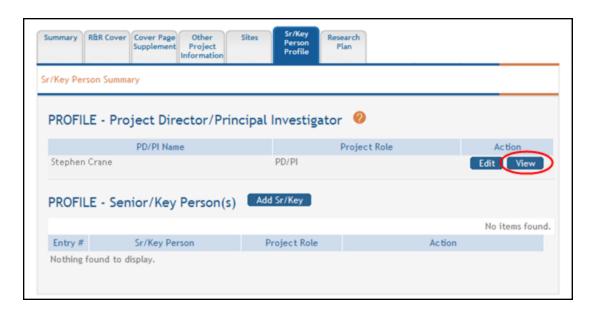
NOTE: The forms in these topics reflect FORMS-F, which must be used for applications with due dates on or after May 25, 2020 (see the most recent <u>NIH FORMS-F notice NOT-OD-20-047</u>, and <u>annotated form set</u> for Forms-F.) For due dates on or before May 24, 2020, use FORMS-E.

For guidance on completing the form in the ASSIST system, refer to the steps below.

4.8.1 Profile - Project Director/Principal Investigator (Project Lead)

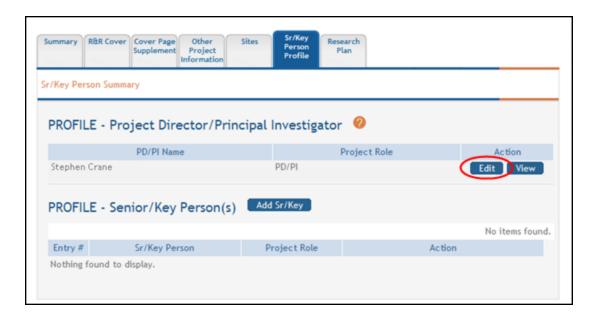
The **Project Director/Principal Investigator** (**Project Lead** for components of a multiproject application) information is carried over from the details entered during the application initiation. Depending on the privileges assigned to you, this information can be edited and/or viewed.

To view the information, select the View button in the Action column for the PD/PI entry in the PROFILE-Project Director/Principal Investigator section of the page.

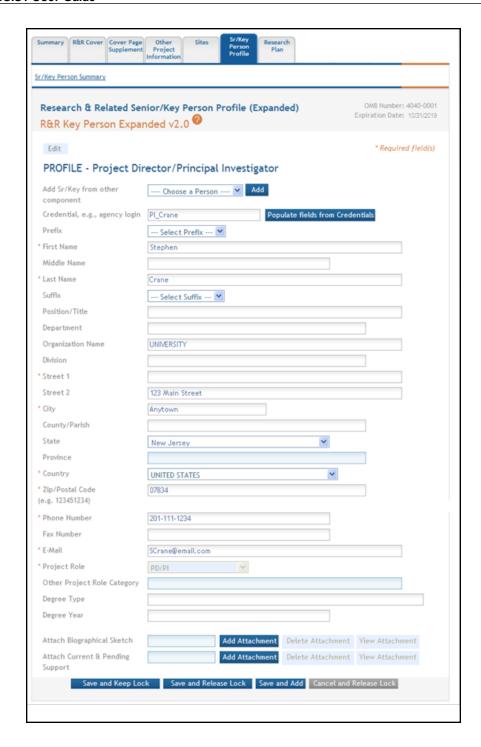


To edit the information, perform the following steps:

1. Select the Edit button in the Action column for the PD/PI or (Project Lead) entry.



The Research & Related Senior/Key Person Profile (Expanded) section displays for the PD/PI (or Project Lead).



- 2. Update the appropriate fields.
- 3. Select one of the save options at the bottom of the form to save the data:
 - a. To save the information and keep the form open for further editing, select the **Save and Keep Lock** button.

- b. To save the information and close the form, select the **Save and Release Lock** button.
- c. To save the data on the current page of the form and to display a new page for entry, select the **Save and Add** button.

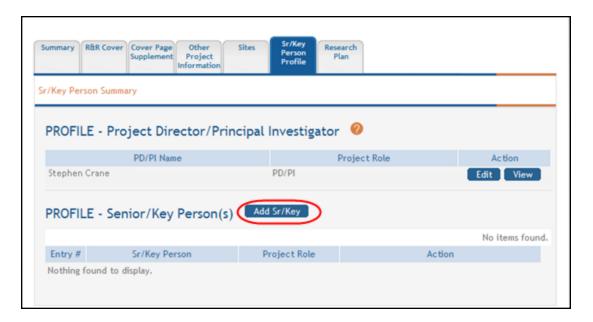
NOTE: Selecting the **Cancel and Release Lock** button - followed by the **Continue** button on the confirmation - returns the form to read-only and does not save any of the entered information onto the form.

4.8.2 Profile - Senior/Key Person(s)

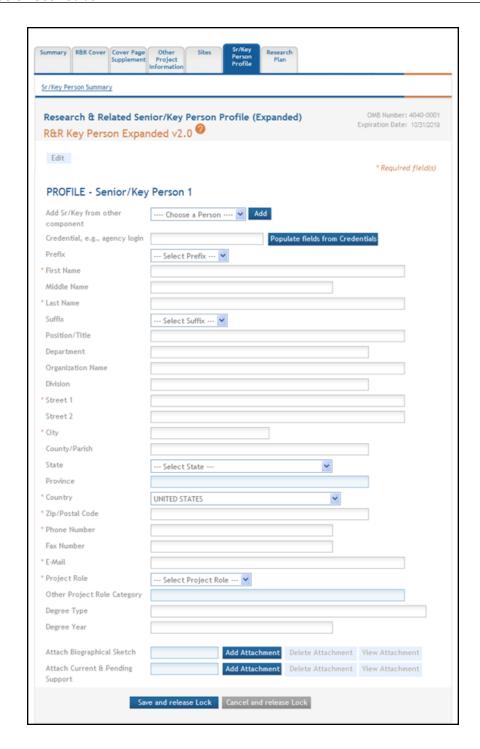
Depending on the privileges assigned to you, actions are available for viewing, adding, editing, and/or removing senior/key persons on a project.

4.8.2.1 Adding Senior/Key Person

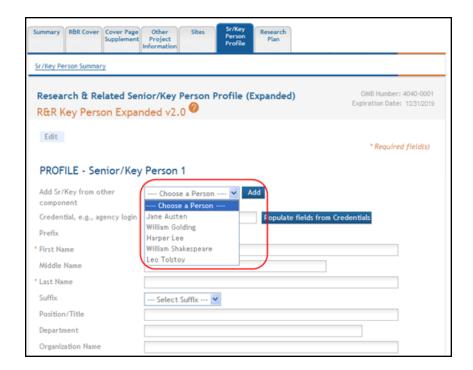
1. Select the Add Sr/Key button from the PROFILE - Senior/Key Person(s) section of the page.



The Research & Related Senior/Key Person Profile (Expanded) section displays for the new Senior/Key Person.



- 2. Enter the person information using one of the following methods:
 - a. Select a name from the Add Sr/Key from other component drop-down list to choose a person from another component and select the Add button.



-OR-

b. Enter the eRA Commons ID of a person into the Credential field and select the Populate fields from Credentials button to populate the information based on the eRA Commons ID.

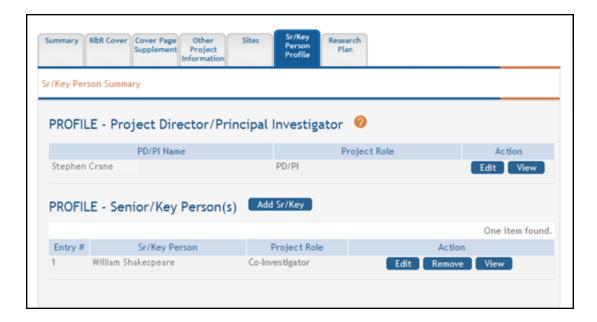


-OR-

- c. Manually enter the first name, last name, address, and phone number information for the person.
- 3. Select a role for the person from the **Project Role** drop-down list.
- 4. Complete any of the relevant optional fields.
- 5. Select one of the save options at the bottom of the form to save the data:
 - a. To save the information and keep the form open for further editing, select the **Save and Keep Lock** button.
 - b. To save the information and close the form, select the **Save and Release Lock** button.
 - c. To save the data on the current page of the form and to display a new page for entry, select the **Save and Add** button.

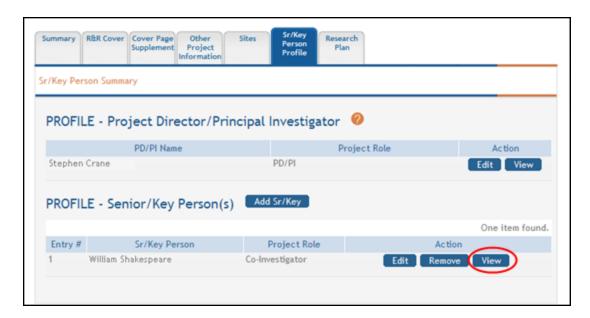
NOTE: Selecting the **Cancel and Release Lock** button - followed by the **Continue** button on the confirmation - returns the form to read-only and does not save any of the entered information onto the form.

The entered person displays on the Sr/Key Person Summary.



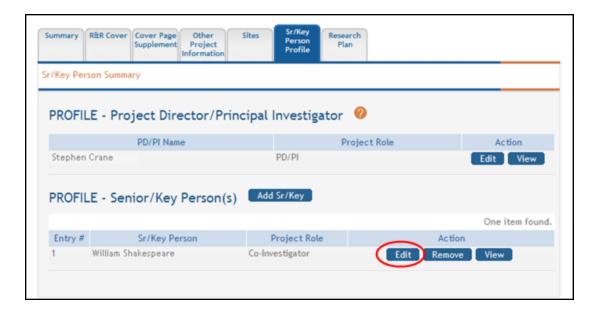
4.8.2.2 Viewing & Editing Senior/Key Person(s)

Select the View button to view the details of the person entry.



To edit the person entry, perform the following steps:

1. Select the **Edit** button for the person entry.



- 2. Enter the appropriate fields.
- 3. Select one of the save options at the bottom of the form to save the data:
 - a. To save the information and keep the form open for further editing, select the **Save and Keep Lock** button.
 - b. To save the information and close the form, select the **Save and Release Lock** button.

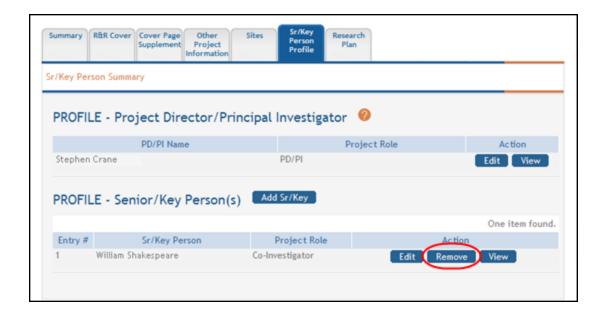
c. To save the data on the current page of the form and to display a new page for entry, select the **Save and Add** button.

NOTE: Selecting the **Cancel and Release Lock** button - followed by the **Continue** button on the confirmation - returns the form to read-only and does not save any of the entered information onto the form.

4.8.2.3 Removing Senior/Key Person(s)

To remove a senior/key person:

1. Select the **Remove** button for the person entry.



A pop-up window displays confirming the deletion.

2. Select the **Continue** button to confirm the removal of the senior/key person entry (selecting **Go Back** returns the *Sr/Key Person Summary* without removing the entry).

The *Sr/Key Person Summary* updates with the selected person removed from the **PROFILE - Sr/Key Person(s)** list.

4.9 Research & Related Budget

For assistance with the information required on this form, please refer to the appropriate application guide on the How to Apply page.

NOTE: The forms in these topics reflect FORMS-F, which must be used for applications with due dates on or after May 25, 2020 (see the most recent <u>NIH FORMS-F notice NOT-OD-20-026</u>, <u>NIH FORMS-F notice NOT-OD-20-047</u>, and <u>annotated form set</u> for Forms-F.) For due dates on or before May 24, 2020, use FORMS-E.

ASSIST users who have been granted budget authority (View or Edit) may add, edit, and/or view budget information using the R&R Budget tab.

NOTE: If a user does not have the View or Edit budget authority, the R&R Budget tab does not display among the tabs for other component forms.

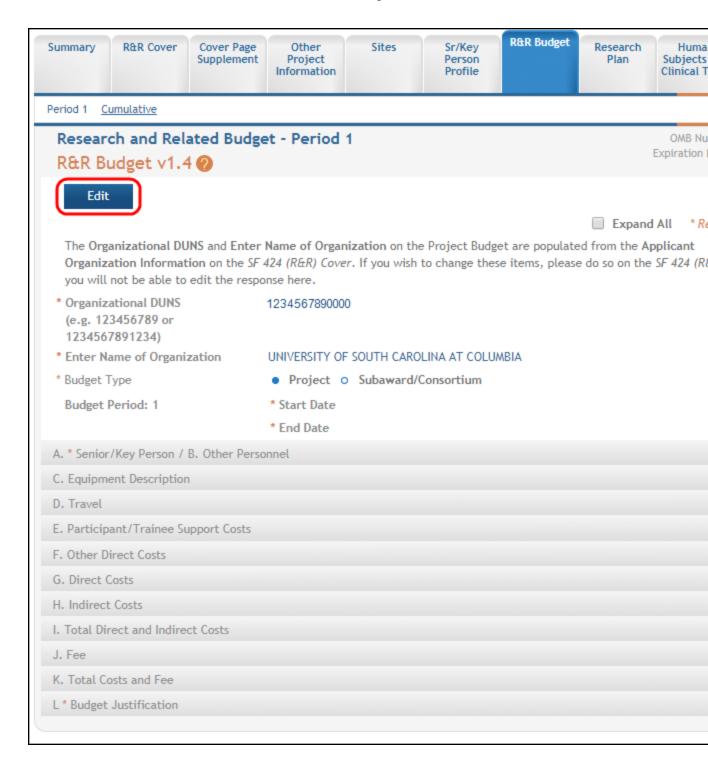
For guidance on completing the form in the ASSIST system, refer to the steps below.

IMPORTANT: Depending on the opportunity, you may be able to add up to five or ten budget periods. Refer to your FOA.

4.9.1 Adding Budget Period 1

To add budget information for Period 1:

1. Select the Edit button to enable the form for editing.

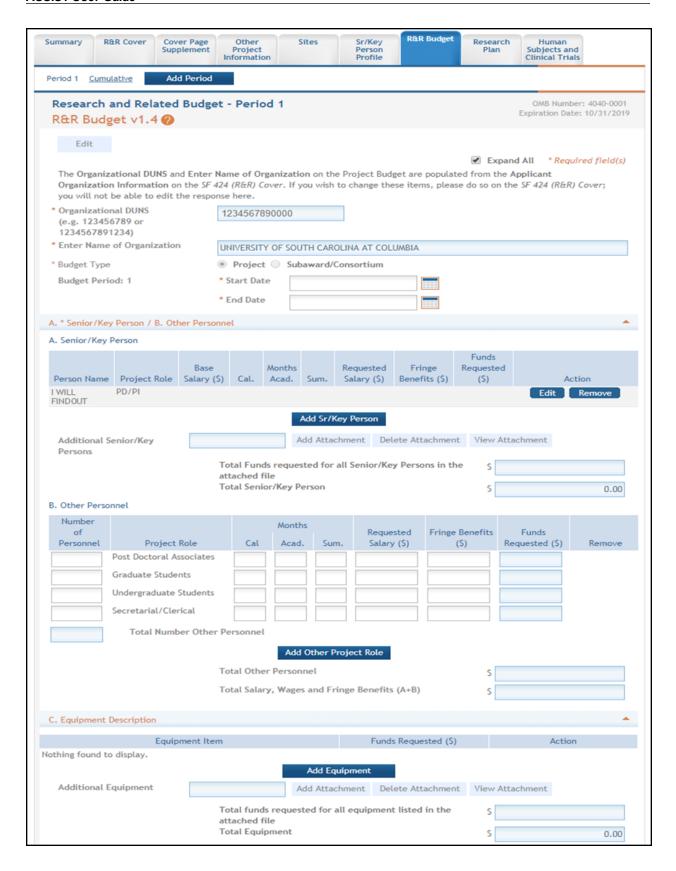


2. Complete the budget information as appropriate. Required fields are marked with an asterisk (*).

3. To save the entered information, select the **Save and Keep Lock** button to keep the form open for further editing -or- select the **Save and Release Lock** button to close the form after saving.

NOTE: Selecting the **Cancel and Release Lock** button - followed by the **Continue** button on the confirmation - returns the form to read-only and does not save any of the entered information onto the form.

First half of the Research and Related Budget form:



Second half of the Research and Related Budget form:

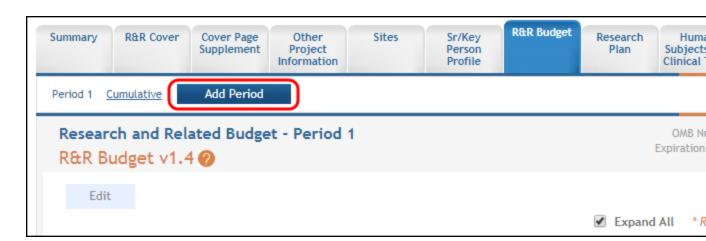
D. Travel		
	Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions) Foreign Travel Costs Total Travel Costs	Funds Requested (S) S S
E. Participant/Trainee Support Cos	ts	_
	1. Tuition/Fees/Health Insurance 2. Stipends 3. Travel 4. Subsistence 5. Other Number of Participants/Trainees Total Participant/Trainee Support Costs	Funds Requested (\$) S S S S S
G. Direct Costs	1. Materials and Supplies 2. Publication Costs 3. Consultant Services 4. ADP/Computer Services 5. Subawards/Consortium/ Contractual Costs 6. Equipment or Facility Rental/User Fees 7. Alterations and Renovations 8.	Funds Requested (\$) \$
	Total Direct Costs (A thru F)	\$
Indirect Cost Type Nothing found to display.	Indirect Cost Rate (%) Add Indirect Cost Total Indirect Costs	ed (\$) Action
Cognizant Federal Agency (Agency Name, POC Name and POC Phone Number)		
I. Total Direct and Indirect Costs		_
	Total Direct and Indirect Institutional Costs (G + H)	S
J. Fee		•
	Funds Requested	s
K. Total Costs and Fee	Funds Requested	5
L * Budget Justification		_
* (Only attach one file)	Add Attachment Delete Attachment	
Save and Keep Lock Save	and Release Lock Cancel and Release Lock Remove Budge	et Period

4.9.2 Adding Another Budget Period

When adding additional budget periods, the information from the previous budget period is carried over and auto-populated into the fields. This information can be edited as necessary.

To add an additional budget period:

1. Select the Add Period button.



Research and Related Budget - Period X displays (where X is the specific budget period being added).

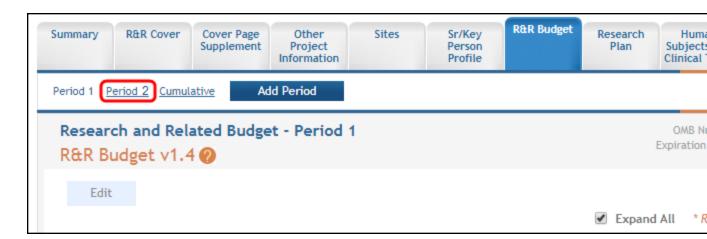
- 2. Enter and/or edit the budget information for the specific period.
- 3. To save the entered information, select the **Save and Keep Lock** button to keep the form open for further editing -or- select the **Save and Release Lock** button to close the form after saving.

NOTE: Selecting the **Cancel and Release Lock** button - followed by the **Continue** button on the confirmation - returns the form to read-only and does not save any of the entered information onto the form.

4.9.3 Editing and Viewing an Entered Budget

Depending on the authority granted, you may view and/or edit existing budget information for any of the entered budget periods. To edit budget information:

1. Select the link for the period to view or edit (e.g., **Period 2** link).



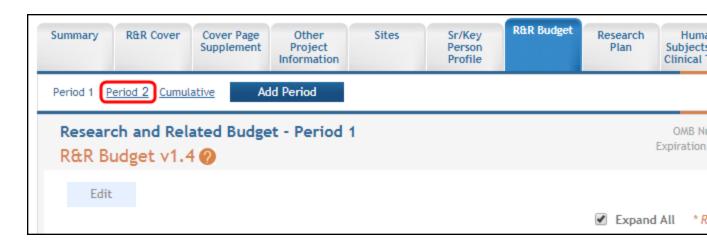
- 2. Select the **Edit** button to edit the information.
- 3. Update the budget information as necessary.
- 4. To save the entered information, select the **Save and Keep Lock** button to keep the form open for further editing -or- select the **Save and Release Lock** button to close the form after saving.

NOTE: Selecting the **Cancel and Release Lock** button - followed by the **Continue** button on the confirmation - returns the form to read-only and does not save any of the entered information onto the form.

4.9.4 Deleting a Budget Period

With Edit Budget authority, an ASSIST user may remove entire budget periods from a component. To delete an entire budget period:

1. Select the link for the period being removed (e.g., **Period 2** link)



- 2. Select the **Edit** button to enable editing.
- 3. Click the Remove Budget Period button.



A confirmation window displays.

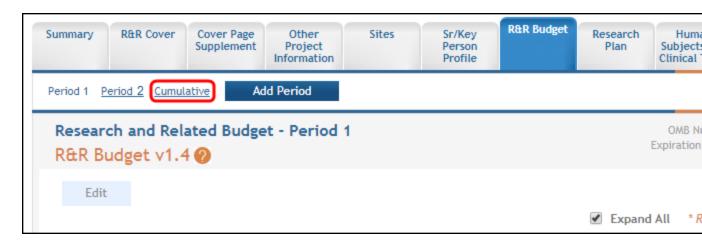
4. Select the **Continue** button to confirm the deletion request.

NOTE: Selecting the **Go Back** button returns the budget period form without deleting it.

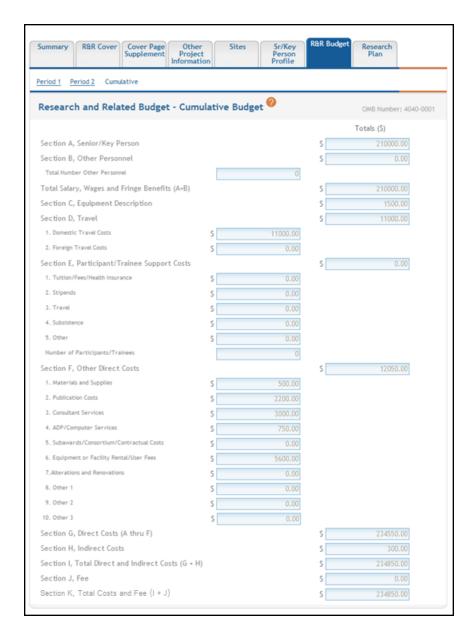
The *R&R Budget* tab information displays, with the link for the removed budget gone. This information is now deleted. The deleted budget period is also removed from the Cumulative Budget information.

4.9.5 Viewing Cumulative Budget

To view the cumulative budget of multiple budget periods, select the Cumulative link.



The Research and Related Budget - Cumulative Budget displays as read-only.



4.10 R&R Subaward Budget

For assistance with the information required on this form, please refer to the appropriate application guide on the How to Apply page.

NOTE: The forms in these topics reflect FORMS-F, which must be used for applications with due dates on or after May 25, 2020 (see the most recent <u>NIH FORMS-F notice NOT-OD-20-026</u>, <u>NIH FORMS-F notice NOT-OD-20-047</u>, and <u>annotated form set</u> for Forms-F.) For due dates on or before May 24, 2020, use FORMS-E.

The R&R Subaward Budget form must be added to the application or to the component of a multi-project application as an optional form. Refer to the help topic titled <u>Add</u>
<u>Optional Forms</u> for more information.

IMPORTANT: The option exists to download, complete offline, and upload subaward budget forms into ASSIST. Refer to the section of this topic titled <u>Completing</u>
<u>Subaward Form Offline</u> for detailed steps.

For guidance on completing the form in the ASSIST system, refer to the steps below.

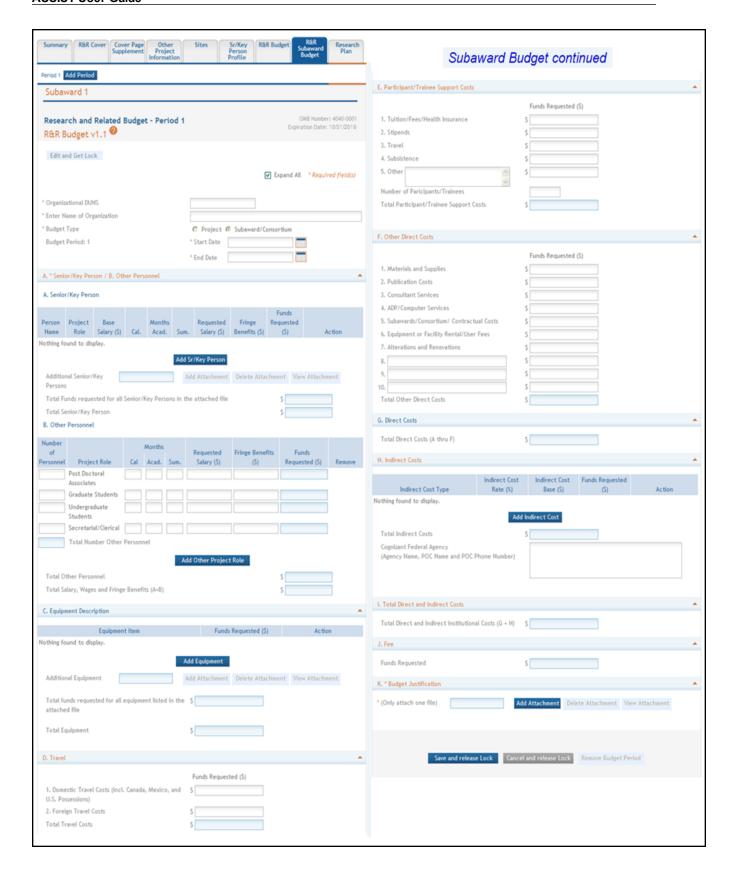
4.10.1 Adding a Subaward

To add a subaward:

1. Select the Add New Subaward button.



The Research and Related Budget - Period 1 for Subaward <X> page displays.

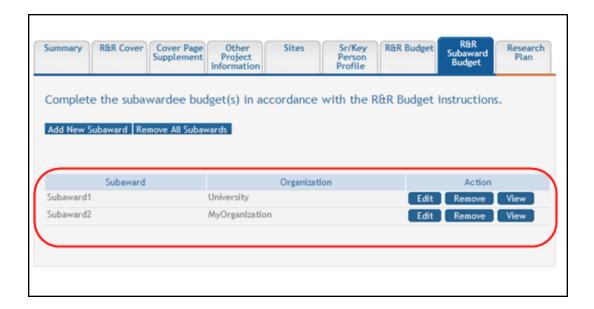


- 2. Complete the budget information as appropriate. Required fields are marked with an asterisk (*).
- 3. To save the entered information, select the **Save and Keep Lock** button to keep the form open for further editing -or- select the **Save and Release Lock** button to close the form after saving.

NOTE: Selecting the **Cancel and Release Lock** button - followed by the **Continue** button on the confirmation - returns the form to read-only and does not save any of the entered information onto the form.

4. Repeat steps, selecting **Add New Subaward** for each additional subaward.

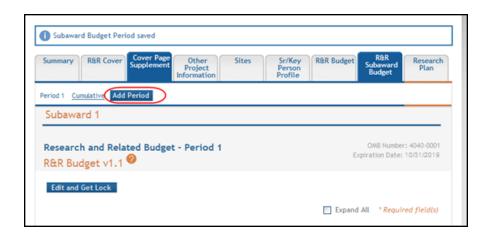
The added subawards display in a table from which they can be accessed using the Edit, Remove, and View buttons.



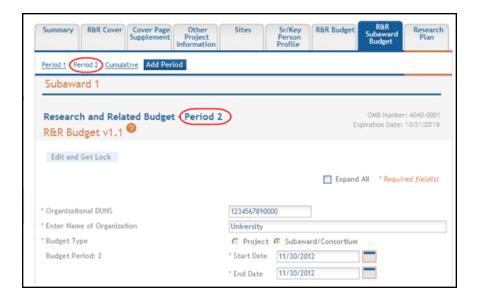
4.10.1.1 Adding Another Budget Period to a Subaward

To add an additional budget period to a subaward:

1. From within the subaward form, select the Add Period button.



The Research and Related Budget - Period X displays (where X is the specific budget period being added).



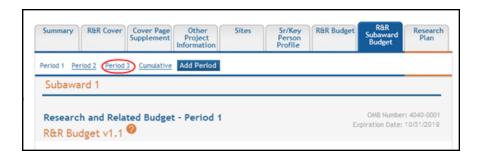
- 2. Enter the budget information for the specific period.
- 3. To save the entered information, select the **Save and Keep Lock** button to keep the form open for further editing -or- select the **Save and Release Lock** button to close the form after saving.

NOTE: Selecting the **Cancel and Release Lock** button - followed by the **Continue** button on the confirmation - returns the form to read-only and does not save any of the entered information onto the form.

4.10.1.2 Editing and Viewing an Entered Budget for a Subaward

To view and/or edit the subaward budget period:

1. From within the subaward form, select the link for the period to view or edit (e.g., **Period 3** link).

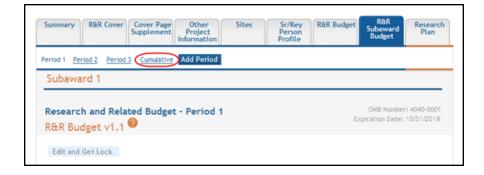


- 2. View the information.
- 3. Select the **Edit** button to edit the information.
- 4. Update the budget information as necessary.
- 5. To save the entered information, select the **Save and Keep Lock** button to keep the form open for further editing -or- select the **Save and Release Lock** button to close the form after saving.

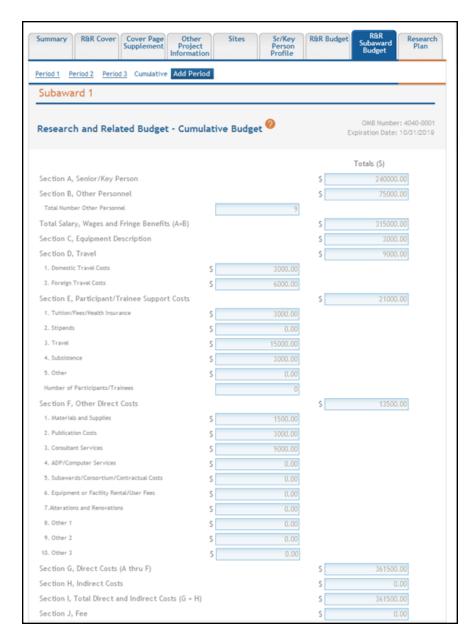
NOTE: Selecting the **Cancel and Release Lock** button - followed by the **Continue** button on the confirmation - returns the form to read-only and does not save any of the entered information onto the form.

4.10.1.3 Viewing Cumulative Budget for a Subaward

To view the cumulative budget for a particular subaward, access the form and select the Cumulative link.



The Research and Related Budget - Cumulative Budget displays as read-only.



4.10.2 Removing Subawards

Subawards can be removed individually or all at once. The steps below provide detail for each method.

4.10.2.1 Removing an Individual Subaward

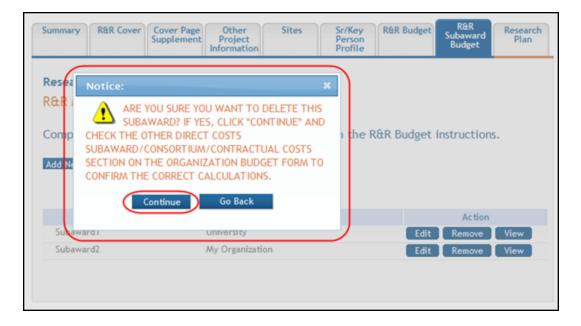
To remove an individual subaward:

1. Select the Remove button from the Action column for the particular subaward being removed.



A confirmation window displays.

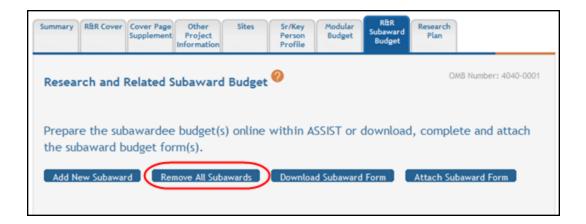
2. Select the **Continue** button to complete the removal.



4.10.2.2 Removing All Subawards

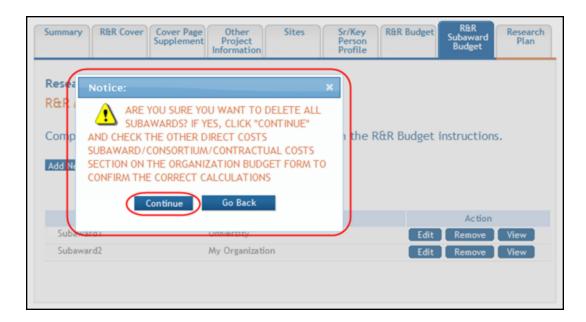
To remove all subawards at one time:

 Select the Remove all Subawards button from the R&R Subaward Budget tab main page.



A confirmation window displays.

2. Select the **Continue** button to move forward and delete the subawards. (Selecting **Go Back** cancels the action.)

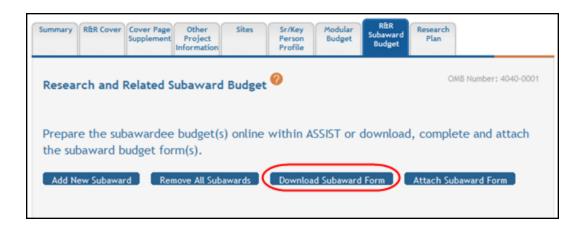


4.10.3 Completing Subaward Form Offline

Applicants have the ability to complete the R&R Subaward Budget forms offline. To do so, the forms must be downloaded, completed and saved to a local device, and then uploaded to ASSIST.

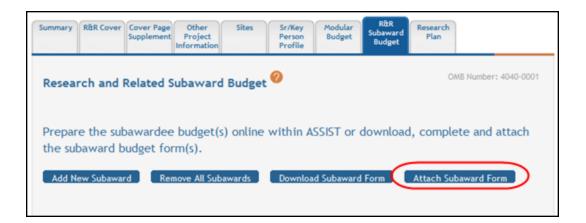
To complete subaward budget forms offline:

1. Select the Download Subaward Form button.



The Research & Related Budget form opens in another browser window. Complete the form and save it locally. Instructions for filling out the form are located in the application guide: https://grants.nih.gov/grants/how-to-apply-application-guide.html.

- 2. Access the R&R Subaward Budget screen in ASSIST.
- 3. Select the Attach Subaward Form button from the screen.

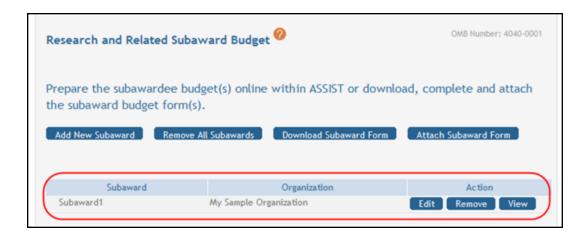


4. When prompted, use the Browse button to search for and select the budget form from your local device and the Submit button to add it to ASSIST.



ASSIST validates the PDF file to ensure that it meets the format requirements of the FOA. Files of an invalid format cannot be uploaded.

5. The Research and Related Subaward Budget screen updates to include the added subaward in the table at the bottom of the screen. Use the **Edit**, **Remove**, and **View** buttons to manage the subaward as necessary.



4.11 Career Development Award Supplemental

For assistance with the information required on this form, please refer to the appropriate application guide on the <u>How to Apply</u> page.

NOTE: The forms in these topics reflect FORMS-F, which must be used for applications with due dates on or after May 25, 2020 (see the most recent <u>NIH FORMS-F notice NOT-OD-20-026</u>, <u>NIH FORMS-F notice NOT-OD-20-047</u>, and <u>annotated form set</u> for Forms-F.) For due dates on or before May 24, 2020, use FORMS-E.

4.11.0.1 New in Forms-F

 A new 'Description of Candidate's Contribution to Program Goals' attachment was added to the Career Development Supplemental form.

4.11.1 For guidance on completing the form in the ASSIST system, refer to the steps below:

1. Select the **Edit** button to enable the form for editing.



2. Attach the applicable sections using the **Add Attachment** buttons.

NOTE: If needed, use the **Delete Attachment** buttons to remove attachments or the **View Attachment** buttons to view them.

3. To save the entered information, select the **Save and Keep Lock** button to keep the form open for further editing -or- select the **Save and Release Lock** button to close the form after saving.

NOTE: Selecting the **Cancel and Release Lock** button - followed by the **Continue** button on the confirmation - returns the form to read-only and does not save any of the entered information onto the form.

4.12 PHS 398 Research Training Program Plan

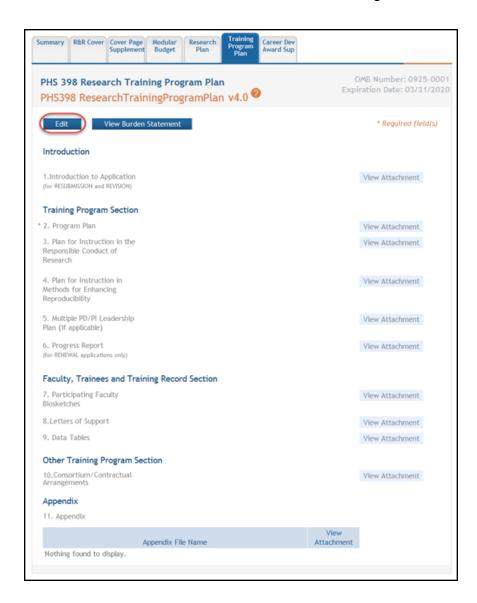
For assistance with the information required on this form, please refer to the appropriate application guide on the How to Apply page.

NOTE: The forms in these topics reflect FORMS-F, which must be used for applications with due dates on or after May 25, 2020 (see the most recent NIH FORMS-F notice NOT-

OD-20-026, NIH FORMS-F notice NOT-OD-20-047, and annotated form set for Forms-F.) For due dates on or before May 24, 2020, use FORMS-E.

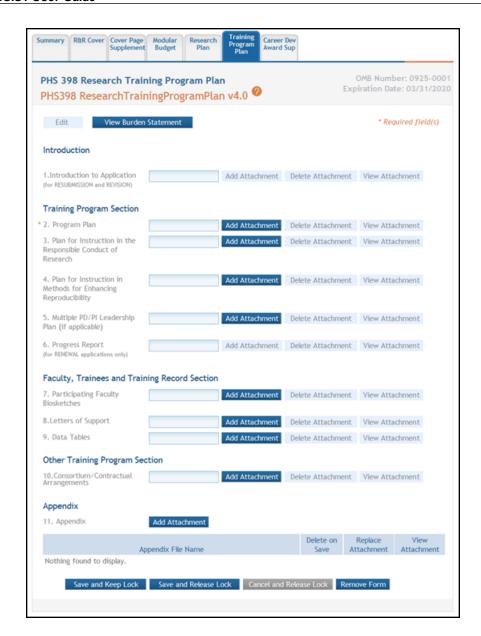
For guidance on completing the form in the ASSIST system, refer to the steps below:

1. Select the **Edit** button to enable the form for editing.



2. Attach the applicable sections of the research plan using the **Add Attachment** buttons.

NOTE: If needed, use the **Delete Attachment** buttons to remove attachments or the **View Attachment** buttons to view them.



3. To save the entered information, select the **Save and Keep Lock** button to keep the form open for further editing -or- select the **Save and Release Lock** button to close the form after saving.

NOTE: Selecting the **Cancel and Release Lock** button - followed by the **Continue** button on the confirmation - returns the form to read-only and does not save any of the entered information onto the form.

4.13 PHS 398 Training Budget

For assistance with the information required on this form, please refer to the appropriate

application guide on the How to Apply page.

NOTE: The forms in these topics reflect FORMS-F, which must be used for applications with due dates on or after May 25, 2020 (see the most recent <u>NIH FORMS-F notice NOT-OD-20-026</u>, <u>NIH FORMS-F notice NOT-OD-20-047</u>, and <u>annotated form set</u> for Forms-F.) For due dates on or before May 24, 2020, use FORMS-E.

ASSIST users who have been granted budget authority (View or Edit) may add, edit, and/or view budget information using the Training Budget tab.

NOTE: If a user does not have the View or Edit budget authority, the Training Budget tab does not display among the tabs for other component forms.

For guidance on completing the form in the ASSIST system, refer to the steps below.

4.13.1 Adding Budget Period 1

To add budget information for Period 1:

1. Select the Edit button to enable the form for editing.

I

- 2. Complete the budget information as appropriate. Required fields are marked with an asterisk (*).
- 3. To save the entered information, select the **Save and Keep Lock** button to keep the form open for further editing -or- select the **Save and Release Lock** button to close the form after saving.

NOTE: Selecting the **Cancel and Release Lock** button - followed by the **Continue** button on the confirmation - returns the form to read-only and does not save any of the entered information onto the form.

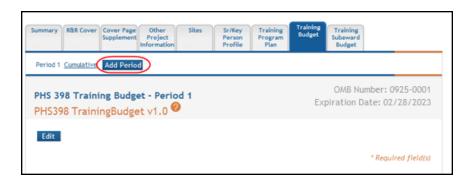
l

4.13.2 Adding Another Budget Period

When adding additional budget periods, the information from the previous budget period is carried over and auto-populated into the fields. This information can be edited as necessary.

To add an additional budget period:

Select the Add Period button.



PHS 398 Training Budget - Period X displays (where X is the specific budget period being added).

- 2. Enter and/or edit the budget information for the specific period.
- 3. To save the entered information, select the **Save and Keep Lock** button to keep the form open for further editing -or- select the **Save and Release Lock** button to close the form after saving.

NOTE: Selecting the **Cancel and Release Lock** button - followed by the **Continue** button on the confirmation - returns the form to read-only and does not save any of the entered information onto the form.

4.13.3 Editing and Viewing an Entered Budget

Depending on the authority granted, you may view and/or edit existing budget information for any of the entered budget periods. To edit budget information:

1. Select the link for the period to view or edit (e.g., **Period 3** link).



- 2. Select the **Edit** button to edit the information.
- 3. Update the budget information as necessary.
- 4. To save the entered information, select the **Save and Keep Lock** button to keep the form open for further editing -or- select the **Save and Release Lock** button to close the form after saving.

NOTE: Selecting the **Cancel and Release Lock** button - followed by the **Continue** button on the confirmation - returns the form to read-only and does not save any of the entered information onto the form.

4.13.4 Deleting a Budget Period

With Edit Budget authority, an ASSIST user may remove entire budget periods from a component. To delete an entire budget period:

1. Select the link for the period being removed (e.g., **Period 3** link)



- 2. Select the **Edit** button to enable editing.
- 3. Click the Remove Budget Period button.



A confirmation window displays.

4. Select the **Continue** button to confirm the deletion request.

NOTE: Selecting the **Go Back** button returns the budget period form without deleting it.

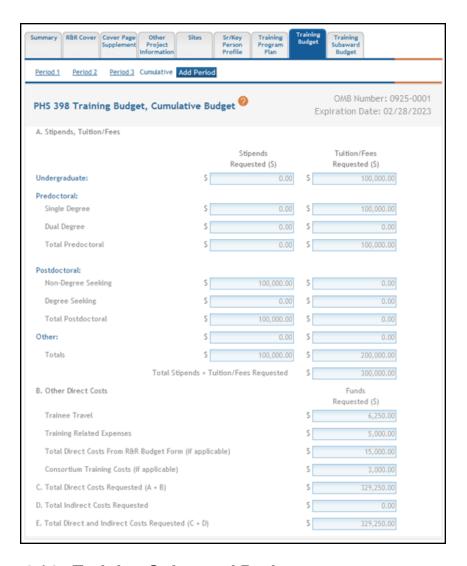
The *PHS* 398 *Training Budget* tab information displays, with the link for the removed budget gone. This information is now deleted. The deleted budget period is also removed from the Cumulative Budget information.

4.13.5 Viewing Cumulative Budget

To view the cumulative budget of multiple budget periods, select the Cumulative link.



The PHS 398 Training Budget - Cumulative Budget displays as read-only.



4.14 Training Subaward Budget

For assistance with the information required on this form, please refer to the appropriate application guide on the <u>How to Apply</u> page.

NOTE: The forms in these topics reflect FORMS-F, which must be used for applications with due dates on or after May 25, 2020 (see the most recent <u>NIH FORMS-F notice NOT-OD-20-026</u>, <u>NIH FORMS-F notice NOT-OD-20-047</u>, and <u>annotated form set</u> for Forms-F.) For due dates on or before May 24, 2020, use FORMS-E.

The Training Subaward Budget form must be added to the component as an optional form. Refer to the help topic titled *Add Optional Forms*.

For guidance on completing the form in the ASSIST system, refer to the steps below.

4.14.1 Adding a Training Subaward

To add a subaward:

Select the Add New Subaward button.

l

The PHS 398 Training Budget- Period 1 for Subaward <X> page displays.

I

- 2. Complete the budget information as appropriate. Required fields are marked with an asterisk (*).
- 3. To save the entered information, select the **Save and Keep Lock** button to keep the form open for further editing -or- select the **Save and Release Lock** button to close the form after saving.

NOTE: Selecting the **Cancel and Release Lock** button - followed by the **Continue** button on the confirmation - returns the form to read-only and does not save any of the entered information onto the form.

4. Repeat steps, selecting **Add New Subaward** for each additional subaward.

The added subawards display in a table from which they can be accessed using

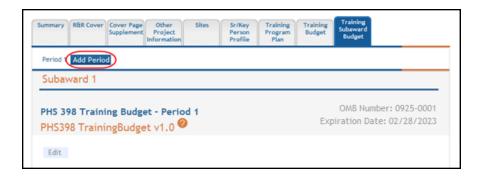
the Edit, Remove, and View buttons.



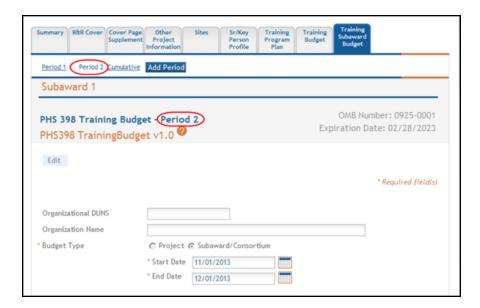
4.14.1.1 Adding Another Budget Period to a Training Subaward

To add an additional budget period to a subaward:

1. From within the subaward form, select the Add Period button.



The PHS 398 Training Budget - Period X displays (where X is the specific budget period being added).



- 2. Enter the budget information for the specific period.
- 3. To save the entered information, select the **Save and Keep Lock** button to keep the form open for further editing -or- select the **Save and Release Lock** button to close the form after saving.

NOTE: Selecting the **Cancel and Release Lock** button - followed by the **Continue** button on the confirmation - returns the form to read-only and does not save any of the entered information onto the form.

4.14.1.2 Editing and Viewing an Entered Training Budget for a Subaward

To view and/or edit the subaward training budget period:

1. From within the subaward form, select the link for the period to view or edit (e.g., **Period 3** link).



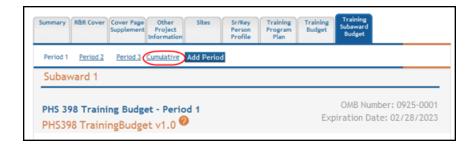
- 2. View the information.
- 3. Select the **Edit** button to edit the information.
- 4. Update the budget information as necessary.

5. To save the entered information, select the **Save and Keep Lock** button to keep the form open for further editing -or- select the **Save and Release Lock** button to close the form after saving.

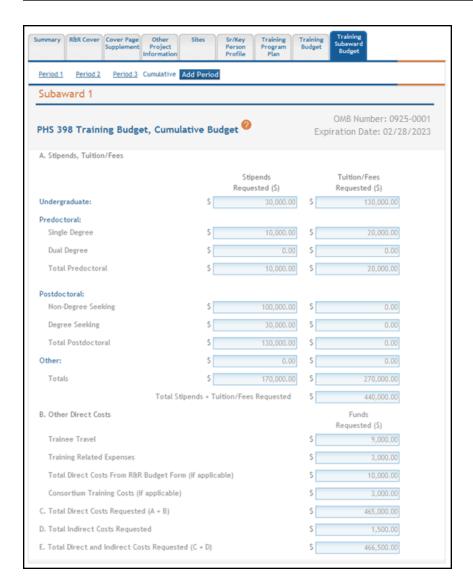
NOTE: Selecting the **Cancel and Release Lock** button - followed by the **Continue** button on the confirmation - returns the form to read-only and does not save any of the entered information onto the form.

4.14.1.3 Viewing Cumulative Training Budget for a Subaward

To view the cumulative training budget for a particular subaward, access the form and select the Cumulative link.



The PHS 398 Training Budget - Cumulative Budget displays as read-only.



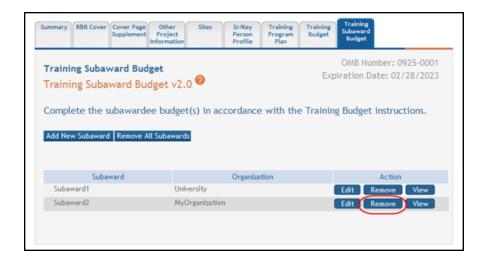
4.14.2 Removing Training Budget Subawards

Training budget subawards can be removed individually or all at once. The steps below provide detail for each method.

4.14.2.1 Removing an Individual Training Budget Subaward

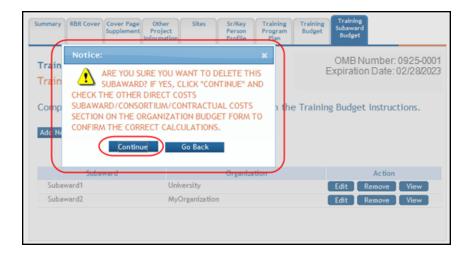
To remove an individual subaward:

1. Select the Remove button from the Action column for the particular subaward being removed.



A confirmation window displays.

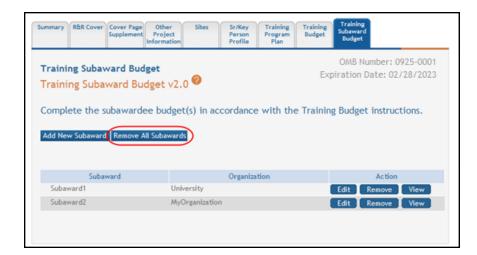
2. Select the **Continue** button to complete the removal.



4.14.2.2 Removing All Training Budget Subawards

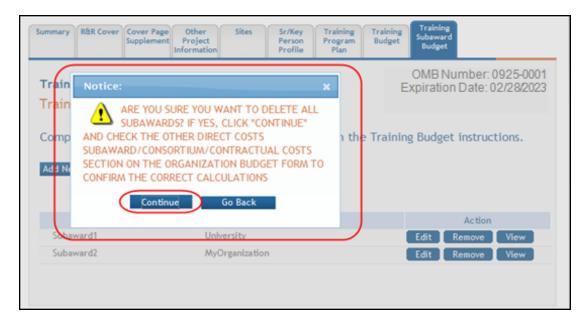
To remove all subawards at one time:

1. Select the Remove all Subawards button from the Training Subaward Budget tab main page.



A confirmation window displays.

2. Select the **Continue** button to move forward and delete the subawards. (Selecting **Go Back** cancels the action.)



4.15 Planned Enrollment Report for Other Components

For assistance with the information required on this form, please refer to the appropriate application guide on the How to Apply page.

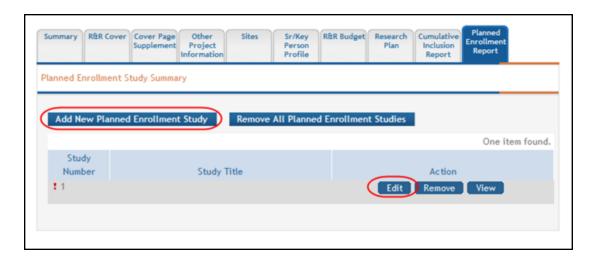
The Planned Enrollment Report form must be added to the application or to the component of a multi-project application as an optional form. Refer to the help topic titled *Add Optional Forms*.

For guidance on completing the form in the ASSIST system, refer to the steps below.

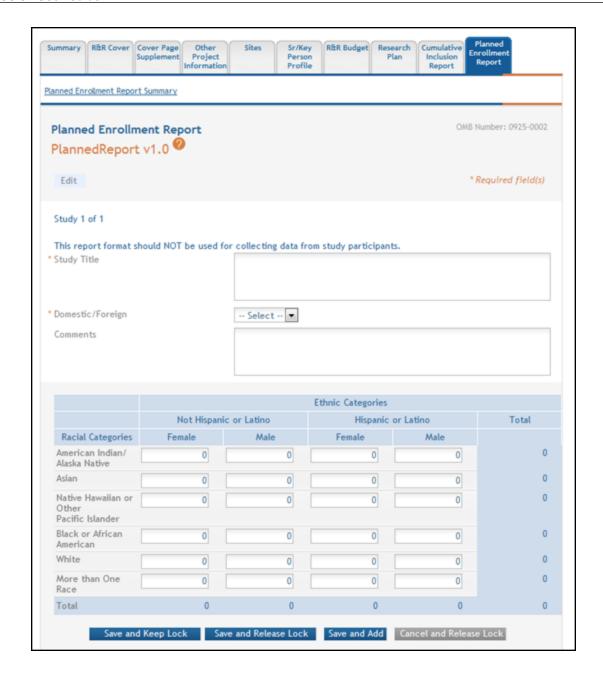
4.15.1 Adding a Planned Enrollment Study

To add a planned enrollment study:

1. Select the Add New Planned Enrollment Study button. If this is the first study you are adding, you can also select the **Edit** button for Study 1 located in the **Action** column of the displayed table.



The Planned Enrollment Report opens for editing.



- 2. Complete the required fields and any other appropriate information. Required fields are marked with an asterisk (*).
- 3. Select one of the save options at the bottom of the form to save the data:
 - a. To save the information and keep the form open for further editing, select the **Save and Keep Lock** options.
 - b. To save the information and close the form, select the **Save and Release Lock** button.

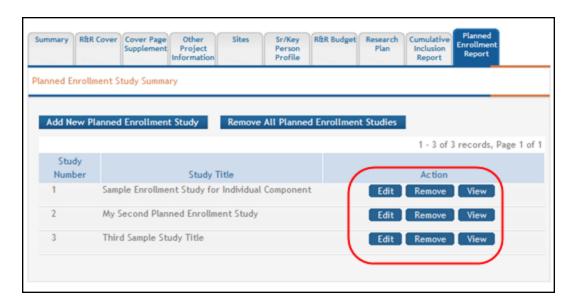
c. To save the data on the current page of the form and to display a new page for entry, select the **Save and Add** button.

NOTE: Selecting the **Cancel and Release Lock** button - followed by the **Continue** button on the confirmation - returns the form to read-only and does not save any of the entered information onto the form.

4. Select the Planned Enrollment Report Summary link to return to the table of enrollment studies.



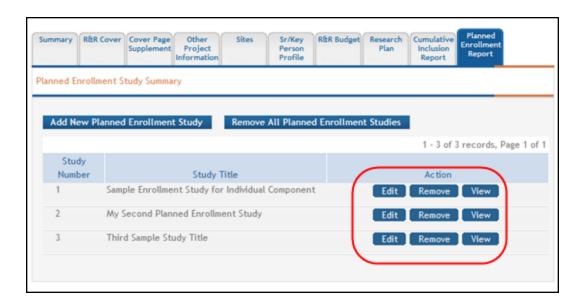
The added studies display in the table from which they can be accessed using the Edit, Remove, and View buttons.



4.15.2 Viewing and Editing the Enrollment Studies

To view and/or edit a planned enrollment study:

1. Select the appropriate button for the specific study to be viewed or edited:



To view the information:

- a. Select the View button to see the form in read-only.
- b. Note that once within the read-only form, you can select the **Edit** button at the top of the form to enter edit mode.

To edit the information:

- a. Select the **Edit** button for the study.
- b. Make your changes.
- c. Select one of the save options at the bottom of the form to save the data:
 - i. To save the information and keep the form open for further editing, select the **Save and Keep Lock** options.
 - ii. To save the information and close the form, select the **Save and Release Lock** button.
 - iii. To save the data on the current page of the form and to display a new page for entry, select the **Save and Add** button.

NOTE: Selecting the **Cancel and Release Lock** button - followed by the **Continue** button on the confirmation - returns the form to read-only and does not save any of the entered information onto the form.

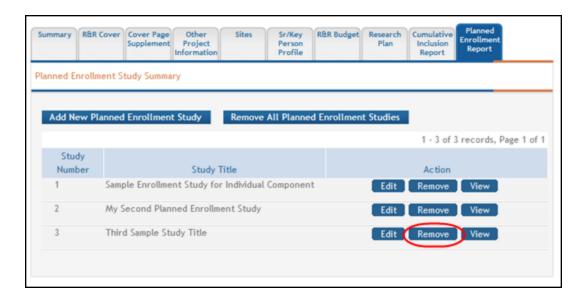
2. Select the Planned Enrollment Report Summary link to return to the table of enrollment studies.



4.15.3 Removing Individual Planned Enrollment Study

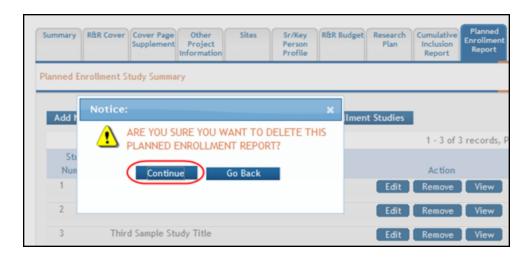
You can remove the studies individually using the buttons found in the **Action** column of the summary table. To remove an individual study:

1. Select the Remove button for the specific study.



A confirmation message pops up prompting you to continue or cancel this action.

2. Select the **Continue** button to continue removing the study.



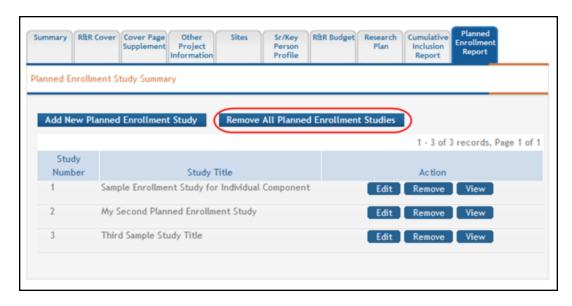
If you wish to cancel, select the Go Back button.

4.15.4 Removing All Planned Enrollment Studies

You can remove all studies at the same time rather than removing each individual study. Removing all studies also removes the entire form from the component.

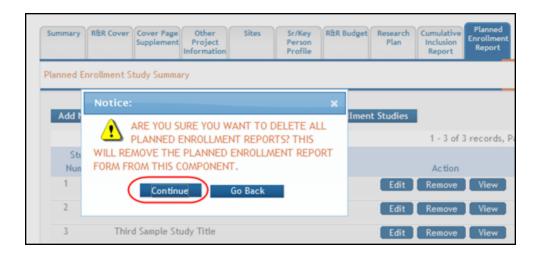
To remove all studies:

1. Select the Remove All Planned Enrollment Studies button at the top of the form.



A confirmation message pops up prompting you to continue or cancel the action.

2. Select the **Continue** button to remove all forms.



If you wish to cancel, select the **Go Back** button.

See Also

Add Optional Forms

4.16 Cumulative Inclusion Enrollment Report for Other Components

For assistance with the information required on this form, please refer to the appropriate application guide on the How to Apply page.

NOTE: The forms in these topics reflect FORMS-E, which must be used for applications with due dates on or after May 25, 2020 (see the most recent <u>NIH FORMS-E notice</u> <u>NOT-OD-17-062</u> and <u>annotated form set</u> for Forms E.) For due dates prior to January 25, 2018, use FORMS-D.

The Cumulative Inclusion Enrollment Report form must be added to the application or to the component of a multi-project application as an optional form. Refer to the help topic titled *Add Optional Forms*.

For guidance on completing the form in the ASSIST system, refer to the steps below.

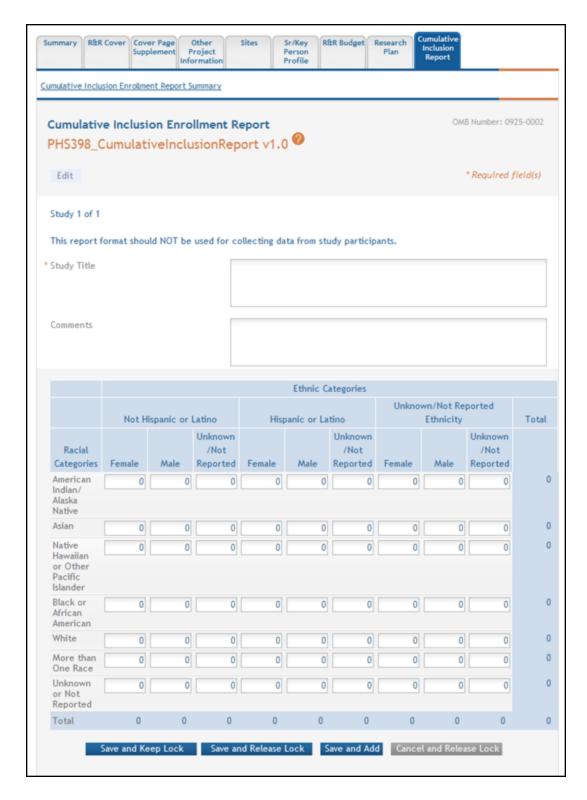
4.16.1 Adding a Cumulative Inclusion Enrollment Study

To add a cumulative inclusion enrollment study:

 Select the Add New Cumulative Inclusion Enrollment Study button. If this is the first study you are adding, you can also select the **Edit** button for Study 1 located in the **Action** column of the displayed table.



The PHS398 Cumulative Inclusion Report opens for editing.

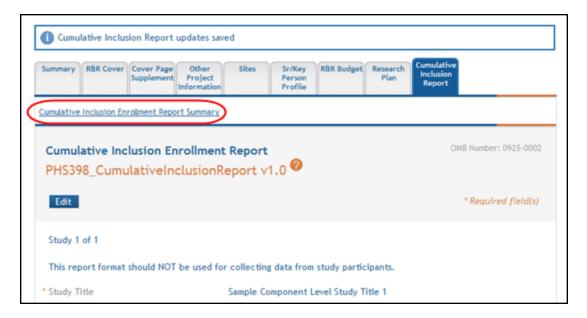


2. Complete the required fields and any other appropriate information. Required fields are marked with an asterisk (*).

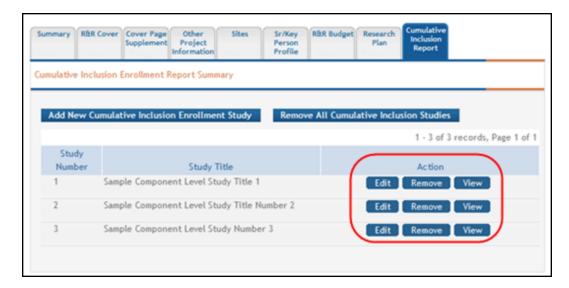
- 3. Select one of the save options at the bottom of the form to save the data:
 - a. To save the information and keep the form open for further editing, select the **Save and Keep Lock** options.
 - b. To save the information and close the form, select the **Save and Release Lock** button.
 - c. To save the data on the current page of the form and to display a new page for entry, select the **Save and Add** button.

NOTE: Selecting the **Cancel and Release Lock** button - followed by the **Continue** button on the confirmation - returns the form to read-only and does not save any of the entered information onto the form.

4. Select the Cumulative Inclusion Enrollment Report Summary link to return to the table of enrollment studies.



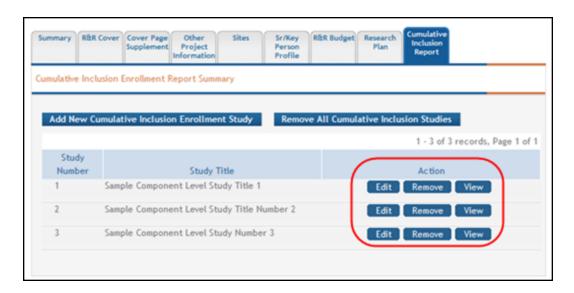
The added studies display in the table from which they can be accessed using the Edit, Remove, and View buttons.



4.16.2 Viewing and Editing the Enrollment Studies

To view and/or edit a cumulative inclusion enrollment study:

1. Select the appropriate button for the specific study to be viewed or edited:



To view the information:

- a. Select the **View** button to see the form in read-only.
- b. Note that once within the read-only form, you can select the **Edit** button at the top of the form to enter edit mode.

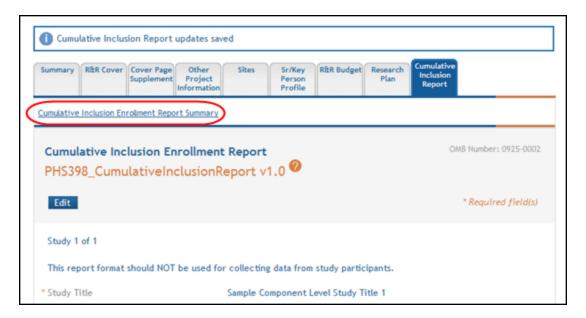
To edit the information:

a. Select the **Edit** button for the study.

- b. Make your changes.
- c. Select one of the save options at the bottom of the form to save the data:
 - i. To save the information and keep the form open for further editing, select the **Save and Keep Lock** options.
 - ii. To save the information and close the form, select the **Save and Release Lock** button.
 - iii. To save the data on the current page of the form and to display a new page for entry, select the **Save and Add** button.

NOTE: Selecting the **Cancel and Release Lock** button - followed by the **Continue** button on the confirmation - returns the form to read-only and does not save any of the entered information onto the form.

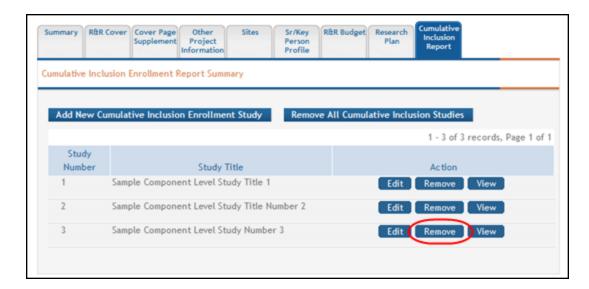
2. Select the Cumulative Inclusion Enrollment Report Summary link to return to the table of enrollment studies.



4.16.3 Removing Individual Cumulative Inclusion Enrollment Study

You can remove the studies individually using the buttons found in the **Action** column of the summary table. To remove an individual study:

1. Select the Remove button for the specific study.



A confirmation message pops up prompting you to continue or cancel this action.

2. Select the **Continue** button to continue removing the study.



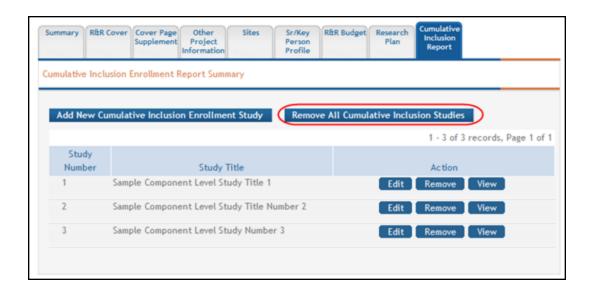
If you wish to cancel, select the **Go Back** button.

4.16.4 Removing All Cumulative Inclusion Enrollment Studies

You can remove all studies at the same time rather than removing each individual study. Removing all studies also removes the entire form from the component.

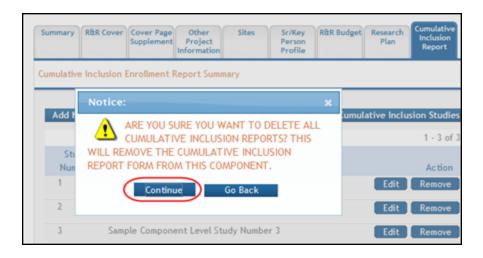
To remove all studies:

1. Select the Remove All Cumulative Inclusion Studies button at the top of the form.



A confirmation message pops up prompting you to continue or cancel the action.

2. Select the **Continue** button to remove all forms.



If you wish to cancel, select the **Go Back** button.

See Also

Add Optional Forms

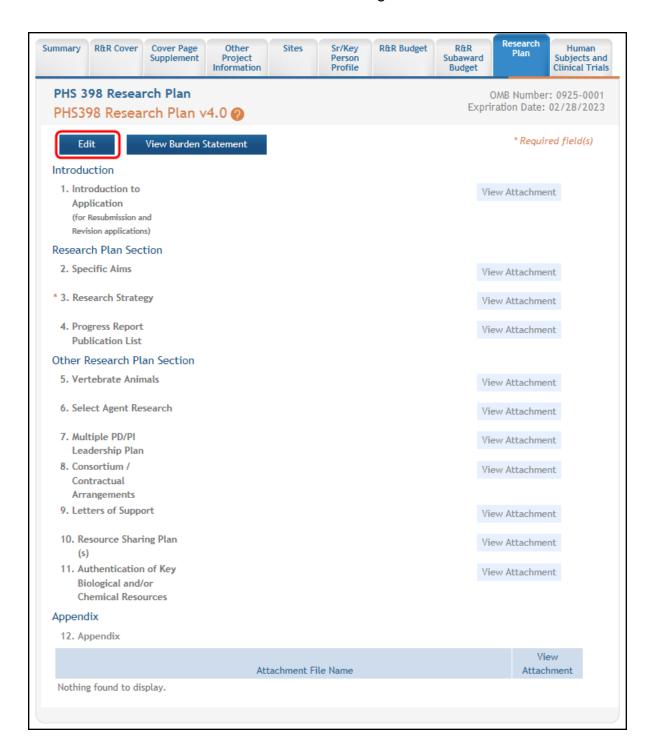
4.17 PHS 398 Research Plan

For assistance with the information required on this form, please refer to the appropriate application guide on the <u>How to Apply</u> page.

NOTE: The forms in these topics reflect FORMS-F, which must be used for applications with due dates on or after May 25, 2020 (see the most recent <u>NIH FORMS-F notice NOT-OD-20-047</u>, and <u>annotated form set</u> for Forms-F.) For due dates on or before May 24, 2020, use FORMS-E.

For guidance on completing the form in the ASSIST system, refer to the steps below.

1. Select the **Edit** button to enable the form for editing.

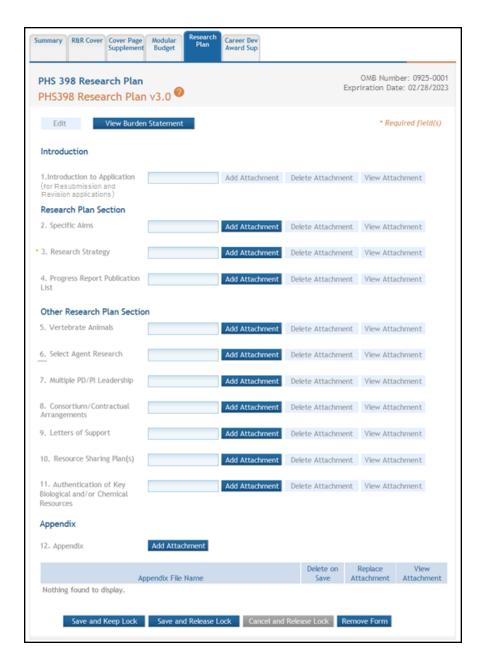


2. Add the appropriate **Research Plan Attachments**. Required fields are marked with an asterisk (*).

3. To save the entered information, select the **Save and Keep Lock** button to keep the form open for further editing -or- select the **Save and Release Lock** button to close the form after saving.

NOTE: Selecting the **Cancel and Release Lock** button - followed by the **Continue** button on the confirmation - returns the form to read-only and does not save any of the entered information onto the form.

Below is the form opened for editing.



4.18 PHS Inclusion Enrollment

Included in Study Record in Forms E

IMPORTANT: The PHS Inclusion Enrollment Report will be discontinued with the rollout of Forms E Applications with due dates beginning in January of 2018. The collection of this data for Forms E applications is moved to the new <u>PHS Human</u> Subjects and Clinical Trials Information Form.

For assistance with the information required on this form, please refer to the appropriate application guide on the How to Apply page.

The PHS Inclusion Enrollment Report form is used for all applications involving NIH-defined clinical research. This form is used to report both planned and cumulative (or actual) enrollment, and describes the sex/gender, race, and ethnicity of the study participants.

For guidance on completing the form in the ASSIST system, refer to the steps below.

4.18.1 Adding a PHS Inclusion Enrollment Report

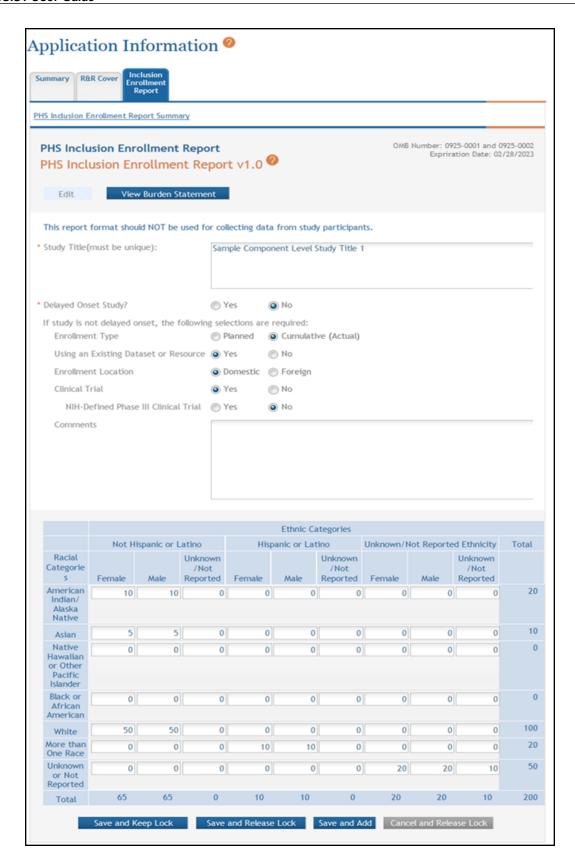
To add an Inclusion Enrollment Report:

 Select the Add New Inclusion Enrollment Study button. If this is the first report you are adding, you can also select the **Edit** button for Study 1 located in the **Action** column of the displayed table.

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The PHS Inclusion Enrollment Report.

The PHS Inclusion Enrollment Report Summary opens.



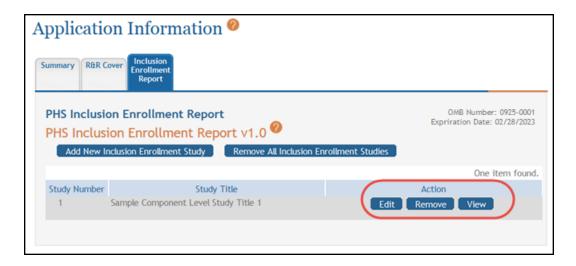
- 2. Complete the required fields and any other appropriate information. Required fields are marked with an asterisk (*).
- 3. Select one of the save options at the bottom of the form to save the data:
 - 1. To save the information and keep the form open for further editing, select the **Save and Keep Lock** options.
 - 2. To save the information and close the form, select the **Save and Release Lock** button.
 - 3. To save the data on the current page of the form and to display a new page for entry, select the **Save and Add** button.

NOTE: Selecting the **Cancel and Release Lock** button - followed by the **Continue** button on the confirmation - returns the form to read-only and does not save any of the entered information onto the form.

4.18.2 Viewing and Editing the Inclusion Enrollment Report

To view and/or edit a cumulative inclusion enrollment study:

1. Select the appropriate button for the specific study to be viewed or edited:



Editing the Inclusion Enrollment Report

To view the information:

1. Select the **View** button to see the form in read-only.

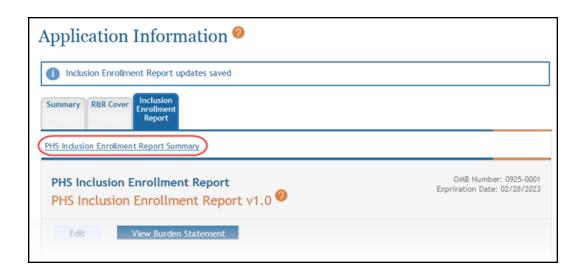
NOTE: Note that once within the read-only form, you can select the **Edit** button at the top of the form to enter edit mode.

To edit the information:

- 1. Select the **Edit** button for the study.
- 2. Make your changes.
- 3. Select one of the save options at the bottom of the form to save the data:
 - a. To save the information and keep the form open for further editing, select the **Save and Keep Lock** options.
 - b. To save the information and close the form, select the **Save and Release Lock** button.
 - c. To save the data on the current page of the form and to display a new page for entry, select the **Save and Add** button.

NOTE: Selecting the **Cancel and Release Lock** button - followed by the **Continue** button on the confirmation - returns the form to read-only and does not save any of the entered information onto the form.

4. Select the **PHS Inclusion Enrollment Report Summary link** to return to the table of enrollment studies.



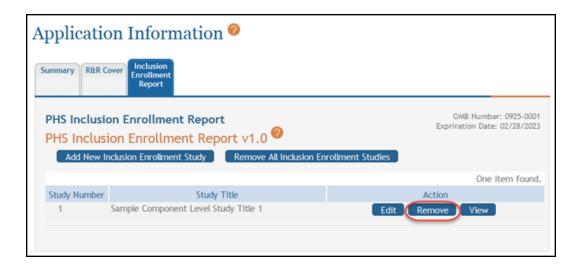
Inclusion Enrollment Report Displaying Summary Link

5. Click the PHS Inclusion Enrollment Report Summary link to return.

4.18.3 Removing Individual Cumulative Inclusion Enrollment Study

You can remove the studies individually using the buttons found in the **Action** column of the summary table. To remove an individual study:

1. Select the Remove button for the specific study.



A confirmation message pops up prompting you to continue or cancel this action.

2. Select the **Continue** button to continue removing the study.



Delete Confirmation screen

3. If you wish to cancel, select the **Go Back** button or click the **X**.

4.18.4 Removing All Cumulative Inclusion Enrollment Studies

You can remove all studies at the same time rather than removing each individual study. Removing all studies also removes the entire form from the component.

To remove all studies:

1. Select the Remove All Cumulative Inclusion Studies button at the top of the form.



A confirmation message pops up prompting you to continue or cancel the action.

2. Select the **Continue** button to remove all forms.



If you wish to cancel, select the **Go Back** button

Add Optional Forms

4.19 Additional Indirect Costs

For assistance with the information required on this form, please refer to the appropriate application guide on the How to Apply page.

NOTE: The forms in these topics reflect FORMS-F, which must be used for applications with due dates on or after May 25, 2020 (see the most recent <u>NIH FORMS-F notice NOT-OD-20-026</u>, <u>NIH FORMS-F notice NOT-OD-20-047</u>, and <u>annotated form set</u> for Forms-F.) For due dates on or before May 24, 2020, use FORMS-E.

ASSIST users who have been granted budget authority (View or Edit) may add, edit, and/or view budget information using the **Additional Indirect Costs** tab on a multiproject application (Overall Component).

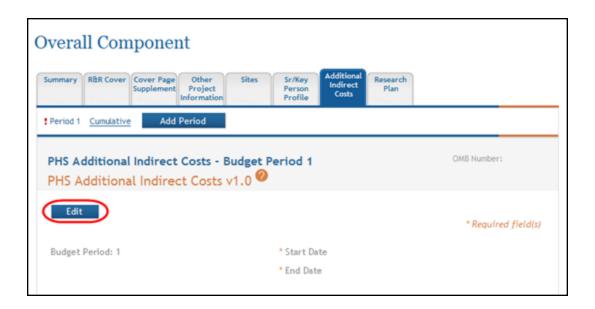
NOTE: If a user does not have the View or Edit budget authority, the **Additional Indirect Costs** tab does not display among the tabs for other forms.

For guidance on completing the form in the ASSIST system, refer to the steps below.

4.19.1 Adding Budget Period 1

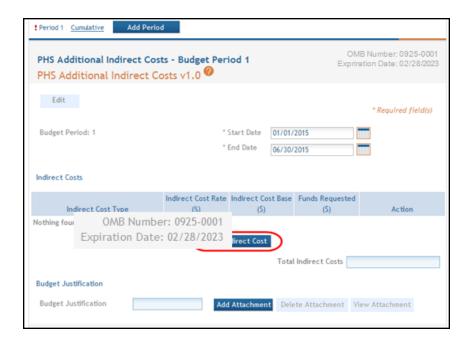
To add budget information for Period 1:

1. Select the Edit button to enable the form for editing.

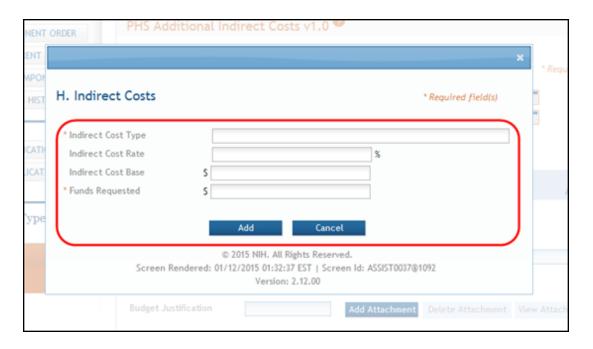


2. Complete the budget information as appropriate. Required fields are marked with an asterisk (*).

- 3. To access the *Indirect Costs* pop-up screen for entering cost information:
 - a. Select the Add Indirect Cost button.

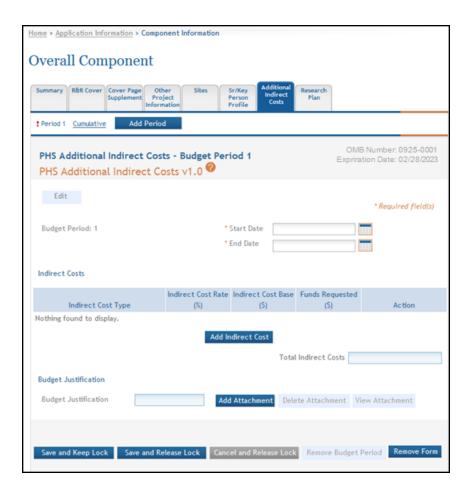


b. Enter the data fields on the Indirect Costs pop-up window. Required fields are marked with an asterisk (*). Select the **Add** button when finished.



- 4. Repeat the steps above to include all indirect costs types as necessary.
- 5. To save the entered information, select the **Save and Keep Lock** button to keep the form open for further editing -or- select the **Save and Release Lock** button to close the form after saving.

NOTE: Selecting the **Cancel and Release Lock** button - followed by the **Continue** button on the confirmation - returns the form to read-only and does not save any of the entered information onto the form.

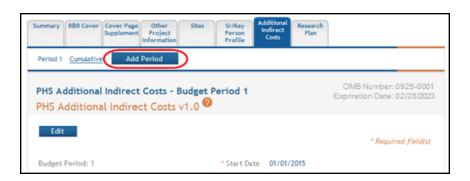


4.19.2 Adding Another Budget Period

When adding additional budget periods, the information from the previous budget period is carried over and auto-populated into the fields. This information can be edited as necessary.

To add an additional budget period:

1. Select the Add Period button.



PHS Additional Indirect Costs - Budget Period X displays (where X is the specific budget period being added).

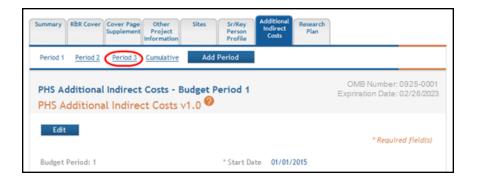
- 2. Enter and/or edit the budget information for the specific period.
- 3. To save the entered information, select the **Save and Keep Lock** button to keep the form open for further editing -or- select the **Save and Release Lock** button to close the form after saving.

NOTE: Selecting the **Cancel and Release Lock** button - followed by the **Continue** button on the confirmation - returns the form to read-only and does not save any of the entered information onto the form.

4.19.3 Editing and Viewing an Entered Budget

Depending on the authority granted, you may view and/or edit existing budget information for any of the entered budget periods. To edit budget information:

1. Select the link for the period to view or edit (e.g., **Period 3** link).



- 2. Select the **Edit** button to edit the information.
- 3. Update the budget information as necessary.

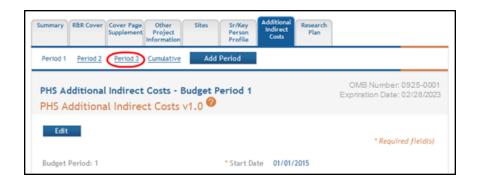
4. To save the entered information, select the **Save and Keep Lock** button to keep the form open for further editing -or- select the **Save and Release Lock** button to close the form after saving.

NOTE: Selecting the **Cancel and Release Lock** button - followed by the **Continue** button on the confirmation - returns the form to read-only and does not save any of the entered information onto the form.

4.19.4 Deleting a Budget Period

With Edit Budget authority, an ASSIST user may remove entire budget periods from a component. To delete an entire budget period:

1. Select the link for the period being removed (e.g., **Period 3** link)



- 2. Select the **Edit** button to enable editing.
- 3. Click the Remove Budget Period button.



A confirmation window displays.

4. Select the **Continue** button to confirm the deletion request.

NOTE: Selecting the **Go Back** button returns the budget period form without deleting it.

The *PHS Additional Indirect Costs* tab information displays, with the link for the removed budget gone. This information is now deleted. The deleted budget period is also removed from the Cumulative Budget information.

4.19.5 Removing the Entire Additional Indirect Costs Form

The *PHS Additional Indirect Costs* form is an optional form which can be removed if it is not needed for the application. With Edit Budget authority, an ASSIST user may remove the form from the application.

To remove the form:

1. Click the Remove Form button while within the PHS Additional Indirect Costs form.



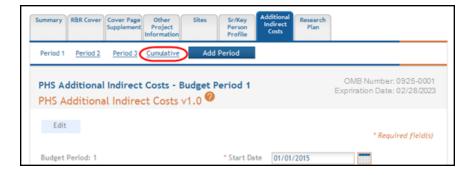
A confirmation window displays.

2. Select the **Continue** button to confirm the removal of the entire form. Select the **Go Back** button to return to the budget period form without removing it.

IMPORTANT: Removing the form deletes the form and all its contents from the application. This action cannot be reversed.

4.19.6 Viewing Cumulative Budget

To view the cumulative budget of multiple budget periods, select the Cumulative link.



The PHS Additional Indirect Costs – Cumulative Budget displays as read-only.



4.20 PHS 398 Modular Budget

For assistance with the information required on this form, please refer to the appropriate application guide on the How to Apply page.

NOTE: The forms in these topics reflect FORMS-F, which must be used for applications with due dates on or after May 25, 2020 (see the most recent <u>NIH FORMS-F notice NOT-OD-20-026</u>, <u>NIH FORMS-F notice NOT-OD-20-047</u>, and <u>annotated form set</u> for Forms-F.) For due dates on or before May 24, 2020, use FORMS-E.

ASSIST users who have been granted budget authority (View or Edit) may add, edit, and/or view budget information using the **Modular Budget** tab on a single-project application.

NOTE: If a user does not have the View or Edit budget authority, the **Modular Budget** tab does not display among the tabs for other forms.

For guidance on completing the form in the ASSIST system, refer to the steps below.

4.20.1 Adding Budget Period 1

To add budget information for Period 1:

1. Select the Edit button to enable the form for editing.

- 2. Complete the budget information as appropriate. Required fields are marked with an asterisk (*).
- 3. To save the entered information, select the **Save and Keep Lock** button to keep the form open for further editing -or- select the **Save and Release Lock** button to close the form after saving.

NOTE: Selecting the **Cancel and Release Lock** button - followed by the **Continue** button on the confirmation - returns the form to read-only and does not save any of the entered information onto the form.

Click here for an image of the form expanded for editing.

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4.20.2 Adding Another Budget Period

When adding additional budget periods, the information from the previous budget period is carried over and auto-populated into the fields. This information can be edited as necessary.

To add an additional budget period:

1. Select the Add Period button.



PHS Modular Budget - Budget Period X displays (where X is the specific budget period being added).

- 2. Enter and/or edit the budget information for the specific period.
- 3. To save the entered information, select the **Save and Keep Lock** button to keep the form open for further editing -or- select the **Save and Release Lock** button to close the form after saving.

NOTE: Selecting the **Cancel and Release Lock** button - followed by the **Continue** button on the confirmation - returns the form to read-only and does not save any of the entered information onto the form.

4.20.3 Editing and Viewing an Entered Budget

Depending on the authority granted, you may view and/or edit existing budget information for any of the entered budget periods. To edit budget information:

1. Select the link for the period to view or edit (e.g., **Period 3** link).



- 2. Select the **Edit** button to edit the information.
- 3. Update the budget information as necessary.
- 4. To save the entered information, select the **Save and Keep Lock** button to keep the form open for further editing -or- select the **Save and Release Lock** button to close the form after saving.

NOTE: Selecting the **Cancel and Release Lock** button - followed by the **Continue** button on the confirmation - returns the form to read-only and does not save any of the entered information onto the form.

4.20.4 Deleting a Budget Period

With Edit Budget authority, an ASSIST user may remove entire budget periods from a component. To delete an entire budget period:

1. Select the link for the period being removed (e.g., **Period 3** link)



- 2. Select the **Edit** button to enable editing.
- 3. Click the Remove Budget Period button.



A confirmation window displays.

4. Select the **Continue** button to confirm the deletion request.

NOTE: Selecting the **Go Back** button returns the budget period form without deleting it.

The *Modular Budget* tab information displays, with the link for the removed budget gone. This information is now deleted. The deleted budget period is also removed from the Cumulative Budget information.

1. Select the **Continue** button to confirm the deletion request.

NOTE: Selecting the **Go Back** button returns the budget period form without deleting it.

The *PHS Additional Indirect Costs* tab information displays, with the link for the removed budget gone. This information is now deleted. The deleted budget period is also removed from the Cumulative Budget information.

4.20.5 Removing the Entire Additional Indirect Costs Form

The *Modular Budget* form is an optional form which can be removed if it is not needed for the application. With Edit Budget authority, an ASSIST user may remove the form from the application.

To remove the form:

1. Click the Remove Form button while within the PHS Modular Budget form.



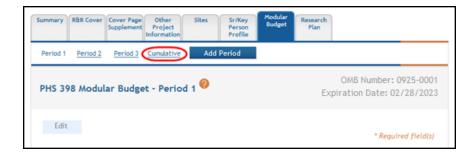
A confirmation window displays.

2. Select the **Continue** button to confirm the removal of the entire form. Select the **Go Back** button to return to the budget period form without removing it.

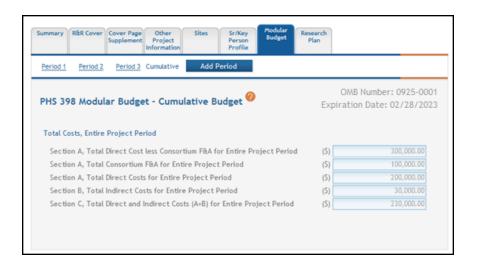
IMPORTANT: Removing the form deletes the form and all its contents from the application. This action cannot be reversed.

4.20.6 Viewing Cumulative Budget

To view the cumulative budget of multiple budget periods, select the Cumulative link.



The PHS 398 Modular Budget - Cumulative Budget displays as read-only.



4.21 PHS Fellowship Supplement

For assistance with the information required on this form, please refer to the appropriate application guide on the <u>How to Apply</u> page.

NOTE: The forms in these topics reflect FORMS-F, which must be used for applications with due dates on or after May 25, 2020 (see the most recent <u>NIH FORMS-F notice NOT-OD-20-047</u>, and <u>annotated form set</u> for Forms-F.) For due dates on or before May 24, 2020, use FORMS-E.

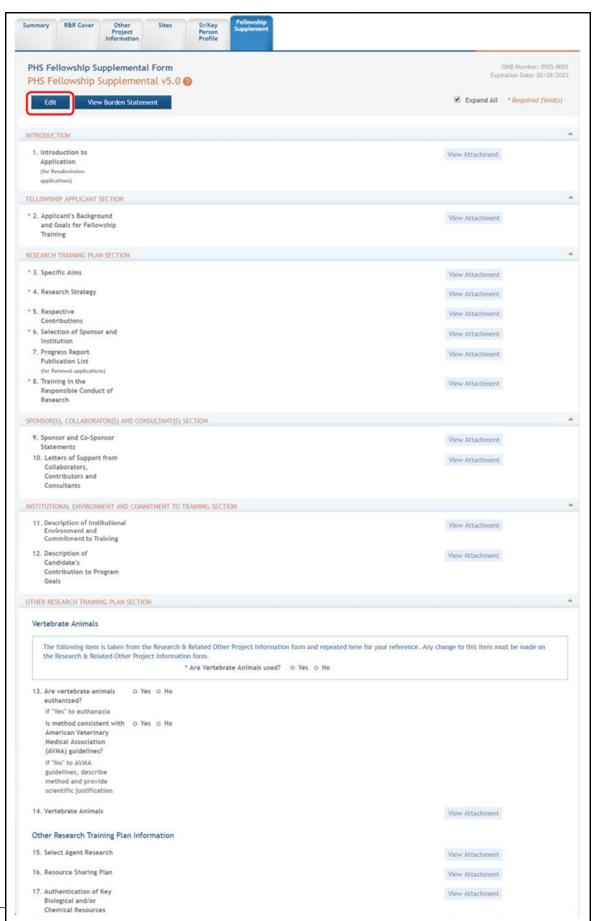
4.21.0.1 New in Forms-F

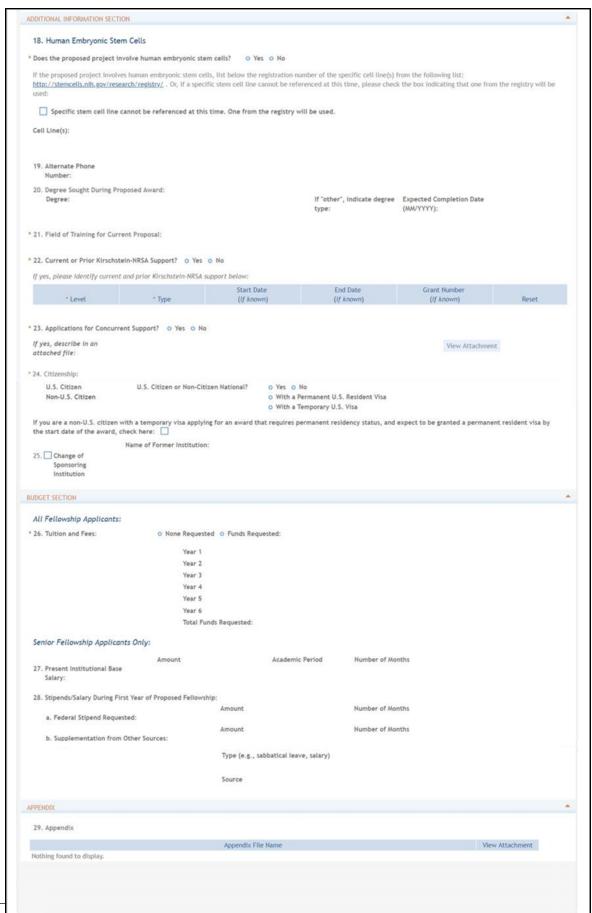
 A new 'Description of Candidate's Contribution to Program Goals' attachment was added to the Fellowship Supplemental form.

4.21.1 For guidance on completing the form in the ASSIST system, refer to the steps below.

1. Select the **Edit** button to enable the form for editing.

First half of the form:





2. Provide the required information for each section. This information may be in the form of attachments, selected radio buttons, or text. Required fields are marked with asterisks (*).

Some questions are specific to SBIR or STTR applications. This is indicated on the screen.

Tip: For assistance with attachments, please refer to the topic titled <u>Manage</u> Attachments.

3. To save the entered information, select the **Save and Keep Lock** button to keep the form open for further editing -or- select the **Save and Release Lock** button to close the form after saving.

NOTE: Selecting the **Cancel and Release Lock** button - followed by the **Continue** button on the confirmation pop-up will return the form to read-only and no information will be saved to the form.

4.22 PHS Assignment Request Form

For assistance with the information required on this form, please refer to the appropriate application guide on the <u>How to Apply</u> page.

NOTE: The forms in these topics reflect FORMS-F, which must be used for applications with due dates on or after May 25, 2020 (see the most recent <u>NIH FORMS-F notice NOT-OD-20-026</u>, <u>NIH FORMS-F notice NOT-OD-20-047</u>, and <u>annotated form set</u> for Forms-F.) For due dates on or before May 24, 2020, use FORMS-E.

4.22.0.1 New in Forms-F

The PHS Assignment Request Form was reworked to improve usability. Among the changes are:

- Clarified instructional text
- Improved field labels
- And a new "Rationale for assignment suggestions" text box.

4.22.1 Steps for Filling out the Form

The PHS Assignment Request form is used for capturing assignment requests.

This form replaces certain information from the application cover letter attachment, and should be used to:

- request an assignment to an institute/center for funding consideration
- request an assignment to a specific study section for initial peer review
- identify individuals who may not be appropriate to review their application
- identify scientific areas of expertise needed to review the application

This form is only visible to receipt and referral staff and scientific review officers, who may need to act on the information.

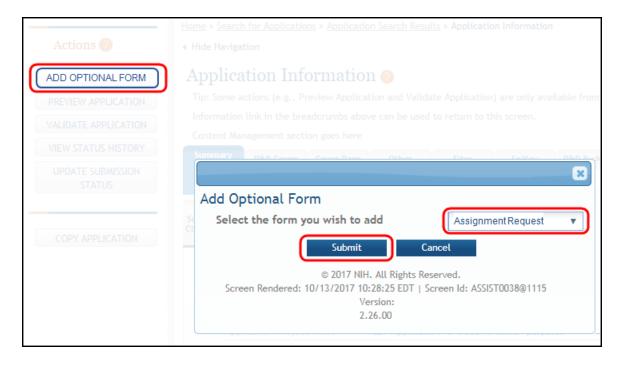
For guidance on completing the form in the ASSIST system, refer to the steps below.

4.22.2 Adding an Assignment Request Form

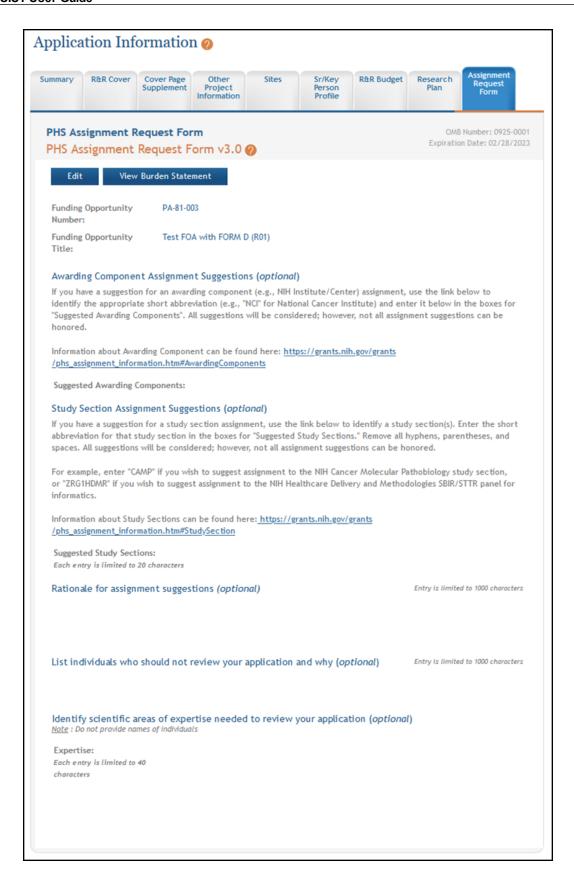
To add an Assignment Request form:

1. Select the **Add Optional Form** button from the **Actions** navigation panel.

The Add Optional Form pop-up window opens for selecting the form to be added. From the drop-down menu, select the Assignment Request form and click on the **Submit** button.



The Assignment Request Form displays.



- 1. Complete the required fields and any other appropriate information. Required fields are marked with an asterisk (*).
- 2. Select one of the save options at the bottom of the form to save the data:
 - a. To save the information and keep the form open for further editing, select the **Save and Keep Lock** options.
 - b. To save the information and close the form, select the **Save and Release Lock** button.
 - c. To delete the form and return to the original application, select the **Remove Form** button.

NOTE: Selecting the **Cancel and Release Lock** button - followed by the **Continue** button on the confirmation - returns the form to read-only and does not save any of the entered information onto the form.

4.22.3 Viewing and Editing the Assignment Request Form

To view and/or edit an assignment request form:

Once the **Save and Release Lock** button has been clicked, the details of the form are displayed as read-only.

To further modify the form, select the **Edit** button.

4.23 SBIR/STTR Information

For assistance with the information required on this form, please refer to the appropriate application guide on the How to Apply page.

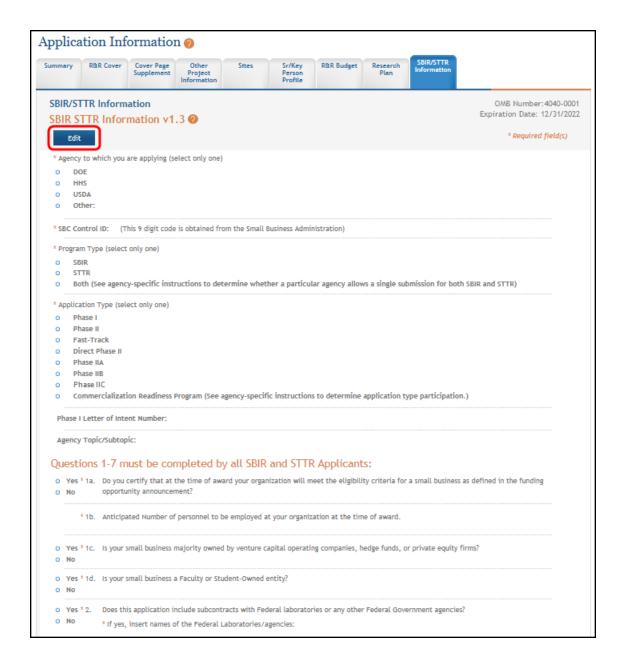
NOTE: The forms in these topics reflect FORMS-F, which must be used for applications with due dates on or after May 25, 2020 (see the most recent <u>NIH FORMS-F notice NOT-OD-20-026</u>, <u>NIH FORMS-F notice NOT-OD-20-047</u>, and <u>annotated form set</u> for Forms-F.) For due dates on or before May 24, 2020, use FORMS-E.

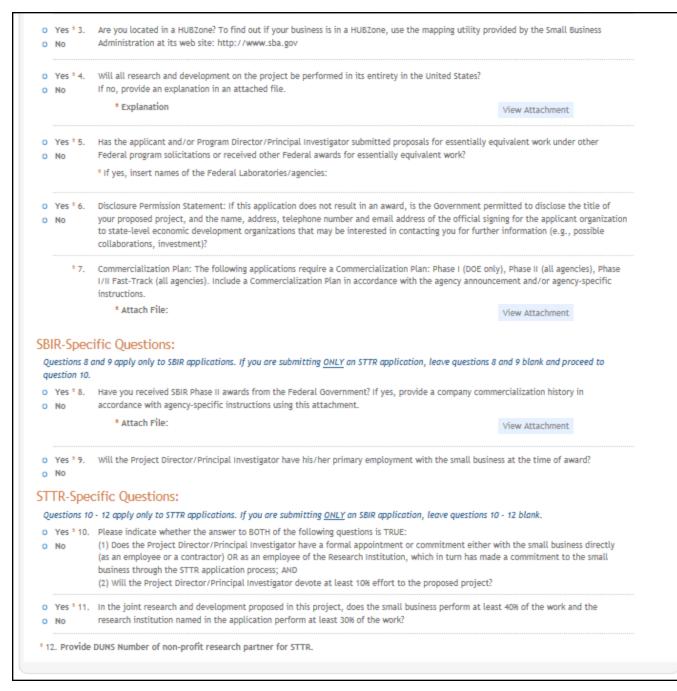
4.23.0.1 New in Forms-F

The *Application Type* field was expanded to include Phase IIC. Though, this new application type was requested by another agency and NIH has no current plans to use it.

4.23.1 For guidance on completing the form in the ASSIST system, refer to the steps below.

1. Select the **Edit** button to enable the form for editing.





The form reopens and is now editable.

Complete the required fields for each section. Required fields are marked with asterisks (*).

Some questions are specific to either SBIR or STTR applications. This is indicated on the screen.

Tip: For assistance with attachments, please refer to the topic titled <u>Manage</u> Attachments.

To save the entered information, select the **Save and Keep Lock** button to keep the form open for further editing -or- select the **Save and Release Lock** button to close the form after saving.

NOTE: Selecting the **Cancel and Release Lock** button - followed by the **Continue** button on the confirmation - returns the form to read-only and does not save any of the entered information onto the form.

4.24 Form and Field Level Validations

ASSIST component forms include validation features at the field level created to identify formatting errors or missing required data well in advance of the submission process. These checks are performed when information is first entered into a field or when the component form is saved.

NOTE: This topic discusses the validations for improperly formatted data and missing required data. This topic does not discuss validating the entire application for submission. Refer to the help topic titled *Validating the Application* for information on submission validation.

4.24.1 Field Data Format Validations

Many component forms contain fields requiring certain types of data (e.g., numeric data in salary fields). ASSIST features field level validation on many form fields to ensure that they information being entered is in the proper format. In these specific fields, ASSIST validates the data upon entry (or after moving the cursor from the field) and immediately displays a pop-alert indicating that the format is not as expected.



When this occurs, read the error message and select the OK button. The field containing the error remains red - and cannot be navigated away from - until the erroneous data is fixed or cleared out.

4.24.2 Required Field Validations

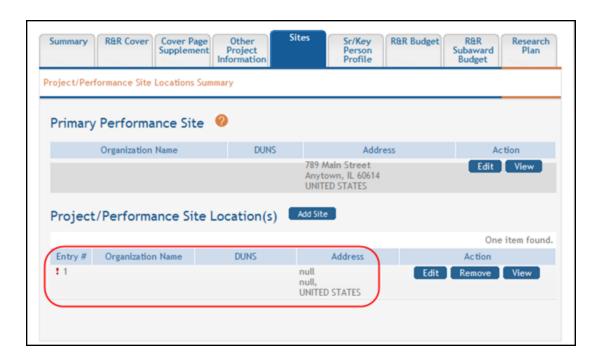
Many of the component forms in ASSIST include fields requesting required information that must exist before the application can be submitted. Required fields are marked with a red asterisk (*). Although the information in these fields is required for submission, component forms can be saved without this information. This is useful when not all the required information is known at the time a form is started. A component form can be started, saved, and completed later when the information is known.

When saving a form with missing required fields, a notice displays indicating that data entry errors were found and providing the options to **Continue** saving the form as-is or to **Return to correct errors**.



To aid in the identification of incomplete forms, ASSIST employs a missing information icon - a red exclamation point (!) - on the summary page of incomplete component forms. The icon indicates the section or field with missing data. If the icon is seen on the summary page, simply edit the appropriate section of the form and provide the required information before saving again.

NOTE: Not all forms contain summary pages.



NOTE: Missing required information can also be identified by performing a component validation. Refer to the help topic titled *Validating an Individual Component*.

4.25 Add Optional Forms

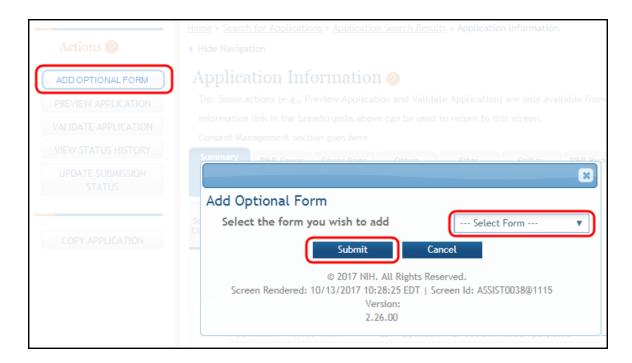
Depending on the funding opportunity, optional forms may exist for both single- and multi-project applications. You can add optional forms using the **Add Optional Form** feature. Only the optional forms available for the specific funding opportunity can be added.

4.25.1 Optional Forms for Single Project Applications

To add optional forms to a single-project application:

1. Select the **Add Optional Form** button from the **Actions** navigation panel.

A pop-up window opens for selecting the form to be added.



2. Choose a form from the drop-down list and select the **Submit** button to add the form to the component.

NOTE: Selecting the **Cancel** button closes the window without added the form to the component.

3. Select the tab of the corresponding form to enter information on the form.

4.25.2 Optional Forms For Multi-Project Applications

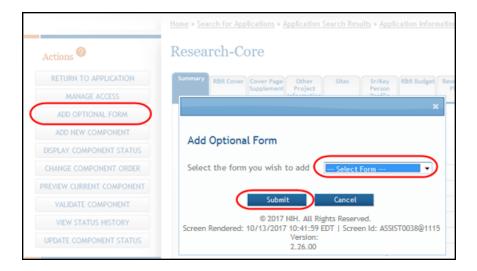
To add optional forms to a multi-project application:

- 1. Select the **Return to Application Info** button on the **Actions** panel to return to the *Application Information* page.
- 2. From the *Application Information* page expand the appropriate component from the **Component Type** section.
- 3. Select a component type to display the *Component Information*.

The Component Information page opens for the component.

4. Select the **Add Optional Form** button from the **Actions** navigation panel.

A pop-up window opens for selecting the form to be added.



- 5. Choose a form from the drop-down list.
- 6. Select the **Submit** button to add the form to the component.

NOTE: Selecting the **Cancel** button closes the window without added the form to the component.

7. Select the tab of the corresponding form to enter information on the form.

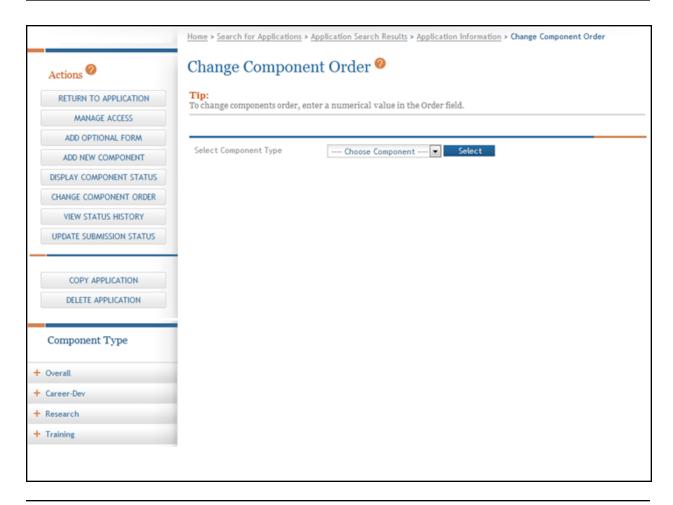
See Also

- Edit Overall Component Forms
- Edit Additional Component Type Forms

4.26 Change Component Order

IMPORTANT: This topic is applicable only to multi-project applications.

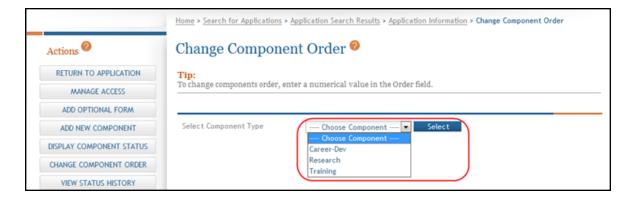
The Change Component Order screen is used to set the order in which your components appear in the submitted application (i.e., the PDF version) for each particular component type. For example, if your application contains four components of the component type *Research*, you can re-arrange those four components into any order you wish. The component order can be changed for components in the status of *Work in Progress*, *Complete*, or *Final*.



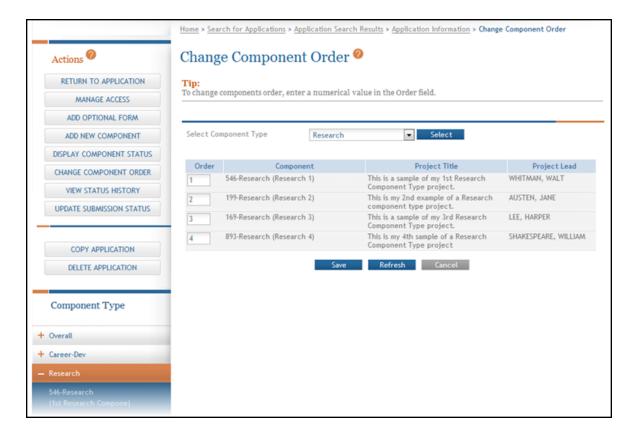
NOTE: Although components *within* a particular component type can be re-ordered, you cannot re-arrange the order of component types.

Access the *Change Component Order* screen by selecting the **Change Component Order** button on the **Actions** panel. Once the screen is opened, follow the steps below to update the order of components of a particular component type:

 Select a component type from the Select Component Type drop-down list and click the Select button. The component types displayed in the list depend on your application's FOA.



The screen updates to display the current Order, Component, Project Title, and Project Lead for each component of the selected component type. Components display in the order in which they were added to the application until they are reordered using this feature. Once components have been re-ordered, they will display in the current (i.e., updated) order.

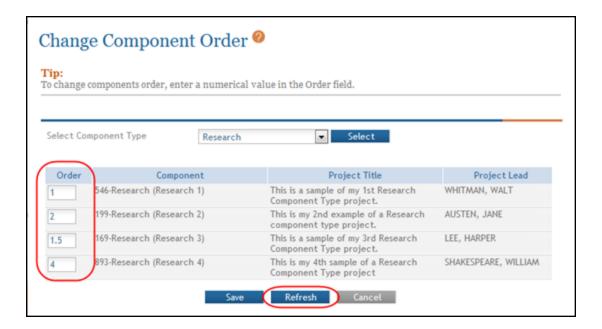


2. Use the text box in the Order column for each component being re-ordered to enter an order value. Make sure to enter a unique value in each **Order** field. You will receive an error if you attempt to save the order of components with duplicate order

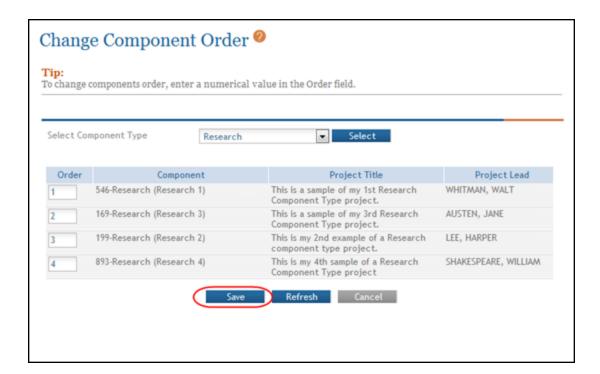
values.

You may use decimal numbers (up to 2 places) and negative numbers to avoid renumbering <u>every</u> component. For example, to re-order a particular component to appear between the first and second components, enter that component **Order** as 1.5.

After updating the values, you can use the **Refresh** button to display the components in the updated order. Refreshing the displayed order <u>does not save</u> the order and you can always use the **Cancel** button to abort the action, even after refreshing the screen.



3. When satisfied with the component order, select the Save button to save your results and return to the Application Information screen.



You can see your changes reflected in the Component Type panel.



See Also

- Actions
- Application Information
- Component Information

4.27 Delete a Component

IMPORTANT: This topic is applicable only to multi-project applications.

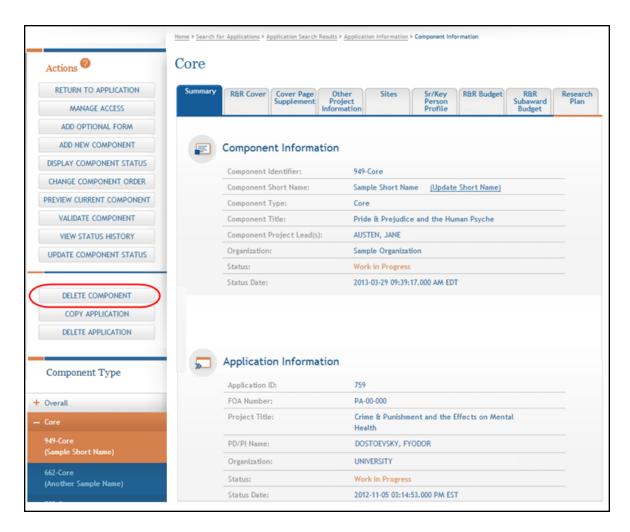
If you are the Signing Official, Administrative Official, or the PI of the lead organization - and/or- you have Entire Application Editor privilege, you have access to the Delete Component feature in ASSIST. The Delete Component features allows you to permanently delete individual components of any status from the application.

IMPORTANT: Deleting components is a permanent action. Once deleted, a component cannot be accessed, retrieved, or viewed. There is no way to recover the component.

NOTE: ASSIST also has a Delete Application feature for deleting an entire application. Individual components do not need to be deleted first when deleting the entire application. Refer to the topic titled <u>Delete the Application</u> for steps on deleting entire applications.

To delete a component:

- 1. Open the *Summary* tab of the component you wish to delete.
- 2. From the Actions panel, select the Delete Component button.



A confirmation message displays as follows: You are about to delete this component. Once this component has been deleted you will no longer be able to retrieve or view it. Do you wish to continue with the delete?



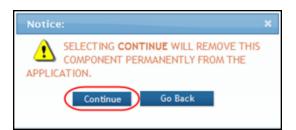
3. Select the appropriate action:

You may cancel the action at this point by selecting the **Go Back** button. If you choose **Go Back**, the delete process ends, you return to the summary tab from which you began, and the following steps are no longer applicable.

-OR-

To continue with the deletion, select the Continue button.

Upon continuing, a second confirmation displays as follows: Selecting Continue will remove this component permanently from the application.



4. This warning provides a final means of aborting the deletion. Carefully select the appropriate action:

To stop the deletion process, select the **Go Back** button. If you choose **Go Back**, the delete process ends, you return to the summary tab from which you began, and the following steps are no longer applicable.

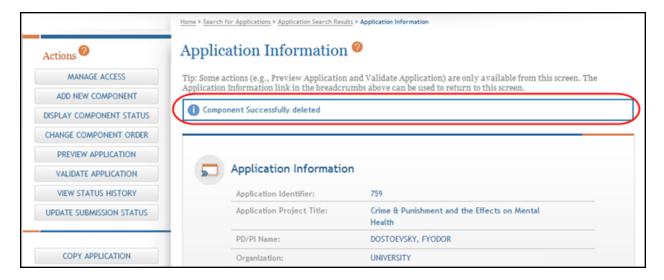
-OR-

To confirm the action and permanently delete the component from the application, select the Continue button. Remember that this action is irreversible. Once the component is deleted, you cannot retrieve it.

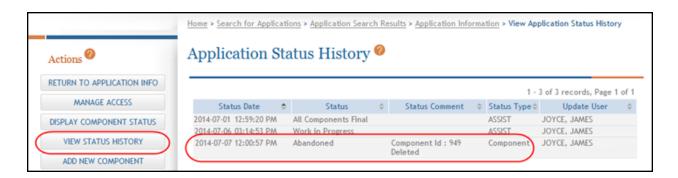
NOTE: You cannot delete a component if one or more of its forms are locked by yourself or another ASSIST user. If a form is locked, you will see the following error on your screen after continuing from the second confirmation screen:

The component cannot be deleted as the following form(s) are currently locked by <User ID> in: <application ID>: <locked form>

The Application Information screen displays with the message *Component successfully deleted*. You will also notice that the component has been removed from the left-side panel of Component Types.



When a component is deleted from an application, the Application Status History reflects this action. The **Status** in the history show as *Abandoned*. The **Status Comment** will indicate that the component was deleted by displaying the following *Component ID: <ID number> Deleted*, along with the name of the ASSIST user who performed the deletion.



5 Application Submission Status Workflow for Multi-Project Applications

IMPORTANT: This topic is applicable only to multi-project applications.

As your multi-project application evolves, its status is updated to reflect the current stage in the submission process. This may be a manual status update or an automatic update performed by ASSIST (i.e., system-generated).

The following provides a definition of the various status levels of an application.

Work in Progress: Allows editing of an application

All Components Final: Indicates that all components are in a status of *Final* (if not *Abandoned*); also indicates that the application is ready for the Validate Application process

All Components Validated: System-generated status set when the Validate Application process runs error-free

Ready for Submission: Manual status which should be set after all internal reviews have taken place

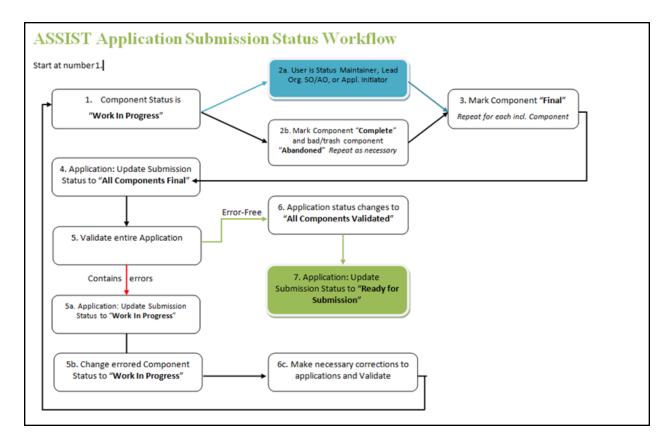
Submitted: System-generated status set after submitting the application to Grants.gov

Submission Errors: System-generated status indicating that the validation process returned errors

Abandoned: Manual status applied to indicate that the application is no longer being worked on

NOTE: The ability to update an application's status is dependent on the status of its components. If an application's components are not in the proper status, certain application status updates cannot be made. Refer to the table in the Update Application Submission Status topic for the valid conditions for updating the application status.

The figure below provides a general overview of the typical flow of an application from *Work in Progress* to *Ready for Submission* status.



See Also

- Display Component Status
- Update Application Submission Status
- Update Component Status
- View Application Status History
- View Component Status History

5.1 Display Component Status

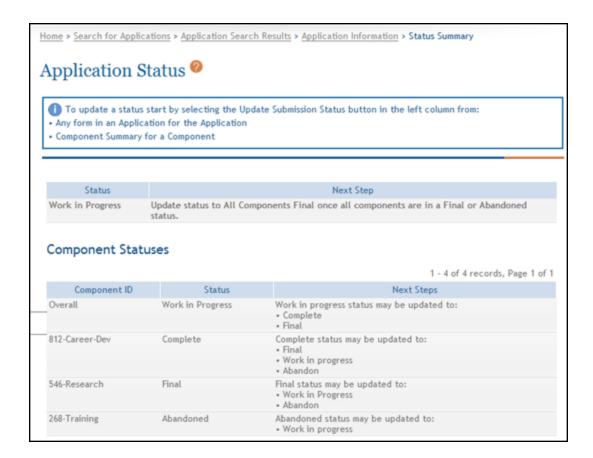
Selecting the Display Component Status button from the Actions panel opens the Status Summary. This screen displays a status summary of the entire application and its components.

IMPORTANT: This topic is only applicable to multi-project applications.

The information on the screen is as follows:

- Component ID (for individual components only)
- Status
- Next Steps

The **Next Steps** gives a description of what type(s) of status update can be performed against the component in its current status.



See Also

- Application Submission Status Workflow for Multi-Project Applications
- Update Component Status
- Update Application Submission Status
- View Application Status History
- View Component Status History

5.2 Update Component Status

IMPORTANT: This topic is only applicable to multi-project applications.

ASSIST users with the appropriate privilege may update the status of an individual component of a multi-project application when necessary as follows:

Table 1: Valid Component Status Changes

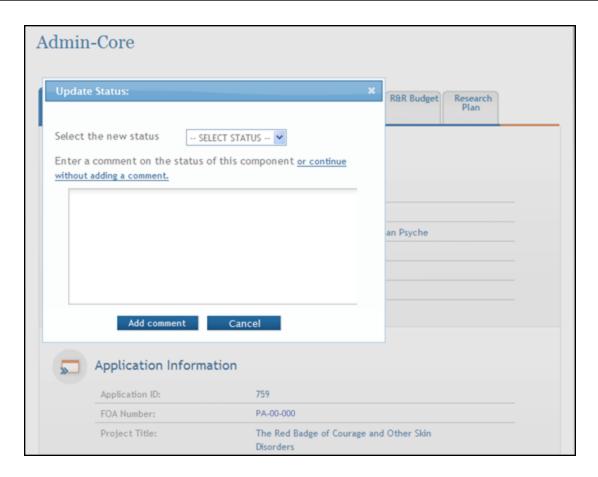
From Status	Available To Status
	Complete
Work in Progress	Abandoned*
	Final
	*Note: An Overall component cannot be abandoned
Complete	Final
Complete	Work in Progress
Final	Work in Progress
Abandoned	Work in Progress

NOTE: In order for an application to be submitted, at least one component of the application must be marked as *Final*. All other components must be in *Final* or *Abandoned* status.

To update the status of a component:

- 1. Select the **Return to Application Info** button on the **Actions** panel to return to the *Application Information* page.
- 2. From the *Application Information* page expand the Overall or other component type from the **Component Type** section of the navigation panel to display the list of components within the section.
- 3. Select a component.
- 4. Click the **Update Component Status** button.

The Update Status window opens.



- 5. Select the appropriate status from the **Select the new status** drop-down list.
- 6. Complete the status update:
 - a. Enter a comment in the provided text box.
 - b. Select the **Add comment** button.
 - -OR-
 - c. Select the link titled **or continue without adding a comment** to update the status without entering a comment in the provided text box.

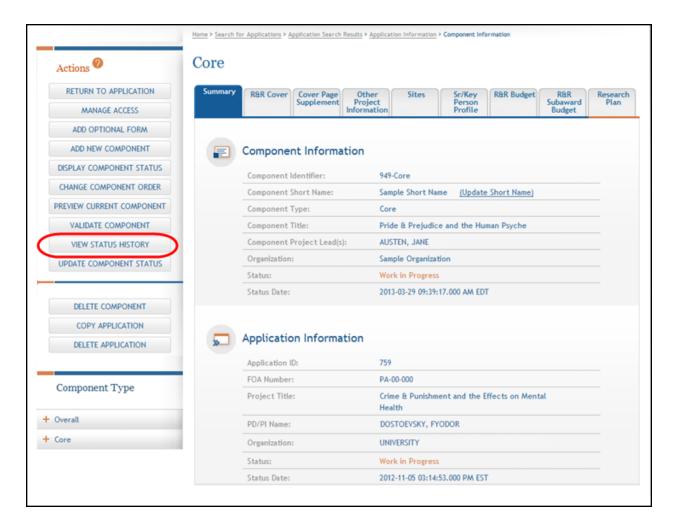
A notification of the change in status is sent to the appropriate individual(s). The application status is changed to the selected status.

NOTE: When marking a component as *Final*, ASSIST validates if any senior/key persons with a bio-sketch exist on another component marked as *Final*. Only one bio-sketch may exist per senior/key person on an application. Refer to the help topic titled *Verify Senior/Key Personnel* for information on this topic.

5.3 Component Status History

IMPORTANT: This topic is only applicable to multi-project applications.

From the Component Information page, select the View Status History button to display the Component Status History page.



The Component Status History page displays the following information for each status change made to the component:

Status Date

This is the time and date on which the status of the component was updated. Updates to the status are performed using the **Update Component Status** button for the specific component.

Status

This field displays the status of the component.

Status Comment

This field displays comments regarding the component status update. Comments are optional when updating the status; therefore, this field may be blank.

Update User

This field indicates by whom the status was updated. It may display the system name (ASSIST) or the actual user who updated the application (Last Name, First Name).



See Also

View Application Status History

5.4 Update Application Submission Status

To update the submission status of the application:

- 1. Select the **Return to Application Info** button on the **Actions** panel to return to the *Application Information* page.
- 2. From the *Application Information* page select the **Update Submission Status** button from the **Action** list.

The Update Status window opens.



- 3. Select the appropriate status from the **Select the new status** drop-down list.
- 4. Complete the status update:
 - a. Enter a comment in the provided text box.
 - b. Select the **Add comment** button.

-OR-

c. Select the link titled **or continue without adding a comment** to update the status without entering a comment in the provided text box.

A notification of the change in status is sent to the appropriate individual(s). The application status is changed to the selected status.

5.4.1 Multi-Project Application Status Flow

The normal flow of status changes for a submitted multi-project application is as follows:

Work in Progress >> All Components Final >> All Components Validated >> Ready for Submission >> Submitted

The table below lists the valid application status changes and conditions.

Table 2: Valid Application Status Changes for Multi-project Applications

Current Status	Valid Status Change	Special Conditions
Work in Progress	All Components Final	At least one component, including the Overall, must be marked as Final; All components must be marked as
		either Final or Abandoned
Work in Progress	Abandoned	
All Components Final	Work in Progress	
All Components Final	Abandoned	
All Components Final	All Components Validated	This status is set by ASSIST once an application in All Components Final status passes validations.
All Components Validated	Ready for Submission	
All Components Validated	Work in Progress	
All Components Validated	Abandoned	
Ready for Submission	Work in Progress	
Ready for Submission	Abandoned	
Submitted	Work in Progress	Agency status is Pending Verification or Refused
Submission Errors	Work in Progress	
Abandoned	Work in Progress	

Refer to the help topic titled *Update Component Status* for information on updating the status of individual components.

5.4.2 Single-Project Application Status Flow

The normal flow of status changes for a submitted single-project application is as follows:

Work in Progress >> Ready for Submission >> Submitted

The table below lists the valid application status changes and conditions.

Table 3: Valid Application Status Changes for Single-project Applications

Current Status	Valid Status Change	Special Conditions
Work in Progress	Abandoned	
Work in Progress	Ready for Submission	
Ready for Submission	Work in Progress	
Ready for Submission	Abandoned	
Submitted	Work in Progress	Agency status is Pending Verification or Refused
Submission Errors	Work in Progress	
Abandoned	Work in Progress	

5.5 View Application Status History

From the Application Information page select the View Status History button to display the Application Status History page.

IMPORTANT: You can access *Application Information* any time by selecting the **Return to Application Info** button on the **Actions** panel.



The *Application Status History* page displays the following information for each status change to the application:

Status Date

This is the time and date on which the status of the application was updated. Updates to the status are performed using the **Update Component Status** button for the specific component.

Status

This field displays the status of the application. Depending on the type of status update, this field may display the submission status, Grants.gov processing status, or Agency status.

Status Comment

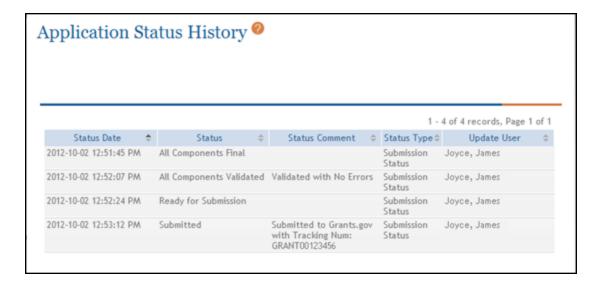
This field displays comments regarding the status update. Depending on the type of status update, this field may display the comments entered upon submission or Grants.gov error details when applicable.

Status Type

This field displays the type of status update performed -ASSIST, Grants.gov, or Agency.

Update User

This field indicates by whom the status was updated. It may display the system name (ASSIST) or the actual user who updated the application (Last Name, First Name).



See Also

• View Component Status History

6 Generating a Preview of the Entire Application

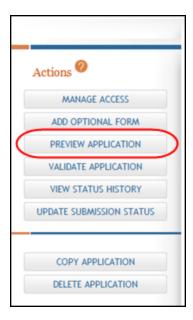
With the appropriate privilege(s), ASSIST users may view, print, and/or locally save a preview of the application image from the *Preview Application* screen.

From this screen, you may perform the following actions:

- Generate and view an initial image preview
- View a previously generated image preview
- Generate subsequent image preview(s)

The Preview Application screen is accessed by selecting the Preview Application button on the Application Information page Actions panel.

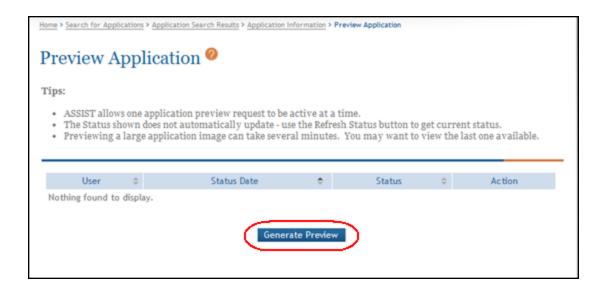
Tip: Select the **Return to Application** button on the **Actions** panel to return to the *Application Information* page.



6.1 Generating and Viewing the Initial Application Image

To generate an initial preview request:

1. Select the Generate Preview button from the Preview Application screen.

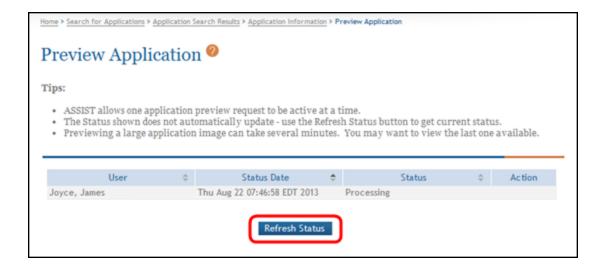


NOTE: If a preview request was generated prior to this request, information on that preview will display in the table. Refer to the help topic titled *Viewing a Previously Generated Image* for more information.

ASSIST queues the request for the preview. The table on the screen updates with the requester information and the status of the request, which could be Waiting to Process, Processing, Failed, and Preview Available.

While the request is processing, the **Refresh Status** button can be used to update the status and to check on the progress of the request. When the request processing is completed, the **View** button displays in the **Action** column.

2. *Optional*: Use the Refresh Status button to update the status and monitor the progress until completed.



3. Select the View button to view the application image.



The application image displays in a separate window. From here, you can review, print, and/or save the image locally if needed.

4. Close the window displaying the PDF.

NOTE: Although unlikely, it is possible that another ASSIST user accessing the application at the same time could generate a preview request for the application while you are in the *Generate Preview* screen. If this occurs, you will see the following error message when you attempt to select the **Generate Preview** button: A 'Generate Preview' request is pending for this application. You may generate another preview when all pending requests have processed.

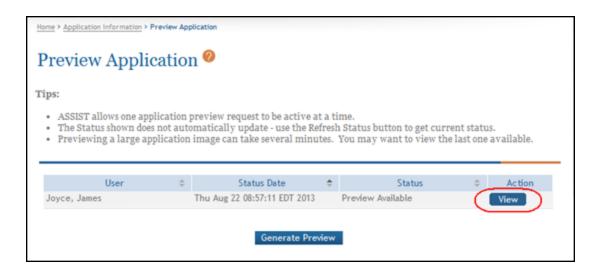
6.2 Viewing a Previously Generated Image

To view an application image previously generated:

1. Open the Preview Application screen.

The screen displays information about the prior preview request. This includes the **User** who submitted the request, the **Status Date**, the **Status** of the request, and the **View** button in the **Action** column.

2. Select the **View** button to view the image.



The application image displays in a separate window. From here, you can review, print, and/or save the image locally if needed.

3. Close the window displaying the PDF.

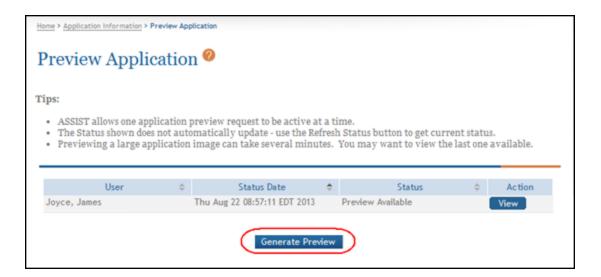
6.3 Requesting a New Application Image

Even if an image currently exists, a new preview can be generated. To request a new preview:

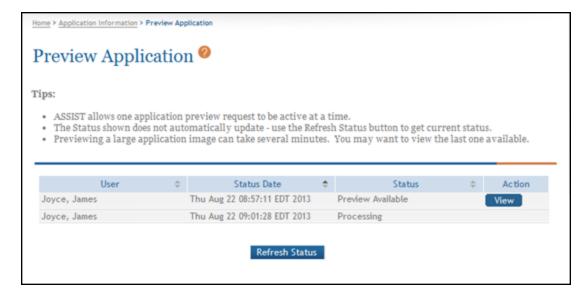
1. Open the *Preview Application* screen.

The screen displays information about the prior request. This includes the **User** who submitted the request, the **Status Date**, the **Status** of the request, and the **View** button in the **Action** column.

- 2. Optional: Select the View button to view the existing image.
- 3. Select Generate Preview button to generate the new request for an image.



ASSIST queues the request for the preview. The table on the screen updates with the requester information and the status of the request, which could be *Waiting to Process*, *Processing*, *Failed*, and *Preview Available*. This information is displayed beneath the previous request.



While the request is processing, the **Refresh Status** button can be used to update the status and to check on the progress of the request. When the request processing is completed, the **View** button displays in the **Action** column. The new image replaces the previously generated one.

4. Select the **View** button to view the application image.

The application image will display in a separate window. From here, you can review, print, and/or save the image locally if needed.

5. Close the window displaying the PDF.

NOTE: Although unlikely, it is possible that another ASSIST user accessing the application at the same time could generate a preview request for the application while you are in the *Generate Preview* screen. If this occurs, you will see the following error message when you attempt to select the **Generate Preview** button: A 'Generate Preview' request is pending for this application. You may generate another preview when all pending requests have processed.

- Application Information
- Previewing a Component or Form

6.4 Previewing a Component or Form

IMPORTANT: This topic applies only to multi-project applications.

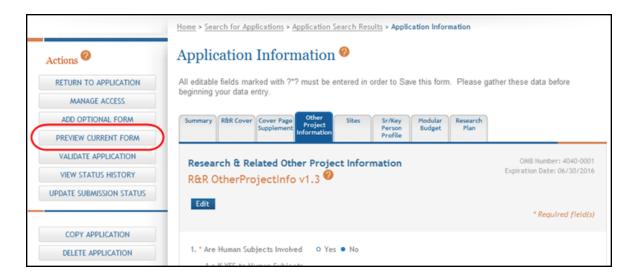
With the appropriate privilege(s), ASSIST users may view and print previews of an application's forms or of the individual components of a multi-project application.

6.4.1 Previewing the Current Form

While working on a form of an application, you can open a preview of what that form looks like as a PDF document.

To preview the form you are working on:

- 1. Select the specific form to preview by clicking its tab.
- 2. From the Actions panel, select the Preview Current Form button.



3. Select the appropriate option to open the document file.

A PDF version of the specific form is generated and displayed within a new browser window.

- 4. *Optional*: Select the print option to print the PDF or the save option to save the PDF locally.
- 5. Close the window displaying the PDF.

6.4.2 Previewing a Component

NOTE: This applies only to multi-project applications.

1. From the Component Information page, select the **Preview Current Component** button from the **Action** section.



A PDF version of the component is generated within a new browser window, showing the component forms and attachments.

NOTE: Application and component summaries and tables of contents are generated only when previewing the <u>entire</u> application, not for individual components. Refer to the help topic titled *Generating a Preview of the Entire Application* for information on previewing an entire application.

- 2. *Optional*: Select the print option to print the PDF or the save option to save the PDF locally.
- 3. Close the window displaying the PDF.

6 Introduction to Non-Research Amendments (for Non-Research Agencies)

Non-research users will utilize the *eRA Commons* to initiate amendment applications and the *Application Submission System & Interface for Submission Tracking (ASSIST)* to complete and submit applications.

The initial step requires logging in to the eRA Commons environment with the role of PD/PI (Project Director/Principal Investigator) or SO (Signing Official).

Eligible users will then see the Non-Research option in the main menu ribbon. Selecting that tab provides access to the Manage Post Award Amendments option which is the starting point for the initiation and submission process.



Please refer to the <u>PD/PI</u> or <u>SO</u>-specific sections for searching for and initiating amendments for eligible grants.

Once an amendment application has been initiated via Manage Post Award Amendments in the eRA Commons, the system will open ASSIST and pre-populate the application with the required forms and select data fields.

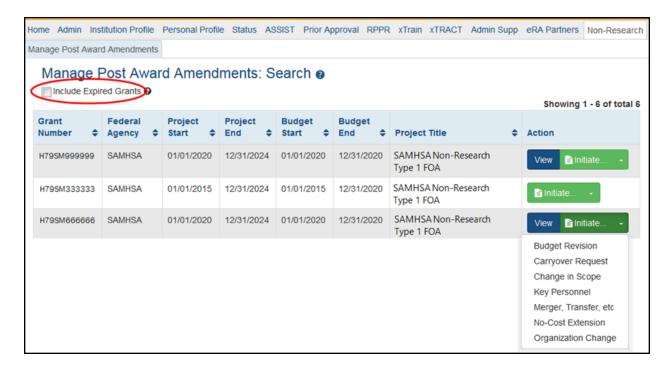
ASSIST provides validations and previews to help to minimize submission and review issues that might otherwise have a detrimental effect on the application.

The topics in this section cover expanded information on this process as well as the unique forms that may be required.

6.5 Search and Initiate -- PD/PI View

When a user with a PD/PI role selects the **Non-Research** tab and then the **Manage Post Award Amendments** tab, the system will present them with a list of grants eligible for amendments. This list will only display those grants on which the user is a PD/PI.

A checkbox is available to show expired grants as well and these may also be amended.

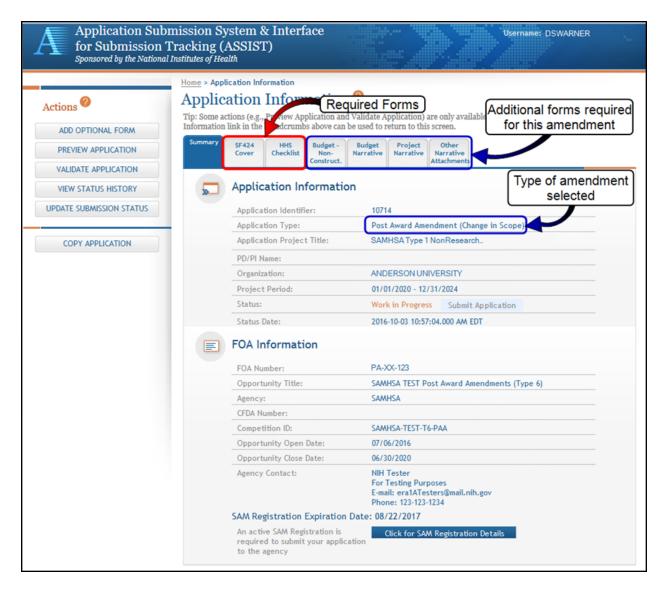


The screen will show buttons in the **Action** column to **Initiate** a new amendment application or to **View** a previous amendment application if applicable.

Clicking on the **Initiate** button will open a menu showing the types of amendment options available.

- Budget Revision
- Carryover Request
- Change in Scope
- Key Personnel
- · Merger, Transfer, etc
- No-Cost Extension
- Organization Change

Clicking on one of the menu options will open the ASSIST module and open all of the forms required for the type of amendment selected.



ASSIST will open to the *Application Information* screen (i.e., Summary tab) showing the **Action** options on the left side and tabs for the required forms above the information section.

Please refer to the core <u>ASSIST Help</u> topics for specific functionality within ASSIST. However, note that *non-research* applications may have required forms that are not standard for research applications. Please see <u>Forms</u> under *Non-Research Amendments* for descriptions of forms unique to non-research applications and amendments.

The forms required are added to the applications depending on the funding announcement and the type of amendment selected. The SF424 and HHS Checklist are always required.

Many fields in the SF424 and some other forms are pre-populated; some of those fields are editable whereas some are read-only. The pre-populated fields have information that has been transferred into the application from the eRA Commons.

- 1. Type of Submission (Pre-populated and Read-only)
- 2. Type of Application, letter (for Revision type), description in Other (if Revision type "E: Other" is selected) (Pre-populated and Read-only)
- 3. Date Received (Automatically populated at the time of submission with the current date)
- 5. Federal Award Identifier (Pre-populated and Read-only)
- 8. a-d (Legal name, Tax ID number, DUNS, and address) (Pre-populated. DUNS is Read-only)
- 10. Name of Federal Agency (Pre-populated)
- 11. Catalog of Federal Domestic Assistance Number and CFDA Title (Prepopulated)
- 12. Funding Opportunity number and Title (Pre-populated and Read-only)
- 13. Competition ID Number and Title (Pre-populated)
- 15. Description of Project (Pre-populated)
- 16. Applicant and Program/Project (Pre-populated)
- 17. Start and End Date (Start Date is Pre-populated and Read-only and End Date is pre-populated)
- 18. Estimated Funding. (These fields are pre-populated with "0.00")

NOTE: All fields with an asterisk [*] are required be completed in order to submit the application.

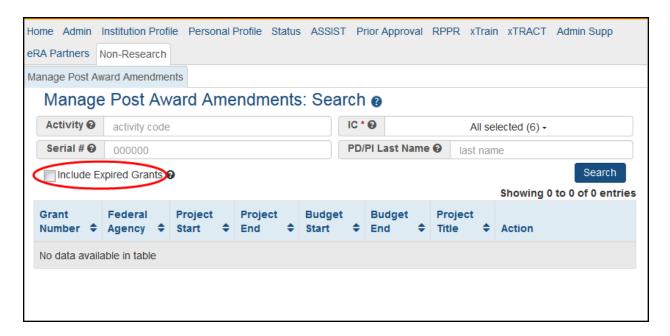
6.6 Search and Initiate - SO View

From the *Non-Research Amendments - View* screen in eRA Commons, the SO will select the amendment actions from the **Initiate** button in the **Action** column for the applicable grant.

NOTE: SAMHSA users who are Business Officials will be given the Signing Official role in eRA Commons.

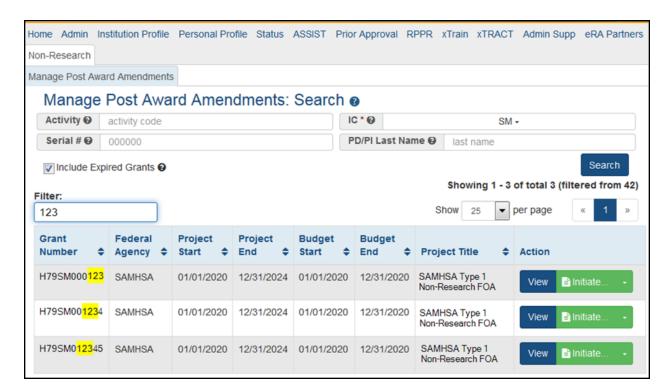
Open **Search** by clicking on the **Non-Research** tab and then the **Manage Post Award Amendments** tab.

The resulting Search screen will provide fields to search by several criteria. If the search criteria fields are left blank and then the **Search** button is clicked, a list of *all* eligible grants for the organization are displayed.

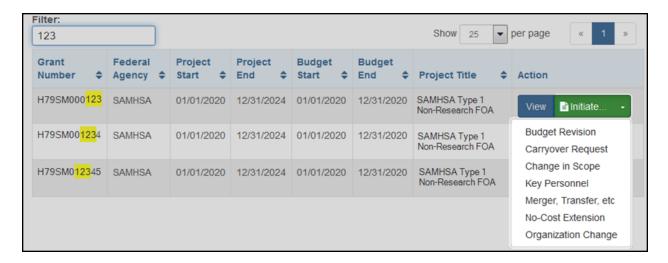


Once the desired criteria has been entered and the **Search** button has been clicked, the resulting list will have an **Initiate** button and, if there are already amendments for that grant, a **View** button. The view option will show a summary of the previous amendments on that grant.

If the list is long, the SO may also use the **Filter** tool to find specific grants or grants with specific criteria (specific PD/PI, for example).



Once the grant to be amended is located, click on the **Initiate** button in the **Action** column on the row for that grant to see a drop-down menu listing the following amendment options:

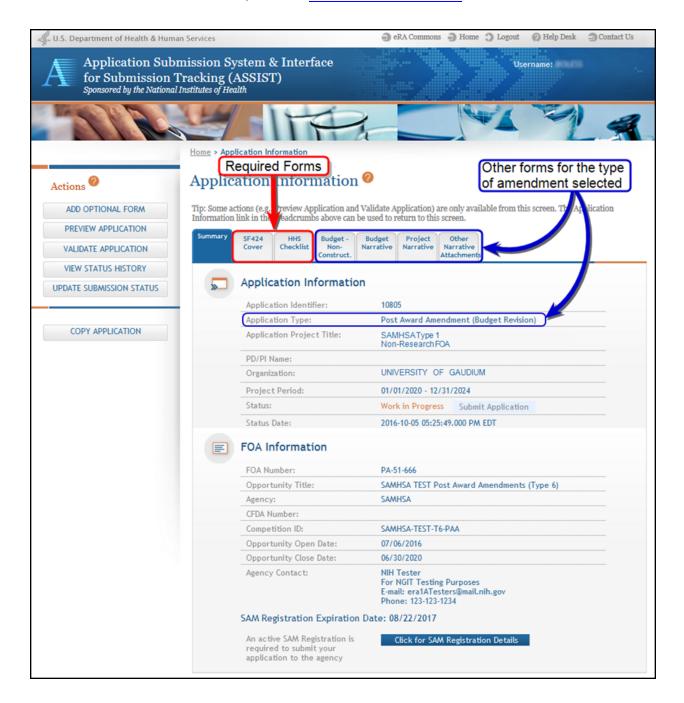


- Budget Revision
- Carryover Request
- Change in Scope
- Key Personnel
- Merger, Transfer, etc

- No-Cost Extension
- Organizational Change

Select the most appropriate type. The user will then be taken to ASSIST to begin the post award amendment application with the amendment-specific forms.

The SF424 and HHL Checklist are always required for these amendment applications. There may also be other forms required that are unique to Non-Research applications. For more detail on these forms, see the Non-Research Forms section.



6.7 Forms

Depending on the funding opportunity and the type of amendment, a combination of the forms below will be included with the ASSIST application package. Note that all of the required forms should automatically load into ASSIST for the Funding Opportunity Announcement (FOA) and amendment type selected, but some forms may be added manually as well.

- SF424 -
 - Instructions: https://www.grants.gov/web/grants/form-instructions/sf-424-instructions.html
- SF424A (Budget Information Non-Construction Programs) -
 - **Instructions:** https://www.grants.gov/web/grants/form-instructions/sf-424a-instructions.html
- SF424B (Assurances for Non-Construction) -
 - Instructions: https://www.grants.gov/web/grants/form-instructions/sf-424b-instructions.html
- SF424C (Budget Information for Construction Programs) -
 - Instructions: https://www.grants.gov/web/grants/form-instructions/sf-424c-instructions.html
- SF424D (Assurances for Construction Programs) -
 - Instructions: https://www.grants.gov/web/grants/form-instructions/sf-424d-instructions.html
- SFLLL (Disclosure of Lobbying Activities) -
 - [need instruction link]
- Project Abstract Summary -
 - https://www.grants.gov/web/grants/form-instructions/project-abstract-instructions.html
- HHS Checklist -
- Budget Narrative Attachment -
- Project Narrative Attachment -
- Other Attachments -

Additional information for the forms above can be found in Non-Research Forms.

6 Non-Research Non-Competing Continuation Overview

SAMHSA grantees are now able to use ASSIST for non-competing continuation applications (non-research only).

They will initiate the application in eRA Commons and prepare and submit it in ASSIST.

NOTE: If a PD/PI is not the initiator of a Continuation application, they will not be able to view or edit the application in ASSIST until an SO (Signing Official) has given them that permission.

Grantees will be able to track the application in eRA Commons through Status; they will also be able to manage their entire non-competing continuation process for their grant using a new Manage Continuations sub-tab in eRA Commons.

Requisite changes will also be made to the Grant Folder.

6.8 Non-Competing Continuation Process

6.8.0.1 How does a PD/PI or BO know when a non-competing continuation application is due?

- 1. The PD/PI and BO are notified via email of the upcoming due date for the required application. The application package is available three (3) months days before the due date or six (6) months before the current budget period end date.
 - a. A reminder email is sent out one (1) month before the due date.
 - b. If the application has not been submitted by the due date, a late notice email is sent the next day.

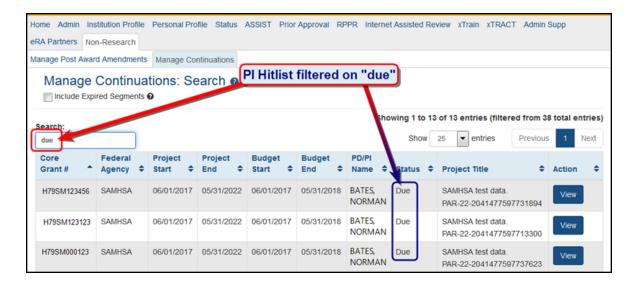
6.8.0.2 How does a PD/PI or BO initiate a non-competing continuation application?

- 1. The application is initiated through Commons.
- 2. Select "Non-Research" and then "Manage Continuations". (click to view)

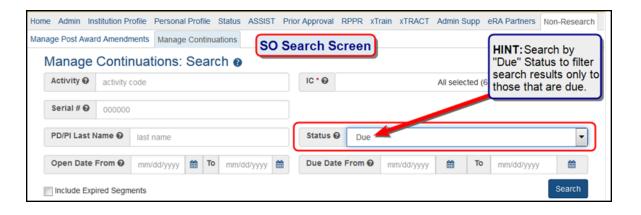


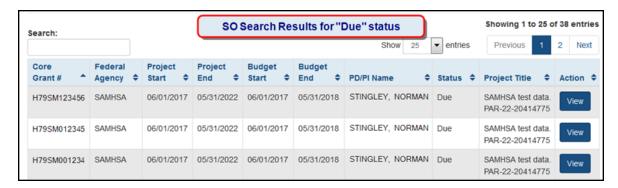
3. The PD/PI will be taken to a screen with a hitlist of their grants. From this list, the PD/PI may sort the applications due by entering that term in the filter field. (click to

view)

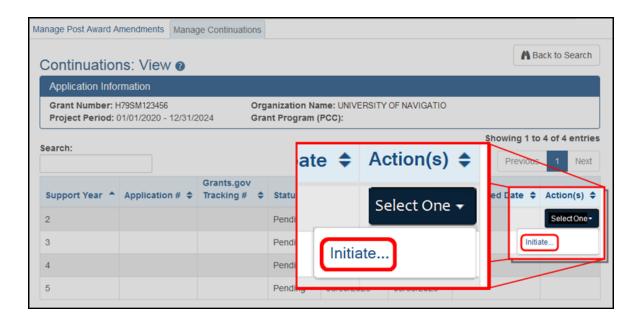


SOs will be able to use the search screen to selectively search for grants that are due. The resulting hitlist will show the results of the search. (click to view SO search screen and results)



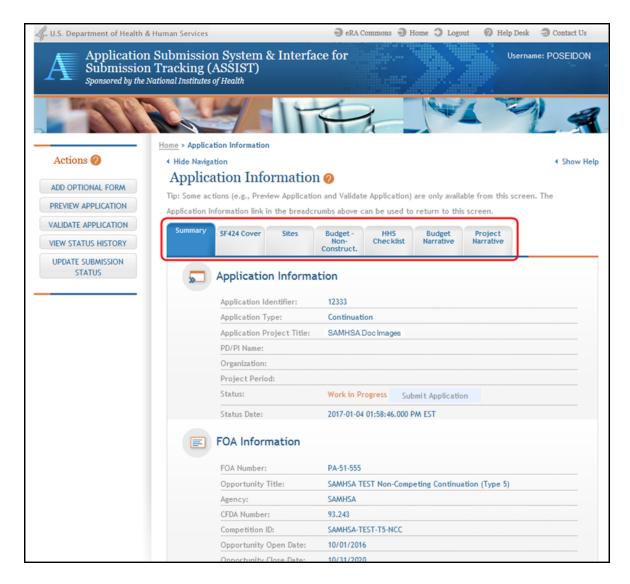


4. From the resulting hitlist, click on the **View** button in the **Action** column for the grant that is due. This action will show the list of support years. The year that is eligible for the continuing application will have a button labeled "**Select One**" in the **Action** column. Select the "*Initiate...*" option from the **Select One** drop-down menu to open the application in ASSIST. (click to view)



5. The *Initiate...* link will open the continuation application in ASSIST in another window or tab (depending on the browser configuration) with the necessary forms preloaded. Other information from the parent application will be preloaded into some fields as well. (click to view ASSIST screen)

NOTE: Some screens may not display correctly in the Internet Explorer browser with *Compatibility Mode* turned on. To ensure that the screens are correctly displayed, turn off *Compatibility Mode* or use a different browser.



- 6. Proceed to complete the required forms, perform validations, and submit the application using the normal ASSIST functionality. See the links below for more information:
 - Non-Research Forms Overview
 - Component Forms
 - Form and Field Level Validations
 - Validate Application
 - Update Submission Status
 - Submit Application

7 Validating the Application

IMPORTANT: This topic is applicable only to multi-project applications.

Before an application can be submitted, it must pass various system and business validations at both the overall application and individual component levels. Validation checks are triggered automatically whenever the status of the application or component is updated by an ASSIST user; however, validation checks can also be run manually if chosen. ASSIST users can choose to validate the entire application or individual components as desired. To validate the entire application, a user must have the Entire Application Editor - All (both Budget and Non-Budget) Access level. To validate a component, a user must have the Editor - All (both Budget and Non-Budget) Access level for that component. Refer to the help topic titled *Manage Access*

7.1 Validating the Entire Application

To perform validations on the entire application:

- 1. Select the **Return to Application Info** button on the **Actions** panel to return to the *Application Information* page.
- 2. Navigate to the *Application Information* page.
- 3. Select the Validate Application button under Actions.



The system begins validating the application. If there are errors or warnings, they are listed on the *Application Errors and Warnings Results* page, which opens as a separate window. Errors must be corrected before the application can be submitted.

With no errors or warnings, a message displays as follows: *No errors or warnings were found*.

NOTE: ASSIST does not perform validations on components in *Abandoned* status.

Refer to the help topic titled *Application Errors and Warnings Results* for information on displayed errors and warnings.

7.2 Validating an Individual Component

To perform validations on an individual component:

- 1. Navigate to the appropriate component by expanding it and selecting it from the **Component Type** section of the left-side navigation panel.
- 2. Select the Validate Component button under Actions.



The system begins to validate the Component. If there are errors or warnings, they are listed on the *Application Errors and Warnings Results* page, which opens as a separate window.

ASSIST cannot perform all validation checks on the application if required components or required forms are missing. When this occurs, error messages to this effect display on the *Application Errors and Warnings Results* page.

If no errors exist and no warnings are necessary, a message displays as follows: *No errors or warnings were found*.

IMPORTANT: If you experience difficulties with the **Validation** function, it may be due to your browser having a pop-up blocker enabled. To correct this, please ensure you

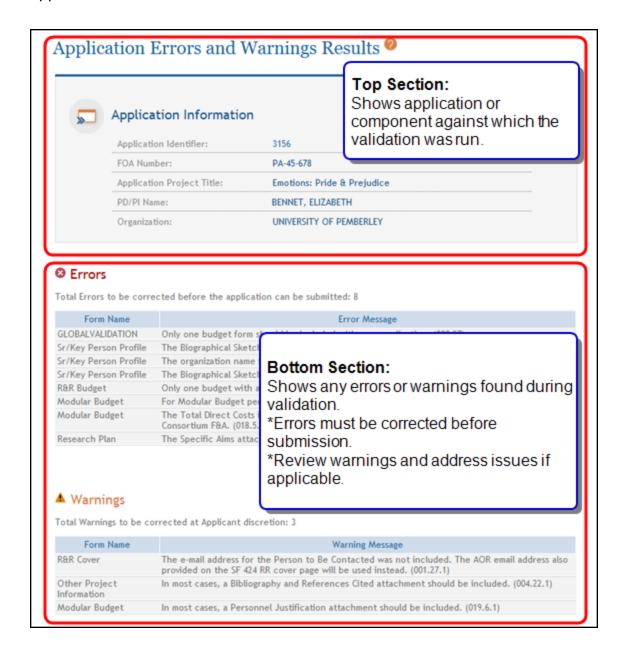
include an exception into your browser's security settings, listing the URL as: *.nih* to allow popups from the NIH.

8 Application Errors and Warnings Results

When an application (or component of a multi-project application) fails validation, any errors and warnings are listed on the Application Errors and Warnings Results page, which opens as a separate window.

At the top portion of the page, ASSIST displays the application (or component) against which the validation was run.

The bottom portion of the page displays the errors or warnings found during validation. While warnings should be reviewed, errors must be addressed in order for an application to be submitted.



The information on this screen includes:

• Component ID & Title (multi-project applications only)

For multi-project applications, lists the component (Overall or other) for which the error or warning exists

Form Name

Lists the form containing the field prompting the error or warning

Error Message

Explains the issue causing the error or warning

The information in the sections for errors and warnings is sortable by selecting the up/down arrows next to the table headings. Selecting the arrows sorts the information in numeric or alphabetic order based on the column heading selected.

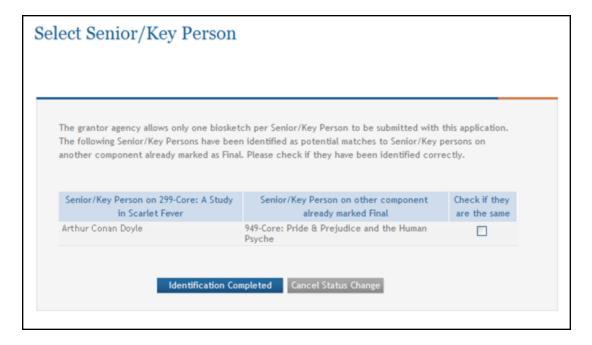
9 Verify Senior/Key Personnel

ASSIST allows a biosketch to be uploaded for each senior/key person entry on a complex application. Only one biosketch may be submitted per senior/key person in the final application, even if that person is on multiple components within the application.

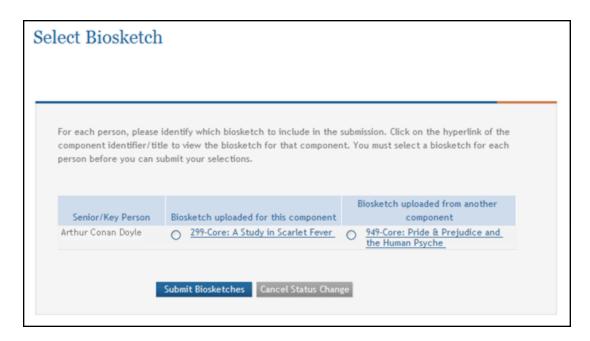
Upon updating a component to *Final* status, ASSIST checks to see whether a biosketch for a senior/key person exists on another component marked as *Final*. If a user has added two or more biosketches for the same Senior/Key Person, ASSIST requests that one of them be selected as the biosketch to include with the application.

ASSIST considers senior/key person entries to be the same person if the Senior/Key Person Profile or PD/PI Profile Credentials match. If senior/key person entries exist where credentials are not provided for both entries, then ASSIST considers senior/key persons to be a potential match if the First Name, Last Name, and Organization Name match.

When ASSIST finds that a bio-sketch for a senior/key person on the current component being set to *Final* potentially matches another senior/key person with a bio-sketch on an existing *Final* component, the Select Senior/Key Person page displays prompting you to indicate whether these are the same person before prompting you to choose which biosketch to use.



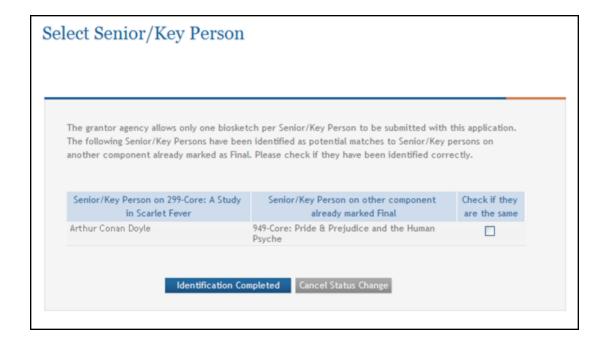
Conversely, if ASSIST determines that the persons are a definite match, based on the same entered credentials, the system does not require you to indicate if the persons are the same, and automatically displays the Select Biosketch page instead.



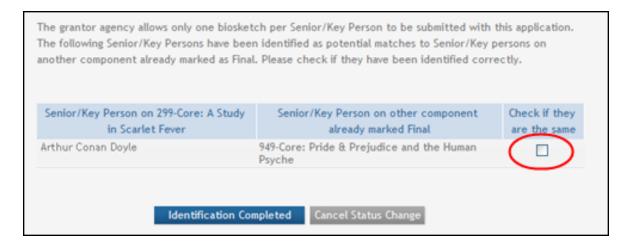
The steps for completing both pages are detailed in the sections that follow.

9.1 ASSIST Identifies Potentially Matched Persons

When ASSIST identifies two key persons as a potential match, the Select Senior/Key Person page displays. The page includes a table displaying the senior/key person of the current component (being marked as *Final*) next to the component previously marked as *Final* containing the potentially same senior/key person.

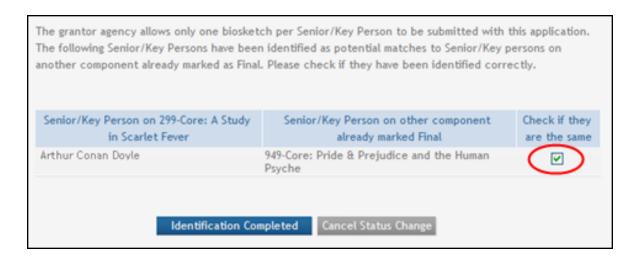


1. If the listed senior/key persons are different, leave the Check if they are the same checkbox unchecked.



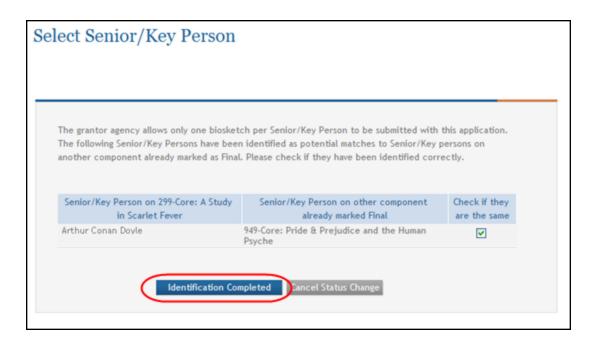
-OR-

If the listed senior/key persons are the same person, click the **Check if they are the same** checkbox to place a checkmark in the box.

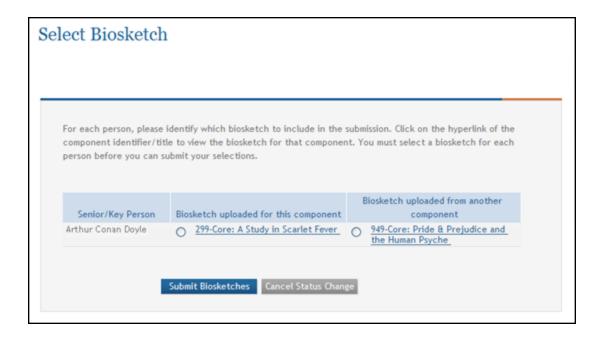


NOTE: To cancel the action without completing the identification, click the **Cancel Status Change** button and the **Continue** button on the subsequent confirmation pop-up message. Selecting the cancel option results in the biosketch selections not being saved and the component not being updated to *Final*.

2. Select the Identification Completed button.



The Select Biosketch page displays.

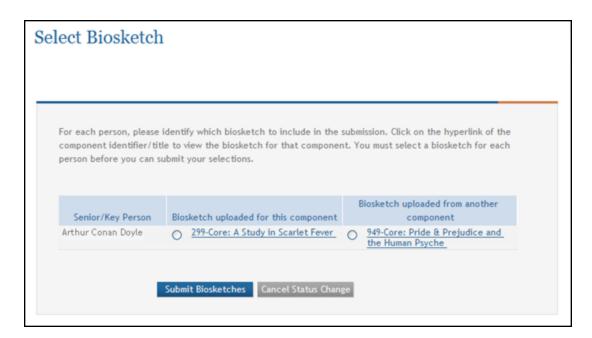


3. Continue with the steps detailed below to complete the Select Biosketch page.

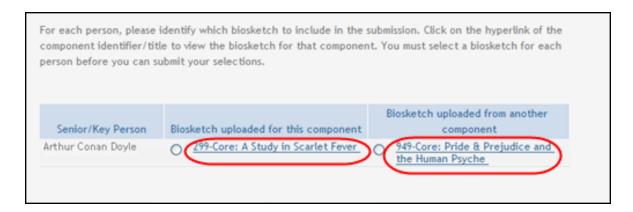
9.2 ASSIST Determines that Persons are a Match

ASSIST displays the Select Biosketch page after you indicate that potentially matching senior/key persons are the same person (on the *Select Senior/Key Person* page) -OR-when ASSIST determines that two senior/key persons have the same credentials and

are therefore a match. This page lists the senior/key person and the titles of the components containing biosketches for that person. The biosketches are viewable by clicking the component title, which is displayed as a link.



Optional: Select the component title link listed under Biosketch uploaded for this
component column to view the biosketch for the current component being
updated as Final or the component title link listed under Biosketch uploaded
from another component column to view the biosketch for the component
previously set to Final status.

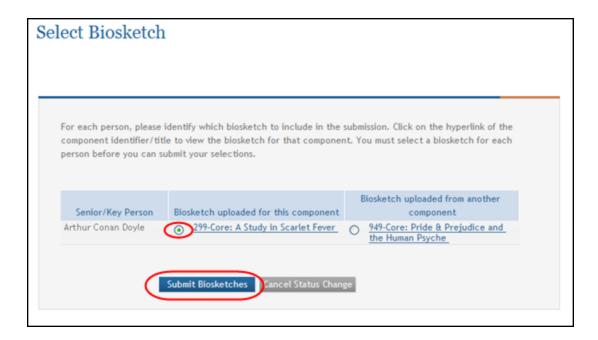


2. Select the biosketch to include in the application by either clicking the radio button for the current component or the radio button for the previously finalized component. Selecting the current component indicates that the biosketch for the

component being finalized should be used for the application, and the other one removed. Selecting the previously finalized component's radio button indicates that the biosketch on the component previously set to *Final* status should be used, and the one on the current component should be removed.

NOTE: Select the **Cancel Status Change** button to cancel the action without selecting a biosketch. Selecting the cancel option results in the biosketch selection not being saved and the component status not being updated to *Final*.

3. Select the **Submit Biosketches** button to complete the selection of which biosketch to submit with the application.



The unselected biosketch is removed from the Senior/Key Personnel form the corresponding component.

10 Application Submission

When an application is complete, it needs to be submitted to the offering agency using the submit feature in ASSIST. An application can be submitted when it passes all validations and the status of the application is *Ready to Submit*. Only ASSIST users with the appropriate privileges can submit an application.

Refer to the help topic titled *Validating the Application* for information on performing validations.

Refer to the help topic titled *Update Application Submission Status* for information on updating the status of an application.

10.1 Submit the Application

Users with the proper privileges may electronically submit the application via ASSIST. In order for an application to be submitted, the application status must be *Ready for Submission*. An application can only be updated to *Ready for Submission* status when it has passed all system and business validations.

Refer to the steps below for submitting either a multi-project application or a single-project application as appropriate.

10.1.1 Submitting Multi-Project Applications

To prepare a multi-project application for submission:

- 1. Verify that at least one component of the application is in *Final* status and that the other components are in either *Final* or *Abandoned* status.
- 2. Verify that the status of the application is *All Components Final*.
- 3. Perform validations against the application using the **Validate Application** button from the **Actions** section.
 - When an application passes validations, its status is updated to *All Components Validated*
- 4. Update the application to *Ready for Submission* using the **Update Submission Status** button from the **Actions** section.

To submit an application:

Only a Signing Official for the Applicant Lead Organization, who is an Authorized Organizational Representative, can submit the application.

- With the application in Ready for Submission status, select the Submit
 Application button from the Application Information screen. The button is located next to the Status field and is only enabled when the application is in Ready for Submission status.
 - ASSIST prompts the user for the Grants.gov Authorized Organization Representative (AOR) credentials.
- 2. Enter the AOR credentials in the **Username** and **Password** fields and select the **Enter** button.

NOTE: These are the Grants.gov credentials and <u>not</u> the ASSIST or eRA Commons credentials.

The information is passed from ASSIST to the Grants.gov system for further processing. In ASSIST, the application is updated to a status of *Submitted*. The dates and times of the submission are recorded. These details can be viewed in the *View Status History* page. In addition, ASSIST sends notification to the appropriate parties to inform them that the application has been submitted. This includes the SO and PD/PI.

10.1.2 Submitting Single-Project Applications

To prepare an application for submission:

- 1. *Optional:* Perform validations against the application using the **Validate Application** button from the **Actions** section.
- 2. Update the application to *Ready for Submission* using the **Update Submission Status** button from the **Actions** section.
- 3. Optional: Provide a comment if desired.

To submit an application:

Only a Signing Official for the Applicant Lead Organization, who is an Authorized Organizational Representative, can submit the application.

 Update the application to Ready for Submission using the Update Submission Status button from the Actions pane.

ASSIST perform validations when the status is updated. If the application fails validation, any errors and warnings are listed on the *Application Errors* and

Warnings Results page, which opens as a separate window. Errors must be corrected before submitting the application.

IMPORTANT: Although you may submit your application with existing Warnings, please make sure to review all warnings and correct the necessary items.

2. With the application in *Ready for Submission Status*, select the **Submit Application** button from the **Actions** area.

ASSIST prompts you for the Grants.gov Authorized Organization Representative (AOR) credentials.

3. Enter the AOR credentials in the **Username** and **Password** fields and select the **Enter** button.

NOTE: These are the Grants.gov credentials and <u>not</u> the ASSIST or eRA Commons credentials.

The information is passed from ASSIST to the Grants.gov system for further processing. In ASSIST, the application is updated to a status of *Submitted*. The dates and times of the submission are recorded. These details can be viewed in the *View Status History* page. In addition, ASSIST sends notification to the appropriate parties to inform them that the application has been submitted. This includes the SO and PD/PI.

See Also

- Update Component Status
- Update Application Submission Status
- Validating the Application
- View Submission Details

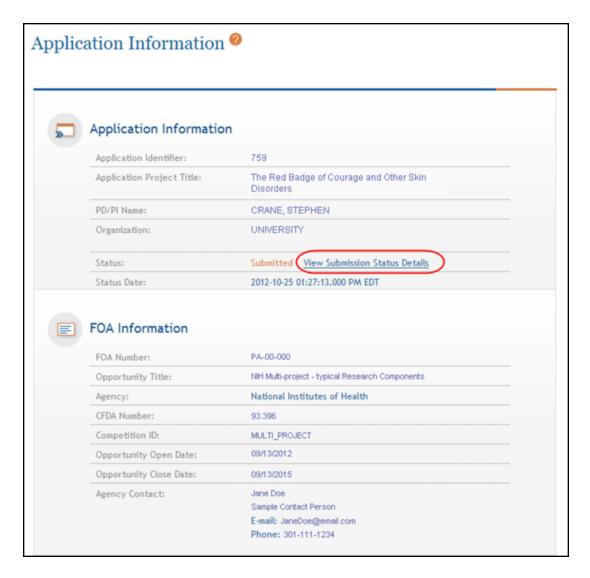
10.2 View Submission Details

After submitting an application to agency, ASSIST users may view the status details of the application. To view these details:

1. Perform a search to locate and select the application.

The Application Information page displays general information including the application Status. The Grants.gov Tracking # will be displayed in the Application Information Summary after Grants.gov has received the submission.

2. Select the View Submission Status Details link located next to the Status of the application.



The submission status details display for ASSIST, Grants.gov, and the Agency.



Application Information

Application information is displayed above the submission status details. This information includes:

Application Identifier

This field displays the unique identifier of the application in ASSIST.

FOA Number

This field displays the Funding Opportunity Announcement number associated with the application.

Project Title

This field displays the title of the project associated with the application.

PD/PI Name

This field displays the name of the Contact PI for the application.

Organization

This field displays the lead organization for the application.

Grants.gov Tracking

This field displays the Grants.gov tracking number. This field is blank if the Grants.gov has not yet received the application.

Last Status Check

This field displays the date and time of the most recent successful request to check the status, either by a user or by the system.

Check for Status Updates button

This button is used to perform an update of the status details.

ASSIST

ASSIST Status details include the following:

Submission Date

This field displays the date and time at which the application was submitted in ASSIST.

Submitting AOR

This field displays the name of the ASSIST user who submitted the application, based on the AOR credentials entered upon submission.

ASSIST Submission Status

This is the ASSIST status of the application.

Submission Status Date

This field displays the date and time at which the latest submission status update occurred.

Grants.gov

If information is available, Grants.gov status details include the following:

View Grants.gov Submission Errors link

This link displays if there are submission errors detected at Grants.gov. Select the link to view a list of errors and warnings from Grants.gov.

Grants.gov Tracking

This field displays the Grants.gov tracking number. This field is blank if Grants.gov has not yet received the application.

Grants.gov Received Date

This field displays the date and time at which Grants.gov received the application.

Grants.gov Processing Status

This field displays the latest Grants.gov application processing status.

Grants.gov Status Date

This field displays the date and time at which the latest Grants.gov status update occurred.

Agency

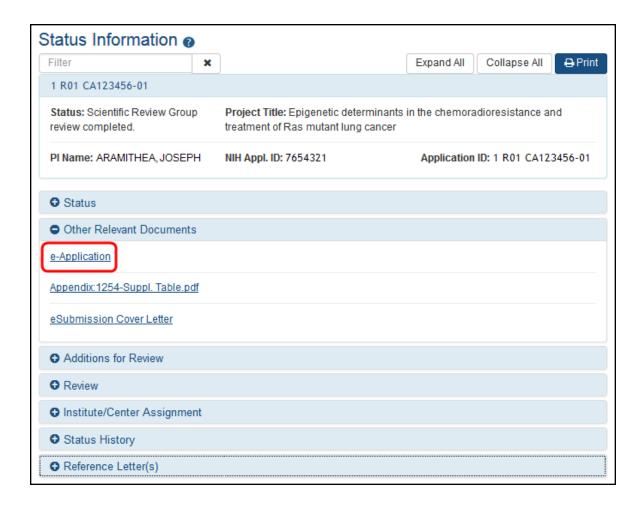
If information is available, Agency status details include the following:

View Agency Submission Errors and Warnings link

This link displays if there are submission errors and/or warnings detected at the grantor Agency. Select the link to view a list of errors and warnings from the grantor Agency.

Agency Tracking

This field displays the unique identifier for the application given by the grantor Agency upon receipt of the application. Selecting the tracking number hyperlink opens the eRA Commons Status Information screen, from which you can view the agency generated application (e-Application) under the *Other Relevant Documents* section.



NOTE: If you are an unauthorized user, you will receive an error message when you attempt to access the link.

Agency Status

This field displays the latest grantor Agency application processing status.

Agency Status Date

This field displays the date and time at which the latest grantor Agency status update occurred.

See Also

View Post-Submission Errors

You are here: Application Submission > View Post-Submission Errors

Revised 3/24/2016

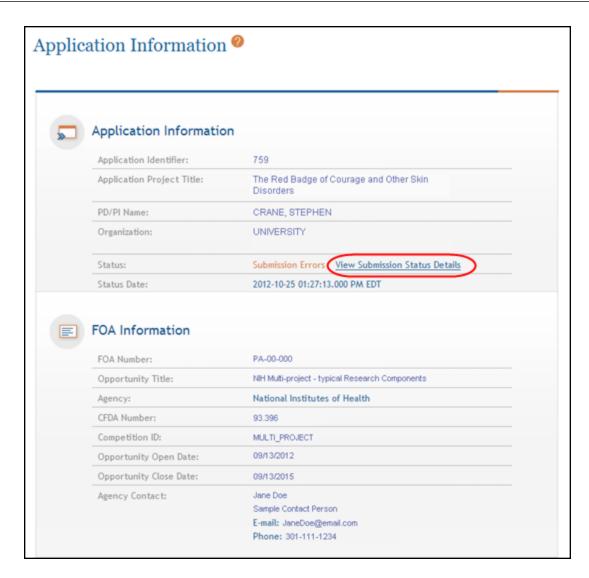
Refer to the <u>Application Submission System & Interface for Submission Tracking (ASSIST) User Guide</u> for a complete PDF version of this help.

10.3 View Post-Submission Errors

When an application is submitted, the offering agency performs certain validations against the application. If errors exist, the application is put into a status of *Submission Errors*. ASSIST users with the proper authority can view these errors and make corrections before re-submitting the application to the Agency.

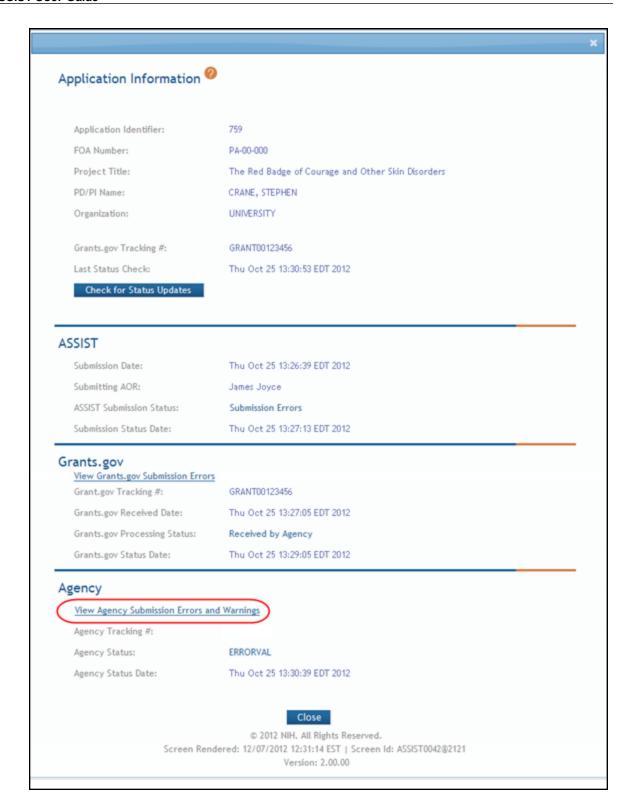
The errors and warnings returned by the Agency and Grants.gov are viewable from the status detail page for the application. To view post-submission errors on an application:

- 1. Perform a search to locate and select the application.
- 2. Select the View Submission Status Details link in the **Status** field of the *Application Information* page.



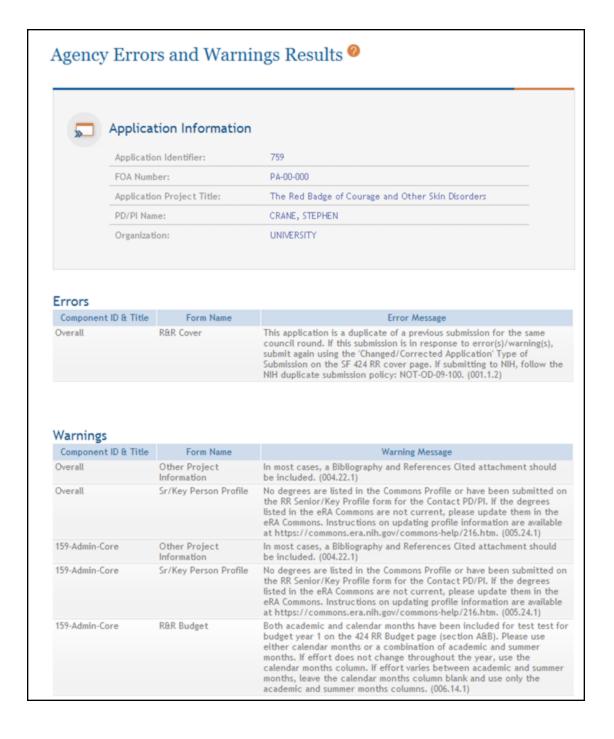
The application status details display in a separate window. Refer to the help topic titled View Submission Details for information about this page. When Grants.gov post-submission errors exist, the View Grants.gov Submission Errors link displays. If Agency errors and warnings exist, the View Agency Submission Errors and Warnings link displays.

3. Select the appropriate link to view the errors and warnings.



10.3.1 Agency Errors and Warnings Results

The Agency Errors and Warnings Results page shows errors and warnings detected during application processing by the grantor Agency. The page is divided, showing Application Information on the top and separate sections for Errors and Warnings beneath. Errors must be corrected before the application can be re-submitted to Agency. Applications can be submitted when warnings exist, but those warnings should be reviewed and considered.



The **Errors** and **Warnings** tables include the following fields:

• Component ID & Title (multi-project applications)

This is the component of the multi-project application for which the error or warning was detected

Form Name

This is the specific form on which the error or warning was detected.

Error Message or Warning Message

This is the error or warning message. For errors, this message contains details for the error with guidance for resolving the issue. For warnings, this message provides further explanation of the warning.

10.4 Revise a Submitted Application

ASSIST users with the authority to edit an entire application may revise an application even after it has been submitted. This is necessary when an application is in *Submission Errors* or *Agency Errors* status and needs to be corrected and re-submitted.

To revise and resubmit an application:

1. From the *Application Information* page select the **Update Submission Status** button from the **Action** list.

The *Update Status* window displays.

- 2. Select the **Work in Progress** status from the **Select the new status** drop-down list.
- 3. Complete the status update:
 - a. Enter a comment in the provided text box.
 - b. Select the **Add comment** button.

-OR-

- c. Select the link titled **or continue without adding a comment** to update the status without entering a comment in the provided text box.
- 4. Select the component needing revision from the **Component Type** section of the page.
- 5. Select the **Update Component Status** button from the **Actions** section of the page.

6. Update the status of the component to **Work in Progress** by selecting it from the drop-down box, entering comments, and selecting the **Add Comment** button.

Once the status of the component is *Work in Progress*, the appropriate component form (s) can be updated. Navigate to the appropriate forms, make the changes, and re-submit the application. Refer to the help topic titled *Submit the Application* for information on submitting the application.