### eRA Instruction Guide for EPPIC-Net OTA Submission

Use these instructions, together with the forms and information found in the EPPIC-Net application packet to complete your application. The EPPIC-Net website and information packet include specific instructions, forms and the Research Opportunity Announcement (ROA) number (see the section labeled "How to apply to EPPIC-Net" on the EPPIC-Net Application Packet information sheet) needed for your application submission.

Please Note: Only requested attachments should be uploaded to eRA Commons.

\*Applications found to include materials not specifically requested will be administratively withdrawn.\*

#### **Prepare to Apply**

NIH typically makes awards to organizations, not individuals. At the time of submission, the Program Director/Principal Investigator (PD/PI) and their organization must be registered at <a href="mailto:eRA Commons">eRA Commons</a>. In addition to the PD/PI, an individual with the role of Signing Official (SO) is needed. If an application is awarded, additional registrations (e.g. <a href="mailto:System Award Management">System Award Management</a>) will be required.

At each stage, EPPIC-Net applications must be submitted using NIH's <u>ASSIST</u> web-based application submission system. Users can access ASSIST directly or through eRA Commons. Registration in SAM or Grants.gov is NOT required. To complete the application, users must have access to a browser, a pdf generator, and Adobe Reader software.

Log into ASSIST using eRA Commons credentials (username and password)



# Initiating the Application

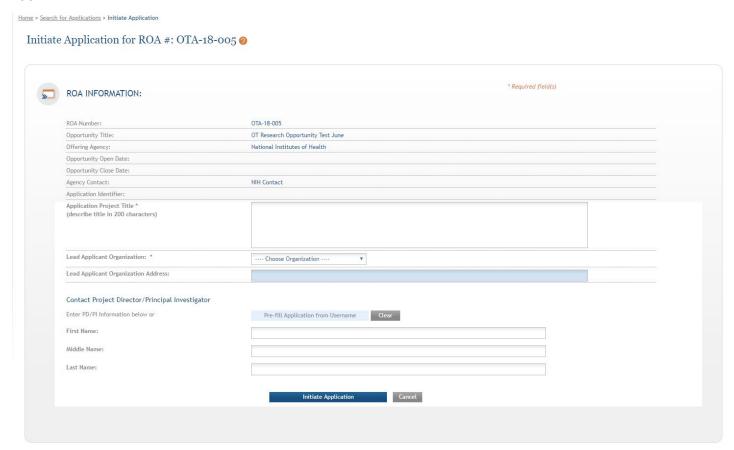
On the ASSIST Welcome screen, enter the OTA ROA number provided in the packet and on the EPPIC-Net website in the "Funding Opportunity Announcement" # field and then click 'Go'. The format should be OTA-XX-XXX.



The Initiate Application screen contains several required elements: At a minimum the Application Project Title must be entered, and the Lead Applicant Organization must be selected from the drop-down menu.

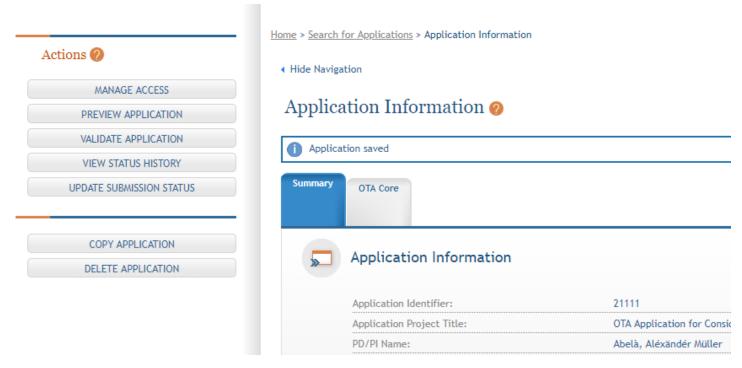
The Contact PD/PI fields may be pre-filled from Commons Username using the button or entered manually. These fields will be available to edit in the application once it has been initiated.

Once required fields have been satisfied, press the "Initiate Application" button to create an application record.



#### **Navigating the Application**

Each application in ASSIST receives a unique Application Identifier at creation (21111 in the example below). This value is displayed on the Application Information Summary page and can be used as a search key on the Search for Applications screen if returning to work on the application at a later time.



Actions are available on the left-hand side of the screen. The Summary screen and any constituent forms in the application are loaded as tabs to the right of the action menu.

Navigate to the OTA Core form by clicking the grey tab for the form. The currently active tab will be highlighted in blue.

# Completing the Application Form

All fields marked by an asterisk (\*) are required. In the UAT environment, the DUNS is listed as a required field but the asterisk can be ignored.

All attachments should be in the format of a PDF file.



Click on "Edit" button to begin data entry. In the "edit" mode, data entry by other users is blocked until the lock-holder either releases the lock or it expires.

At the bottom of the form there are several saving options:

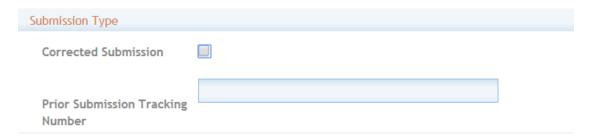


Save and Keep Lock: saves data and restricts data entry access to current user

Save and Release Lock: saves data and releases form to other users

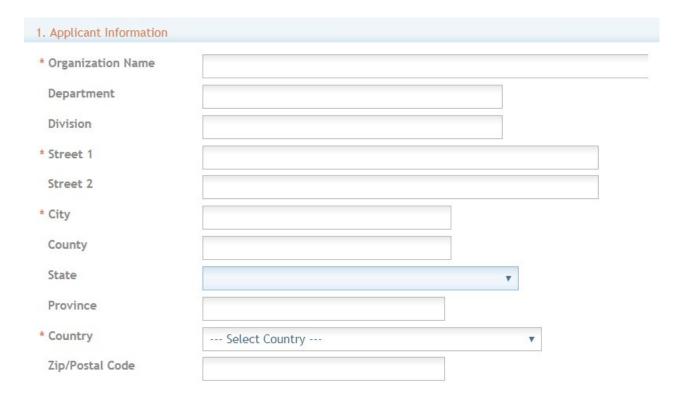
Cancel and Release Lock: does not save data and releases form to other users

Submission Type: If the application is being resubmitted after correcting errors/warning, check "Corrected Submission" and enter prior submission tracking number as it appears in the footer of the prior submission.



Application Type: All applications should be entered as "New" Applications. Do NOT check the "Resubmission" box even if the asset has previously been submitted as part of a prior EPPIC-Net Preliminary Application.

# 1. Applicant Information



Organization Name: This field is required. Enter the name of the organization for the SO

Contact and Address fields: Enter the field data for the Applicant Organization as each label indicates. The Organization Name, Street 1, City, and Country are required fields. The State and ZIP/Postal Code fields will become required upon Country selection of United States. Note that ZIP/Postal Code must be entered in ZIP+4 (nine-digit postal code) format. Province is enabled for all non-US countries and required for Canada.

2. Employer Identification (EIN) or (TIN): Enter either the organization's Taxpayer Identification Number (TIN) or Employer Identification Number (EIN) as assigned by the Internal Revenue Service. If your organization is not in the United States, enter 44-4444444. Your EIN may be 12 digits, and if this is the case, enter all 12 digits. In the UAT environment you can enter 0s.

2. Employer Identification (E	IN) or (TIN)
Employer Identification	
3. Descriptive Title Of Applic	ant's Project
* Descriptive Title of Applicant's Project	
4. Project Period	
Start Date	
End Date	

- 3. Descriptive Title of Applicant's Project: This field is required. The descriptive title is limited to 200 characters, including spaces and punctuation.
- 4. Project Period: This is not a required field for EPPIC-Net applications. Applicants may elect to leave the project period field blank.

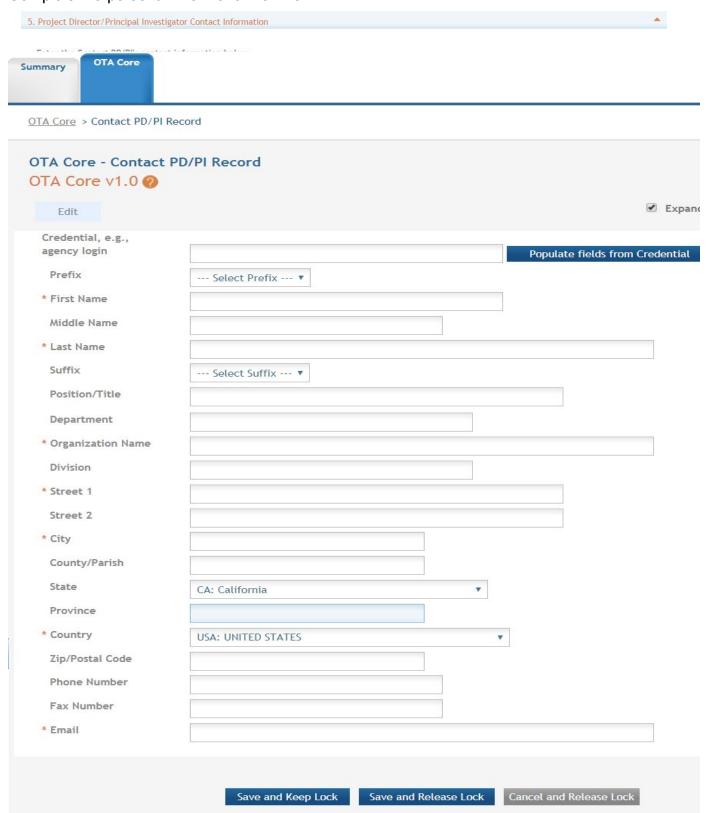
The Start Date is an estimate. The project period should not exceed what is allowed in the ROA.

The End Date is an estimate and must occur in the future of the Start Date.

5. Project Director/Principal Investigator (PD/PI) Contact Information.

You should save the data before editing PD/PI data. If not, it will ask you to save it to continue.

The PD/PI is the individual responsible for the overall scientific and technical direction of the project. Complete the personal information for the PD/PI.



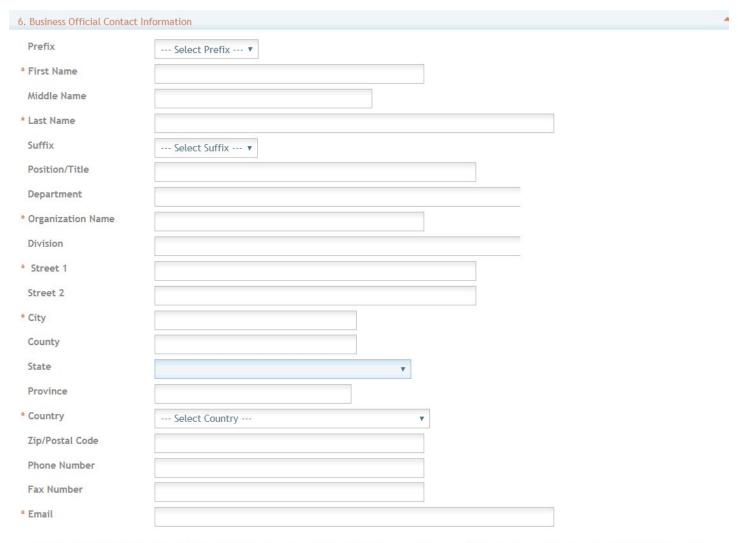
In the eRA Commons profile, the person listed here must be affiliated with the applicant organization entered in "1. Applicant Information". A commons ID is required for the PD/PI.

If submitting an application with multiple PD/PIs, the main or primary PD/PI should be entered in the first or top section as the Contact PD/PI. The "Add Additional PD/PI" button may be used to add other PD/PIs. Following data entry, the user may "Edit" or "View" the PD/PI entries; Additional PD/PI entries can also be individually removed from the application. Additional PIs are not required to have a Commons ID.

Contact and Address fields: Enter the field data for the PD/PI as each label indicates. The Organization Name, Street 1, City, and Country are required fields. The State and ZIP/Postal Code fields will become required upon Country selection of United States. Note that ZIP/Postal Code must be entered in ZIP+4 (nine-digit postal code) format. Province is enabled for all non-US countries and required for Canada.

Following data entry, Save changes. To return to the main form use 'Save and Release Lock' or click the 'OTA Core' breadcrumb under the blue 'OTA Core' form tab.

6. Business Official Contact Information



By signing this application, I certify (1) to the statements contained in the list of certifications\* and (2) that the statements herein are true, complete and accurate to the best of my knowledge. I also provide the required assurances\* and agree to comply with any resulting terms if I accept an award. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. (U.S. Code, Title 218, Section 1001)
\*\* I agree

#### Complete the information for the Business Official Contact.

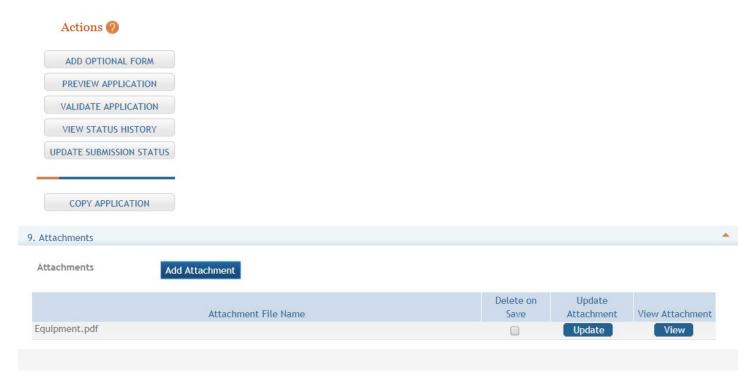
Contact and Address fields: Enter the field data for the Business Official as each label indicates. The Organization Name, Street 1, City, Country, and Email are required fields. The State and ZIP/Postal Code fields will become required upon Country selection of United States. Note that ZIP/Postal Code must be entered in ZIP+4 (nine-digit postal code) format. Province is enabled for all non-US countries and required for Canada.

Assurances: The applicant organization is responsible for verifying its eligibility and the accuracy, validity, and conformity with the most current institutional guidelines of all the administrative, fiscal, and scientific information in the application, including the Facilities and Administrative rate. Deliberate withholding, falsification, or misrepresentation of information could result in administrative actions, such as withdrawal of an application, suspension and/or termination of an award, debarment of individuals, as well as possible criminal and/or civil penalties. The signer further certifies that the applicant organization will be accountable both for the appropriate use of any funds awarded and for the performance of the grant-supported project or activities resulting from this application. The grantee institution may be liable for the reimbursement of funds associated with any inappropriate or fraudulent conduct of the project activity.

7. Estimated Project Funding: This is not a required field for EPPIC-Net applications. Applicants may choose to leave the Estimated Project Funding field blank, enter \$0, or enter the estimated amount needed to fund their proposed project. As a reminder, EPPIC-Net funds will not be awarded to the applicant; funding for EPPIC-Net projects will be awarded to the Clinical Coordinating Center and distributed to the Hub trial sites to conduct the funded trial.

7. Estimated Project Funding	(\$)				*
Total Funds Requested					
8. Cover Letter					*
Cover Letter		Add Attachment	Delete Attachment	View Attachment	

- 8. Cover Letter: The cover letter should include the application title and is for internal use only. In the cover letter please note if there are any special considerations or explanatory details regarding the submission of the application, including whether a specific area of scientific expertise would be helpful in reviewing the application. Please also list any companies or individuals you believe would be in conflict with the review of your asset. Do NOT recommend or request individual reviewers; only identify individuals or companies you believe to be in conflict. Please limit the cover letter to 250 words. The cover letter should be submitted as a PDF file (see "Attachments" below).
- 9. Attachments: Only upload requested attachments. Please do not upload additional materials.
  \*Applications found to include materials not specifically requested will be administratively withdrawn.
  \*Applications found to be missing specifically requested materials will be administratively withdrawn.
  Attach files using the "add attachment" button. Attachments should be in the format of a PDF file.
  Each attachment should have a unique file name. To delete an uploaded attachment, check 'Delete on Save' and the file will be removed upon next save. Individual attachments can be replaced or updated by clicking the 'Update' button of the corresponding row. Three attachments should be uploaded to complete the preliminary application process: (1) a cover letter (described above), (2) the fillable PDF "EPPIC-Net Preliminary Asset Application," and (3) a statement of support from the asset owner documenting that the applicant has permission to access and use the asset in the proposed study. All applications must include all three attachments, including a Statement of support (3); applications found to be lacking any of the attachments will be administratively withdrawn. Please do not upload additional attachments; applications found to be including materials not specifically requested will be administratively withdrawn.

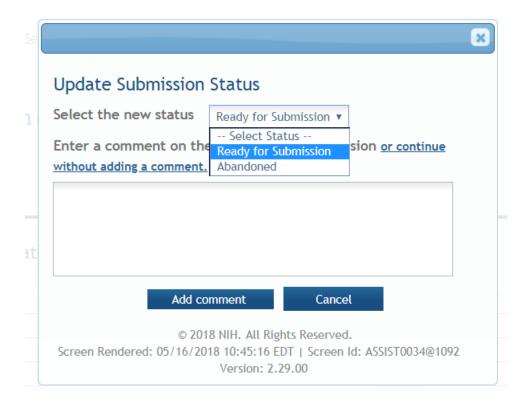


### Submitting your Application

Validating your application: Select "Validate Application" from the left-hand panel to check your application for business errors and warning. Errors must be corrected prior to submission. Warnings will not stop or prevent your application from being submitted.

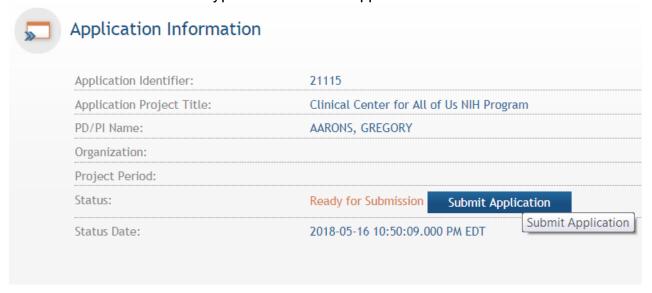
Preview Application: presents the PDF version of the application. This is a view of the assembled image nearly identical to what the reviewers/evaluators will assess.

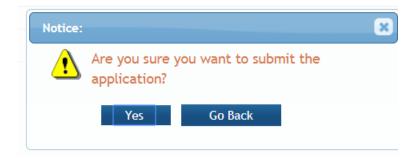
Update Submission Status: Prior to submission, the status must be updated to "Ready for Submission" which will also perform additional validations against business errors prior to changing the status. Click "Add Comment" or "continue without adding a comment" to continue.



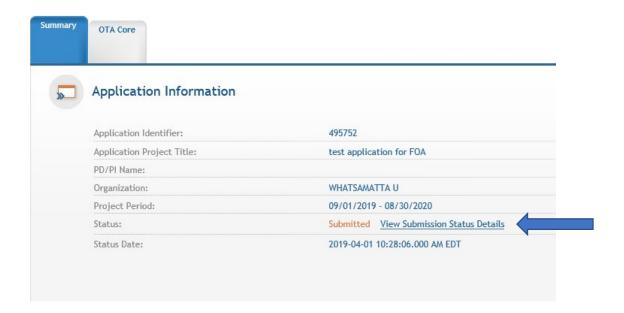
#### Submission

Once the application has been placed in "Ready for Submission" status, the Signing Official will be able to click "Submit Application". After a confirmation that the SO does wish to submit the application, it will be sent to NIH for processing. The status can be viewed and updated by clicking the "View Submission Status Details" hyperlink next to the application status.





Follow the status of your submission in eRA Commons by clicking status detail button



This will take you to the submission status. You can click on the accession (agency tracking) number (e.g., 4271519) to access the application in eRA Commons.

