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Applications found to include materials not specifically requested will be administratively withdrawn.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 <u>eRA Commons</u>. 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. <u>System Award Management</u>) 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)

Application Sul Tracking (ASSI Sponsored by the National	omission System & Interface for Submission ST) al Institutes of Health
14	
Login	Note: Effective March 22, 2018: If you are registering a new entity in SAM.gov, you must provide an original, signed notarized letter stating that you are the authorized Entity Administrator before your registration will be activated. Read FAOs to learn more about this process change.
User Name	Note: When application and grant reporting submission delays occur because the applicant or recipient organization is officially closed due to a natural disaster or other emergency, the NIH will consider accepting
Password	late applications and reports, on a case-by-case basis. Please reference notice <u>NOT-OD-17-106</u> in the NIH Guide for Grants and Contracts for additional details.
Login Cancel Forgot Password/Unlock Account?	Submit grant applications electronically to NIH and other Public Health Service Agencies

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.

Application Submission Sponsored by the National Institutes	on System & Interface for Submission Tracking (ASSIST) sof Health
	2 a Mines Maria M
Welcome	Welcome to the Application Submission System & Interface for Submission Tracking (ASSIST)
	INITIATE APPLICATION Funding Opportunity Announcement # (Example: PA-XX-XXX or LITC-ABCD-XX-000) The National Institutes of Health posts Funding Opportunity Announcements (FOAs) in the <u>NIH Guide for Grants & Contracts</u> and in <u>Grants.gov's Search Grants</u> . Each resource has robust search functionality to identify opportunities of interest. ASSIST can only be used to prepare and submit applications when explicitly stated in the FOA.
	SEARCH FOR APPLICATION Search Applications

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.

ROA INFORMATION:	* Required field(s)
ROA Number:	OTA-18-005
Opportunity Title:	OT Research Opportunity Test June
Offering Agency:	National Institutes of Health
Opportunity Open Date:	
Opportunity Close Date:	
Agency Contact:	NIH Contact
Application Identifier:	
(describe title in 200 characters)	
Lead Applicant Organization: *	···· Choose Organization ···· v
Lead Applicant Organization Address:	
Contact Project Director/Principal Investigato	r
Enter PD/PI Information below or	Pre-fill Application from Username Clear
First Name:	
Middle Name:	
Lines Manager	

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.

	Home > Search for Applications > Application Information	1
Actions 🕖	Hide Navigation	
MANAGE ACCESS		
PREVIEW APPLICATION	Application Information 🤣	
VALIDATE APPLICATION	Application saved	
VIEW STATUS HISTORY		
UPDATE SUBMISSION STATUS	Summary OTA Core	
COPY APPLICATION	Application Information	
DELETE APPLICATION		
	Application Identifier:	21111
	Application Project Title:	OTA Application for Consid
	PD/PI Name:	Abelà, Aléxändér Müller

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.

	Home > Search for Applications > Application Search Results > Application Information
Actions 🕖	 Hide Navigation
RETURN TO APPLICATION	Application Information
MANAGE ACCESS	Application mormation 🥹
PREVIEW CURRENT FORM	Summary OTA Core
VALIDATE APPLICATION	
VIEW STATUS HISTORY	
UPDATE SUBMISSION STATUS	NIH Other Transaction Application Form
	OTA Core v1.0 🚷
COPY APPLICATION	Edit
DELETE APPLICATION	Submission Type

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:



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.

Submission Type	
Corrected Submission	
Prior Submission Tracking Number	

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

1. Applicant Information		
* Organization Name		
Department		
Division		
* Street 1		
Street 2		
* City		
County		
State	•	
Province		
* Country	Select Country	×
Zip/Postal Code		

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.

 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.

5. Project Director/Principal Investigate	or Contact Information	*
Summary OTA Core	,	
OTA Core > Contact PD/PI Red	cord	
OTA Core - Contact Pl OTA Core v1.0 @	D/PI Record	🕑 Expand
Credential, e.g.,		
agency login	Populate fields from	Credential
Prefix	Select Prefix 🔻	
* First Name		
Middle Name		
* Last Name		
Suffix	Select Suffix 🔻	
Position/Title		
Department		
* Organization Name		
Division		
* Street 1		
Street 2		
* City		
County/Parish		
State	CA: California	
Province		
* Country	USA: UNITED STATES	
Zip/Postal Code		
Phone Number		
Fax Number		
* Email		
	Save and Keep Lock Save and Release Lock Cancel and Release Lock	Contract (1) (1) (1) (1) (1) (1) (1) (1) (1) (1)

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

6. Business Official Contact In	formation
Prefix	Select Prefix 🔻
* First Name	
Middle Name	
* Last Name	
Suffix	Select Suffix 🔻
Position/Title	
Department	
* Organization Name	
Division	
* Street 1	
Street Z	
County	
State	· · · · · · · · · · · · · · · · · · ·
Province	
* Country	Select Country v
Zip/Postal Code	
Phone Number	
Fax Number	
* Email	

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) **** | 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.

Check "I agree" to provide the required certifications and assurances.

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	(5)	
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.

Actions 🕗				
ADD OPTIONAL FORM				
PREVIEW APPLICATION				
VALIDATE APPLICATION				
VIEW STATUS HISTORY				
UPDATE SUBMISSION STATUS				
COPY APPLICATION				
9. Attachments				
Attachments Add	d Attachment			
	Attachment File Name	Delete on Save	Update Attachment	View Attachment
Equipment.pdf			Update	View

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.

Update Submission	Status
Select the new status	Ready for Submission 🔻
Enter a comment on the without adding a comment.	Select Status Ready for Submission Abandoned
Add co	omment Cancel

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.

>	Application Information		
	Application Identifier:	21115	
	Application Project Title:	Clinical Center for All of Us NIH Program	
	PD/PI Name:	AARONS, GREGORY	
	Organization:		
	Project Period:		
	Status:	Ready for Submission Submit Application	
	Status Date:	2018-05-16 10:50:09.000 PM EDT	



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

Application Information	
Application Identifier:	495752
Application Project Title:	test application for FOA
PD/PI Name:	
Organization:	WHATSAMATTA U
Project Period:	09/01/2019 - 08/30/2020
Status:	Submitted View Submission Status Details
Status Date:	2019-04-01 10:28:06.000 AM EDT

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.

