NIH Grant Application Preparation & Submission

Ready!  
Set!  
Submit!

Sheri Cummins & Laurie Roman

October 2016
How to Apply – Application Guide

General Application Process Information

Form & Field Instructions

Organization Registration

Your organization must be registered in multiple systems to submit. Start early – can take 6 weeks!

- **DUNS** – provides unique organization identifier
- **SAM** (System for Award Management) – needed to do business with government
  - Requires annual renewal
- **Grants.gov** – required to submit grants
- **eRA Commons** – required to do business with NIH
- **SBA** (Small Business Administration) – required for SBIR/STTR applications

## Understand Key Systems & Roles

<table>
<thead>
<tr>
<th>Grants.gov</th>
<th>eRA Commons</th>
</tr>
</thead>
<tbody>
<tr>
<td>• E-Business Point of Contact (EBiz POC)</td>
<td>• Signing Official (SO)</td>
</tr>
<tr>
<td>• Authorized Organization Representative (AOR)</td>
<td>• Principal Investigator (PI)</td>
</tr>
<tr>
<td></td>
<td>• Component leads on a multi-project application</td>
</tr>
</tbody>
</table>

NIH posts all funding opportunity announcements (FOAs) in:
- Grants.gov
- NIH Guide for Grants and Contracts

Take a tour of an annotated FOA for tips and key information

Section IV. Application and Submission Information includes announcement-specific instructions that may differ from the application guide instructions

Follow All Guidance

- Notices in the NIH Guide for Grants and contracts
- Funding Opportunity Announcement
  - Section IV. Application and Submission Information
- Application Guide
  - Including Supplemental Instructions
Avoid Common Errors: Format Attachments

- Use simple PDF-formatted files
  - Do not use Portfolio or similar feature to bundle multiple files into a single PDF
  - Disable security (e.g., password protection, encryption)
- Keep filenames to 50 characters or less
- Use meaningful filenames
- Do not include headers or footers
  - Section headings as part of the text (e.g., Significance, Innovation, Approach) are encouraged
- Follow guidelines for fonts and margins

## Avoid Common Errors: Follow Specified Page Limits

<table>
<thead>
<tr>
<th>Section of Application</th>
<th>Activity Codes</th>
<th>Page Limits * (if different from FOA, FOA supersedes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introduction to Resubmission and Revision Applications</td>
<td>For all Activity Codes (including each applicable component of a multi-component application)</td>
<td>1</td>
</tr>
<tr>
<td>Specific Aims</td>
<td>For all Activity Codes that use an application form with the Specific Aims section (including each component of a multi-component application)</td>
<td>1</td>
</tr>
<tr>
<td>Research Strategy</td>
<td>For Activity Code <strong>DF1</strong></td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>For Activity Codes <strong>R03, R13, U13, R13, U13, R21,R35, R36, R41, R43, SC2, SC3, X01</strong>, X02**, R50</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>For Activity Code <strong>DP2</strong></td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>For Activity Codes <strong>DP3, DP5, G08, G11, G13, RC2, RC4, RF1, R01,R15, R18, R21/R33, R24, R28, R33, R34, R42, R44, R61/R33, SB1, SC1, S12, U01, UC2, UH2,UH3, UG1, UC4, UF1, UG3/UH3, UH2/UH3, U01, U18, U24, U2C, U34, U42, U44, X01</strong>, X02**</td>
<td>12</td>
</tr>
<tr>
<td></td>
<td>For all other Activity Codes</td>
<td>Follow FOA instructions</td>
</tr>
<tr>
<td>Commercialization Plan</td>
<td>For Activity Codes <strong>R42, R44, SB1, UT1, U44, UB1</strong> (Attachment 7 on SBIR/STTR Information form)</td>
<td>12</td>
</tr>
<tr>
<td>Biographical Sketch</td>
<td>For all Activity Codes (including <strong>DF1</strong> and <strong>DF2</strong> which previously had special page limits)</td>
<td>5</td>
</tr>
</tbody>
</table>

* FOA instructions always supersede these instructions.

Avoid Common Errors: Use Format Pages

Format Pages

The Application Guide will direct you to attach a number of files to your application. Below you will find a comprehensive listing of the format pages you will use to include the requested information. You may create a page similar to any format provided as long as all the requisite information is included. You must convert all files to PDF format before including them in your application.

**Biosketches**
Prepare biographical sketches for applications and progress reports using these instructions, format pages, samples, and FAQs.

**PHS Inclusion Enrollment Forms**
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.

**Instructions for Submission of a Reference Letter**
Submit reference letters for mentored career development and individual fellowship awards directly into the eRA Commons.

**Data Tables**
Use data tables with Institutional Research Training grant applications.

**Additional Senior/Key Person Profile Format**
Use for applications requiring over 100 senior/key people.

**Additional Performance Site Format**
Use for applications requiring over 300 performance sites.

http://grants.nih.gov/grants/forms/format-pages.htm
Application Checks (Validations)

- We *really* care about the details

- Multiple levels of application checks for completeness
  - Grants.gov
  - eRA systems
  - Agency staff

On-time Submission

Error-free applications must be accepted by Grants.gov with a time stamp on or before 5:00 p.m. local time of the submitting organization on the due date.

Important reminders:

- **NIH recommends submitting early (days, not minutes!)** to allow time for correcting any errors found during the application viewing window prior to the due date.
- NIH’s late policy does not allow corrections after the due date.
- All registrations and SAM renewal must be completed before the due date.
Overview of Process

Find Opportunity

Initiate application

Enter application data

Submit

Make a submission plan

Define team and provide application access

Finalize application and prepare for submission

Track status and view final application image
Understanding the Structure of Multi-Project Applications
• Single Overall component
• Provides an overview of the entire application
Some number of additional **component types**

- Component types vary by opportunity
- Funding opportunity announcements indicate the types of components expected in a responsive application
Some number of components within a component type
• Announcements indicate the required minimum and/or maximum number of components expected
Sample excerpt from FOA (section IV)

Component Types

Research Strategy page limit per component

<table>
<thead>
<tr>
<th>Component Types Available in ASSIST</th>
<th>Research Strategy/Program Plan Page Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>6</td>
</tr>
<tr>
<td>Project</td>
<td>12</td>
</tr>
<tr>
<td>Core (use for ELSI Consultation/Services Core)</td>
<td>6</td>
</tr>
<tr>
<td>Admin Core (use for Administrative Core)</td>
<td>6</td>
</tr>
</tbody>
</table>

Additional page limits described in the SF424 Application Guide and the Table of Page Limits must be followed.

Instructions for the Submission of Multi-Component Applications

The following section supplements the instructions found in the SF424 (R&R) Application Guide, and should be used for preparing a multi-component application.

The application should consist of the following components:
- Overall: required
- Project: required, minimum of three, maximum of five
- ELSI Consultation/Services Core: optional, maximum of 1
- Administrative Core: required, maximum of one

Required and option components for responsive application
Multi-project Application Forms

Overall Component
PD/PIs: Cher D. Money, Ben A. Round
Organization: A
Project Title: Research Center to Cure the Diseases of the World

Component Type: Admin Core
Admin Core-001
Project Title: Administrative Core
Project Lead: Jed I. Knight
Organization: A
Subaward Budget
Organization: B

Component Type: Core-001
Core-001
Project Title: Research Core

Required Forms
- SF424 (R&R)
- Project/Performance Sites
- R&R Other Project Info
- R&R Senior/Key Persons
- PHS 398 Cover Page Supplement
- PHS 398 Research Plan

“Optional” Forms
- PHS Additional Indirect Costs
- PHS Assignment Request Form

Component Type: Project-002
Project-002
Project Title: Fabulous Research Focus 2
Project Lead: Quin T. Sential
Organization: B

“Optional” Forms
- R&R Subaward Budget
- PHS Inclusion Enrollment Report

Component Type: Project-003
Project-003
Project Title: Fabulous Research Focus 3
Project Lead: Ima Doer
Organization: C
Multi-project Application Assembly

Understand how your application image will be assembled by NIH for funding consideration

– The Overall component is presented first
  • Including system-generated data summaries

– Additional component types are presented in alphabetical order (e.g., Cores before Projects)
  • Components of the same type are grouped together
  • Components are identified by type and sequential number (e.g., Core-001, Core-002)

Check out this resource:
ASSIST is NIH's online system for the preparation, submission & tracking of grant applications through Grants.gov to NIH
The following slides will follow steps outlined in these handy Getting Started guides:


### Funding Opportunities

- Human Heredity and Health in Africa (H3Africa)
- Household Air Pollution Investigation Network (HAPIN)
- Medical Education Partnership Initiative (MEPI)
- Archived Funding Opportunities

#### Human Heredity and Health in Africa (H3Africa)

<table>
<thead>
<tr>
<th>Title</th>
<th>NIH Guide</th>
<th>RFA Number</th>
<th>Common Fund Contact</th>
<th>Application Receipt Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Human Heredity and Health in Africa (H3Africa): Coordinating Center (U24)</td>
<td>8/9/15</td>
<td>RFA-RM-16-017</td>
<td>Jennifer Troyer <a href="mailto:troyer@mail.nih.gov">troyer@mail.nih.gov</a>, 301-402-2852</td>
<td>Letter of Intent: 9/15/2016, Receipt Date: 11/15/2016</td>
</tr>
<tr>
<td>Notice of Change in Award Information for RFA-RM-16-017: Human Heredity and Health in Africa (H3Africa): Coordinating Center (U24)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Human Heredity and Health in Africa (H3Africa): Research Projects (U01)</td>
<td>8/9/16</td>
<td>RFA-RM-16-016</td>
<td>Jennifer Troyer <a href="mailto:troyer@mail.nih.gov">troyer@mail.nih.gov</a>, 301-312-3276</td>
<td>Letter of Intent: 9/15/2016, Receipt Date: 11/15/2016</td>
</tr>
<tr>
<td>Notice of Change in Award Information for RFA-RM-16-013: Human Heredity and Health in Africa (H3Africa): Ethical, Legal and Societal Issues (ELSI) Research Program (U01)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Human Heredity and Health in Africa (H3Africa): Ethical, Legal, and Societal Issues (ELSI) Collaborative Centers (US4)</td>
<td>8/9/16</td>
<td>RFA-RM-16-014</td>
<td>Ebony Madden <a href="mailto:madden@nih.gov">madden@nih.gov</a>, 301-503-5620</td>
<td>Letter of Intent: 9/15/2016, Receipt Date: 11/15/2016</td>
</tr>
<tr>
<td>Human Heredity and Health in Africa (H3Africa): Ethical, Legal, and Societal Issues (ELSI) Research Program (U01)</td>
<td>8/9/16</td>
<td>RFA-RM-16-013</td>
<td>Ebony Madden <a href="mailto:madden@nih.gov">madden@nih.gov</a>, 301-503-5620</td>
<td>Letter of Intent: 9/15/2016, Receipt Date: 11/15/2016</td>
</tr>
<tr>
<td>Human Heredity and Health in Africa (H3Africa): Global Health Bioinformatics Research Training Program (U2R)</td>
<td>8/9/16</td>
<td>RFA-RM-16-012</td>
<td>Laura Piovitch <a href="mailto:Piovitch@nih.gov">Piovitch@nih.gov</a>, 301-357-2277</td>
<td>Letter of Intent: 9/15/2016, Receipt Date: 11/15/2016</td>
</tr>
</tbody>
</table>

[https://commonfund.nih.gov/globalhealth/grants](https://commonfund.nih.gov/globalhealth/grants)
Step 2: Make a Submission Plan

- Verify registrations are in place

- Determine application preparation responsibilities
  - What parts of the application will each team member contribute?
  - Who will be responsible for data entry?
    - What are their eRA Commons IDs?
  - Who will submit?
  - Who will verify submitted and assembled application is correct?

- Make sure everyone is aware of the process
  - Internal review & approval process
  - Internal deadlines
Step 3: Login to ASSIST & Initiate Application

• Login to ASSIST at [https://public.era.nih.gov/assist](https://public.era.nih.gov/assist) using your eRA Commons ID and password

• Use the Initiate Application feature and your FOA number to get started on your application

• Or, access applications already in progress using the Search feature
Use your eRA Commons credentials to access ASSIST

https://public.era.nih.gov/assist
Welcome to the Application Submission System & Interface for Submission Tracking (ASSIST)

INITIATE APPLICATION

Funding Opportunity Announcement #: RFA-RM-16-003

The National Institutes of Health posts Funding Opportunity Announcements (FOAs) in the NIH Guide for Grants & Contracts and in Grants.gov’s Find Grant Opportunities. 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
Initiate Application for FOA #: RFA-RM-16-003

After initiation, the Lead Application Organization Name and Lead Application Organization DUNS cannot be changed.

FOA INFORMATION

* Required field(s)

- **FOA Number:** RFA-RM-16-003
- **Opportunity Title:** Limited Competition - Stimulating Peripheral Activity to Relieve Conditions (SPARC): Technologies to Understand the Control of Organ Function by the Peripheral Nervous System (OT2)
- **Offering Agency:** National Institutes of Health
- **CFDA Number:**
- **CFDA Description:**
- **Competition ID:** FORMS-D
- **Opportunity Open Date:** 03/15/2016
- **Opportunity Close Date:** 03/29/2016
- **Agency Contact:** eRA Service Desk
  Monday to Friday 7 am to 8 pm ET
  http://grants.nih.gov/support/
- **Application Identifier:**
- **Application Project Title (describe title in 200 characters):**
- **Lead Applicant Organization:** WHATSAMATTA U
- **Lead Applicant Organization Address:** 6705 Rockledge Drive MLG
  BETHESDA, MD 208171814
- **Lead Organization DUNS:** 6162081090000
- **SAM Registration Expiration Date:** 09/08/2017

Enter Project Title

Drop-down list of organizations affiliated with your eRA Commons account

Data pre-populated from organization selection

FOA information pulled from Grants.gov
Initiate: Pre-population

Visibility to SAM registration expiration date & details

Can manually enter PD/PI information or provide eRA Commons username to auto-populate
Using ASSIST

Access on-line ASSIST help (this is NOT the application guide)

Screen tips

ASSIST messages

Available actions vary based on application context and access
Adding Components to Multi-project Applications

- Overall component is automatically created when application is initiated
- Use the Add Component action to add other components identified in funding opportunity announcement
The **Overall Component** is added upon initiation.

Form navigation for the selected component.
Adding Additional Components

Add New Component.

Allowable component types defined in the FOA are presented.

Continue adding components to build out the application shell.
Step 4: Provide Application Access to Your Team

- ASSIST automatically provides application access to some individuals based on their eRA Commons role or role on the application

- Examples:
  - Users with Commons accounts that have the Signing Official (SO) or Administrative Official (AO) role have edit access to all applications for their organization
  - All PD/PIs (once eRA Commons credentials are provided) have edit access for the entire application
  - User who initiates the application has edit access for the entire application
Manage Access

• Signing Officials (SOs) can provide application access to additional users with Commons IDs
• Application access can be controlled across these variables:
  – Read vs. Edit
  – Budget vs. Non-budget data
  – Entire application vs. specific components (multi-project)
Manage Access – Single-Project

User Access Summary

View Access History
Click on the User name to add access to other components for the user.

<table>
<thead>
<tr>
<th>User</th>
<th>Primary Organization</th>
<th>Project Role</th>
<th>Budget</th>
<th>Non-Budget</th>
<th>All</th>
<th>Access Maint</th>
<th>Status Maint</th>
</tr>
</thead>
<tbody>
<tr>
<td>RENAROUND</td>
<td>WHATSAMATTA U</td>
<td>PD/PI</td>
<td>None</td>
<td>None</td>
<td>Edit</td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td>CHERDMONEY</td>
<td>WHATSAMATTA U</td>
<td>PD/PI</td>
<td>None</td>
<td>None</td>
<td>Edit</td>
<td>N</td>
<td>Y</td>
</tr>
</tbody>
</table>

Add New User

Provide Commons ID
Delegate ability to control access to the application
Control access level
Delegate ability to change application status
To assign different access levels to Budget and Non-Budget data (e.g. View Budget and Non-Budget selections should be used. To assign the user the same access to both Budget and Non-budget data, the **All select** should be used. The user will be given the access assigned in the selections made.

<table>
<thead>
<tr>
<th>Project Role</th>
<th>Component ID: Title</th>
<th>Budget</th>
<th>Non-Budget</th>
<th>All</th>
<th>Maintainer</th>
<th>Maintainer</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Entire Application</strong></td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Overall Component</strong></td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>031-Admin-Core: Administrative Core</strong></td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>485-Core: Research Core</strong></td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>828-Core: Communications Core</strong></td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>847-Project: Fabulous Research Project Focus 1</strong></td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>687-Project: Fabulous Research Project Focus 2</strong></td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>027-Project: Fabulous Research Project Focus 3</strong></td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Control access to the application as a whole (all components)**

**Limit access to a specific component**
Step 5: Enter Application Data

- Use tabs across top of screen to navigate between forms.
- For multi-project applications, use left component navigation to move between components.
- Use **Add Optional Form** action as needed.
- Use **Validate Application** action to check your data against NIH business rules.
Click each tab to access form data entry screens

Clicking **Edit** blocks other users from editing form
Adding Optional Forms

Select form and click **Submit**

The form tab is added to navigation
Validate Application

Errors and Warnings are displayed

In multi-project applications you can also Validate Component
Step 6: Finalize your application

- Use the **Preview Application** action to check your application image in the NIH format used for review consideration.

- Use the **Update Submission Status** action to move from Work in Progress to Ready for Submission status.
In multi-project applications you can also Preview Component.
Application preview does not include Cover Letter, PHS Assignment Request Form or Appendices which are maintained separately post-submission.
Multi-project Component Status

• Work In Progress – only status that allows editing
• Complete – component data entry is complete
• Final – component has been reviewed by applicant organization and incorporated into the application
Once a component is marked ‘Complete’ or ‘Final’ no additional edits can be made unless someone with appropriate authority (i.e. AO, SO, Status Maintainer, or Initiator) returns the status to ‘Work in Progress’.

Select status and enter comment for Status History.

Status on Summary page is updated.
Display Component Status

- Provides all application/component status on a single screen

Although the Status is set to **Final** for each component, the Application Information still shows a Status of **Work in Progress**.
Multi-project Submission Status

• **Work In Progress** – Allows editing
• **All Components Final** – Can only be updated once each component status is Final
• **Ready for Submission** – Before status is changed, the system does a final validation check on your application
• **Submitted** – Automatically set after submitting to Grants.gov
Step 7: Submit Your Application

• Use the **Submit** button on the Summary tab to submit to NIH through Grants.gov
  – Must be logged into ASSIST with an eRA Commons account with the Signing Official (SO) role
  – Provide valid **Grants.gov Authorized Organization Representative (AOR) username and password** when prompted
Logged into ASSIST with an eRA Commons account with SO role

Application Status must be set to **Ready for Submission**.
Applications are submitted from ASSIST to Grants.gov.

Enter your Grants.gov AOR credentials and click Enter.

Message will appear indicating the application was sent to Grants.gov.
Step 8: Track your application

- Use the **View Submission Details** link to track your application status
  - If your application successfully processed through to eRA Commons, the Agency Tracking # (e.g., AN1234567) will be hyperlinked to the eRA Commons detailed status screen
  - Carefully check your assembled application image (e-Application) and associated documents in the Other Relevant Documents section of the screen
Click **View Submission Status Details**
Happy path…

- **ASSIST** = **Submitted**
- **Grants.gov** = **Agency Tracking Number Assigned**
- **Agency** = **Processed**

**Agency Tracking #** link brings you to the detailed status screen in eRA Commons
**Viewing Your Final Assembled Application Image**

**Status Information**

**General Grant Information**
Status: [ ]

**Other Relevant Documents**
- e-Application
- Appendix: appendix 1.pdf
- eSubmission Cover Letter
- Additions for Review (0 documents)

**eApplication** is the application image reviewers will use so check it carefully.

Also check the **Cover Letter, PHS Assignment Request** and **Appendices** which are stored separate from the image.
ASSISTance
Overall Component

Tips:
- For Multi Project Applications:
  - In the Overall component, only enter the PD/PI and any multi-PD/Pis for the entire application.
  - For other components, enter all Sr/Key for that component and use roles other than PD/PI.
  - Each Sr/Key person gets one biosketch covering their involvement for the entire application. It does not matter if the component is chosen to include the single biosketch.
  - A system-generated Summary of Sr/Key persons and their biosketches will appear with the Overall application as assembled. Biosketches will not be included in component previews.

PROFILE - Project Director/Principal Investigator

Search feature

On-line ASSIST Help

Logistics of using ASSIST

Click on question mark icon to access ASSIST help

Access to application guide for additional guidance on field content information
Links & Resources

• How to Apply – Application Guide

• ASSIST: public.era.nih.gov/assist

• Online help: era.nih.gov/erahelp/ASSIST/

• Annotated form set

• eRA ASSIST Training page:
  http://era.nih.gov/era_training/assist.cfm
eRA Service Desk

Web: [http://grants.nih.gov/support/](http://grants.nih.gov/support/)
Toll-free: 1-866-504-9552
Phone: 301-402-7469
Hours: Mon-Fri, 7a.m. to 8 p.m. Eastern Time
(Except for Federal holidays)

Although we’ve worked closely with Grants.gov, ASSIST is a system developed and managed by NIH.

The eRA Service Desk should be your first stop for support.
QUESTIONS