

NIH Electronic Submission Guide

Prepared by Research Services Office, University of Toronto
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Research Services Office Contacts:

For faculty appointed within Dalla Lana School of Public Health, Applied Sci & Eng, Dentistry, Forestry, Kinesiology & PE, Nursing, Pharmacy, UTM, and Medicine (last names A-M only).

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Options for Submission

NIH offers two options* for the submission of an application. Applicant can complete either a PDF application package downloaded from grants.gov or a web based version of the application package through NIH's new ASSIST System. **This package will focus on applications using NIH PDF application package.** For more information on using ASSIT, please contact the RSO contact noted above.

*note some applications may only be submitted using one of the two options listed above. Please see the program announcement to confirm which options are available for the specific funding opportunity.

Overview

Electronic submission to NIH consists of two systems working together:

- 1) **Grants.gov:** The U.S. Federal Government's on-line portal to find and apply for Federal grants funding. This is the site where applicants can search for funding opportunities, download application packages and instructions as well as submit completed applications. The University of Toronto is fully registered with Grants.gov.
- 2) **NIH eRA Commons:** The NIH electronic Research Administration system that allows applicants/grantees to electronically receive and transmit application and award information. Once applications have been submitted NIH retrieves its applications from Grants.gov for agency validation. Applicants can then check the status of their application using their Commons UserID and Password.

Preliminary Steps

- 1) Register with NIH eRA Commons. <https://commons.era.nih.gov/commons/>

If you do not already have an NIH eRA Commons UserID and Password please inform the Research Services Office contact and they will initiate your account.

If you already have an existing account on the NIH eRA Commons as a review panelist but not as a Principal Investigator (PI) please provide your UserID Research Services Office contact in order to add the PI status to the account and to affiliate the account with the University of Toronto.

- 2) In order to access, complete and submit applications, applicants need to download and install a compatible Adobe Reader. For minimum system requirements and download instructions, please see the Grants.gov User Guide or visit <http://www.grants.gov/web/grants/applicants/adobe-software-compatibility.html>

Basic Application Steps

IMPORTANT: The Internal deadline for all NIH grant application is 4 business days prior to the NIH submission deadline.

1. Review the Program Announcement for the Opportunity you wish to apply. Ensure that **Non-domestic (non-U.S.) Entities (Foreign Institutions) are eligible to apply.**

2. Contact the RSO Contact to let them know that you plan to apply. Please provide the PA/RFA number to which you are applying and the deadline date you are working toward.
3. Download the Application package from Grants.gov. Ensure that you sign-up for any updates to the program. Also ensure that you have the latest version of the forms: ADOBE-FORMS-C for application submitted before May 24, 2016 and ADOBE-FORMS-D for application submitted after that date.
4. Download the SF424 (R&R) Application Guide, as well as the Funding Opportunity Announcement. These both contain important information needed to prepare the application. You should also consult the website of the appropriate NIH Institute to ensure your proposed project has relevance to that Institute's mission and objectives.
5. Let the RSO Contact know if your project will have co-applicants from other Canadian and/or foreign institutions. Template institutional approval documents will be provided. Institutional approval is required from the RSO equivalent for all non-UofT co-applicants (including those conducting their part of the project at UofT affiliated hospitals).
6. Complete the all of the Mandatory Documents plus any of the optional documents (some that are likely mandatory despite the term "optional"). Convert all attachments to PDF format, name using the rules found in the NIH Application Guide and then attach to application. Save and email the entire .pdf file to the RSO Contact.
7. Once the application is complete, please upload and submit it in UofT's My Research Application (MRA) system <https://ppm-wd.utoronto.ca/iri/portal>. This system has replaced the RIS/Blue form. The system will route the application for department/division, faculty and research services office approval. This process should be initiated in advance of internal deadline as the application cannot be submitted without these approvals.
8. Have all UofT personnel listed as Key Personnel on the grant complete the NIH FCOI Tutorial and Financial Interests Report. Forward the FCOI tutorial certificates and completed financial interests report forms to the NIH administrator at RSO. More information and links to these documents can be found here. <http://www.research.utoronto.ca/faculty-and-staff/research-ethics-and-protections/ethical-conduct/public-health-service-financial-conflict-of-interest/>
9. Once the application is received via MRA by RSO, the application will undergo an administrative review. RSO will provide any comments/revision requests within 24hrs of receipt of the application. The final application must be forwarded to RSO 2 days in advance of the NIH deadline. The application will undergo a final review to ensure all items noted in the initial review have been addressed.
10. The RSO Contact submits the final application to Grants.gov. An application is considered "on-time" if it is accepted error free by NIH by 5pm local time of the deadline date. **As the NIH system can (at high volume times) take 24-48hours to review and return any errors or warnings that must be addressed by the deadline. RSO is unable to guarantee that final applications received later than 2 days in advance of the submission deadline will be submitted successfully to NIH.**
11. Grants.gov processes the application and performs an initial validation review. If successful, NIH automatically "retrieves" the application from Grants.gov. If the application does not

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pass Grants.gov validation an email will be sent to the Principal Investigator and RSO Contact for corrections and re-submission.

12. Once an application has been submitted, Grants.gov and eRA Commons will send a series of status email notifications indicating any errors or warnings with the application. However, since email may be unreliable, PIs should check the status of the application by logging on to the eRA Commons with Username and Password. Errors will prevent the application from moving on to study section assignment therefore a changed/corrected application must be submitted to Grants.gov (back to step 5) by the NIH submission deadline. If there are no errors the application will automatically move forward for processing by the Division of Receipt and Referral after two business days.
13. PIs may then track the status of the application as it moves through the review process by logging into his/her eRA Commons account. Research Services recommends that PIs check their applications once they receive the : ***“Validations Complete/Check Assembled Application, Grants.gov Tracking Number GRANT xxxxxxxx, PI name”*** from the eRA Commons. Please let the NIH administrator at Research Services know if any problems are detected otherwise the application will proceed for NIH review as submitted.

**SF424 Version: Adobe Forms D
University of Toronto-specific information and a few tips**

Below is a list of the U of T details and tips you will need in order to complete the forms:

SF424 (R&R)

Item 5 Applicant Information:

DUNS – 259999779
 Legal Name – The Governing Council of the University of Toronto
 Department – leave blank
 Division – leave blank
 Street 1 – McMurrich Building, 3rd floor
 Street 2 – 12 Queen's Park Crescent West
 City – Toronto
 County – leave blank
 State – leave blank
 Province – Ontario
 Country – use drop down menu to select CAN: CANADA
 ZIP/Postal Code – M5S 1S8

Person to be contacted on matters involving this application

Prefix – leave blank
 First Name – Krista
 Middle Name – leave blank
 Last Name – Montgomery
 Suffix – leave blank
 Phone Number – 416-946-2155
 Fax Number – 416-971-2010
 Email – krista.montgomery@utoronto.ca

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OR

Prefix – leave blank

First Name – Jason

Middle Name – leave blank

Last Name – Darby

Suffix – leave blank

Phone Number – 416-946-5568

Fax Number – 416-971-2010

Email – j.darby@utoronto.ca

Item 6 Employer Identification (EIN) or TIN: 1900002838A2

Item 7 Type of Applicant: use drop down menu to select W: Non-domestic (non-US) Entity

Item 12 Proposed Project Start Date: Please select the appropriate start date.
See <http://grants.nih.gov/grants/funding/submissionschedule.htm> for all programs.

For example, here are the earliest start dates for new R01 applications:

Application Deadline

February 5

June 5

October 5

Earliest Start Date

December 1

April 1

July 1

Item 13: Congressional District of Applicant: 00-000

Item 15: Please enter the total budget into sections 15a & 15c

15b: Enter amount if cost sharing is a requirement

15d: Enter amount if income will be generated through the research (e.g. royalties from patents derived from research or user fees charge to others for equipment purchased with NIH funding)

Item 16: Is application subject to review by State Executive Order 12372 process?

Select b. NO Program is not covered by E.O. 12372

Item 19 Authorized Representative: use the same info provided in Item 5 Person to be contacted on matters involving this application and add:

Position/Title: Research Funding Manager

Project/Performance Site Location(s)

For Primary Site:

DUNS Number: 259999779

Project/Performance Site Congressional District: 00-000

For all other Project/Performance Site Locations:

DUNS Number: enter their DUNS Number

Project/Performance Site Congressional District: enter their District if US or 00-000 for outside US

Research and Related Other Project Information

Item 1a Human Subjects Assurance Number: If the project involves human subjects enter in 00005463 even if IRB approval is pending.

Item 2a Animal Welfare Assurance Number: If the project involves vertebrate animals enter in A5013-01 even if IACUC approval is pending.

Item 7 Project Summary/Abstract: This attachment should be no more than 30 lines.

Item 8 Project Narrative: This attachment should be no more than 2-3 sentences.

Item 12: Other Attachments: Foreign Justification: As a foreign applicant, NIH requires that an attachment entitled Foreign Justification be attached here. This justification must describe how the proposed project has specific relevance to the mission and objectives of the NIH and has the potential for significantly advancing the health sciences in the US; whether similar research is being done in the United States and whether there is a need for additional research in this area. This justification will be assessed on whether the project presents special opportunities for furthering research programs through unusual talent, resources or characteristics of the research project (e.g., human subjects, animals, disease, equipment, techniques, environmental conditions) that exist in other countries and either not readily available in the US or augment existing US resources.

Research & Related Senior/Key Person Profile (Expanded)

Credential, e.g., agency login: Enter your eRA Commons user name.

Project Role: Choose appropriate. Please note that NIH does not use the Co-PI role or Co-investigator, so either choose PD/PI or Other and then type in Collaborator

Note: Credential – eRA commons user name must be entered for each PD/PI.

Biographical Sketch: Attachment should not exceed 5 pages. Please note: NIH has recently revised their instructions, as well as the template for the Biographical Sketch. Ensure that Biosketch completed using the appropriate template as per the submission deadline of your application. Visit <https://grants.nih.gov/grants/forms/biosketch.htm> to more information and to access templates

PHS 398 Cover Page Supplement

Enter the required information into each section (as applicable). See NIH Guidelines

PHS 398 Research Plan

Always verify the page limits specific to your RFA or PA.

Item 10: Multiple PD/PI Leadership Plan: If your application includes multiple PD/PIs you are required to upload a plan. Please see the NIH guide for further direction on this requirement.

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Item11: Consortium/Contractual Agreements: If your application includes a subaward, a copy of their completed, signed facepage and statement of intent must be uploaded into this field.

Tip: Only add documents to the items that are applicable to your application. (e.g. if your application does not include human subjects, do not upload documents into the human subjects section)

Research and Related Budget

ALL foreign applications applicants must use the Research and Related Budget forms even if the funding announcement indicates that Modular Budget guidelines apply. Your entire budget must be in U.S. dollars. The Currency Conversion Rate used to prepare budget should be noted in budget justification

Tip: Please note that a budget period may only be for 12 month period or less. To add additional periods, please click on the “add period” button on the bottom of page 3 of the budget forms.

Section A & B. Personnel:

- For the PI Project Role always use PD/PI.
- Always include the Calendar Months effort for all personnel listed even if no salary is being requested. U of T operates on a 12-month appointment basis so Academic and Summer months are not used. (e.g. 10% effort = 1.2 cal month)
- Please ensure that salary requested conforms to the appropriate NIH Salary caps: http://grants.nih.gov/grants/policy/salcap_summary.htm
- The University’s fringe benefit rate for Appointed Positions is 20.0%, Non-appointed Position 10%, Postdoctoral Fellows 10% +\$50 per month and Students is 0%. <http://www.finance.utoronto.ca/services/benefits/rates.htm>

Section H. Indirect Costs (required for each year that budget is requested):

- Indirect Cost Type: Foreign F&A Policy
- Indirect Cost Rate: 8%
- Indirect Cost Base: enter in the amount from Section G: Direct Costs minus any equipment cost.
- Funds Requested: Multiply the Indirect Costs Base by the Indirect Cost Rate
- Cognizant Federal Agency: enter Per NIH NOT-OD-01-028 dated March 29, 2001

Budget Justification.

This file must provide the details of each expense that you have included in your budget including a description of each personnel, including the UofT PI and the roles and responsibilities in the project, as well as salary and benefits to be included. All materials and supplies should have a brief description, as well as a rough calculation of how you have calculated the total amount to be requested for each item. Supplies include various categories, such as chemicals, reagents, glassware, disposable plastic ware, vertebrate animals, among others.

Research and Related Subaward Budget Attachments

If you application includes subsites, you must include an separate budget for each site, which is uploaded into this form.

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Tip: The total costs of the subsites are inputted into the subaward/consortium/contractual costs (Section 4, Item 5) of the main budget.

Note: The subsites indirect costs although calculated in the total direct costs of the budget, do not count towards the total allowable direct costs dictated by NIH. Please ensure you review your budget thoroughly to ensure that the UofT direct costs and direct costs of the subsites do not exceed the allowable costs for the funding mechanism.