NIH R01 Guide – Forms I
Research Project Grants

This checklist is meant to be used as a tool and does not replace the detailed requirements for submission information, which are found in the Notice of Funding Opportunity (NOFO) and the SF424 (R&R) Application Packages – Research Instructions for NIH and Other Agencies, Forms Version I Series (Released December, 2025)- due dates on or after January 25, 2026

PI Name: _____

Title: _____

A "**new**" application must have a different title from any other PHS project submitted for the same application due date with the same PD/PI. A "**resubmission**" or "**renewal**" application should normally have the same title as the previous grant or application. If the specific aims of the project have significantly changed, choose a new title. A "revision" application must have the same title as the currently funded grant. NIH and other PHS agencies limit title character length to 200 characters, including the spaces between words and punctuation.

Project Dates: _____

Standard Due Dates for Competing Applications: https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/due-dates.htm

AIDS and AIDS-Related Application Due Dates. *NEW:* Beginning with applications for Advisory Council Review in January 2027 (i.e., application due dates on or after May 25, 2026), we will no longer accept applications submitted on dedicated AIDS application due dates (NOT-OD-26-029). You can submit your AIDS applications to non-dedicated dates.: https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/due-dates.htm

Solicitation: _____

Parent Announcements (For Unsolicited or Investigator-Initiated Applications): https://grants.nih.gov/grants/guide/parent_announcements.htm

Format Attachments Requirements

Attachments must be in PDF format: https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/format-attachments.htm

- Font size: Must be 11 points or larger. Smaller text in figures, graphs, diagrams and charts is acceptable, as long as it is legible when the page is viewed at 100%. ◦ Some PDF conversion

software reduces font size. It is important to confirm that the final PDF document complies with the font requirements.

- Type density: Must be no more than 15 characters per linear inch (including characters and spaces).
- Line spacing: Must be no more than six lines per vertical inch.
- Text color: No restriction. Though not required, black or other high-contrast text colors are recommended since they print well and are legible to the largest audience.
- Filename Rules: eRA Commons enforces a 50-character limit for filenames used for attachment in grant applications (see: *Increased system enforcement of filename rules*)
- Do not include headers or footers in your attachments.
- Headings (e.g., Significance, Innovation) within the text of your attachments improve readability and are highly encouraged.
- **Hyperlinks and URLs are only allowed when specifically noted in the notice of funding opportunity (NOFO) and form field instructions**. It is highly unusual for a NOFO to allow links in Specific Aims, Research Strategy and other page-limited attachments.
    - When allowed, you must hyperlink the actual URL text so it appears on the page rather than hiding the URL behind a specific word or phrase (hypertext). Examples:
        - NIH (https://www.nih.gov/)
        - https://www.nih.gov/
    - See Hyperlinks within Common Forms FAQs for clarification of when hyperlinks can be used in Biographical Sketch Common Form and associated NIH Biographical Sketch Supplement.

Abbreviated Application Instructions & Attachments

R.200 - SF424 (R&R) Form

Fill-in required information in ASSIST application, as per Instructions Pages R-17 to R-30
Western UEI: CNBKJKNXAJM1
Western EIN: 98-6001623
SF424 Block 5: Your supporting Research Grants Specialist
SF242 Block 19: Penny Pexman, 1593 Western Rd. SSB 5150, London, ON N6G 1G9, pp_vpr@uwo.ca

☐ **Cover Letter Attachment** *(no page limit but generally 1 – 2 pages)*

Attach the cover letter (only as applicable), addressed to the Division of Receipt and Referral, in accordance with the announcement and/or the agency specific instructions. This attachment is made available to appropriate staff only. The cover letter **should not be used for assignment requests**. The PHS assignment form is used for that purpose. Instead the cover letter should be used to relay such information as listed on Pages R-29 and R-30

R.210 – PHS 398 Cover Page Supplement Form

Fill-in required information in ASSIST application, as per Instructions Pages R-31 to R-35

R.220 – R&R Other Project Information Form

Fill-in required information in ASSIST application, as per Instructions Pages R-36 to R-44.

Pay special attention to '1. Are Human Subjects Involved?' – this is a required field. Whether you answer "Yes" or "No" to the "Are Human Subjects Involved?" question here, your answer will populate the relevant field in the R.500 – PHS Human Subjects and Clinical Trials Information form. Follow the R.500 – PHS Human Subjects and Clinical Trials Information form instructions to complete the relevant questions in that form.

Information on Attachments below:

☐ **Project Summary/Abstract** *(30 lines of text maximum)*

State the application's broad, long-term objectives and specific aims, making reference to the health relatedness of the project (i.e., relevance to the mission of the agency).
Full instructions Page R-42

☐ **Project Narrative** *(2 or 3 sentence maximum)*

Using no more than two or three sentences, describe the relevance of this research to public health.
Full instructions Page R-42

☐ **Bibliography & References Cited** *(no page limit)*

The "Bibliography & References Cited" attachment should include any references cited in R.400 - PHS 398 Research Plan Form and in the R.500 - PHS Human Subjects and Clinical Trials Information form. You are allowed to cite interim research products. Note: interim research products have specific citation requirements. See related Frequently Asked Questions for more information. Use of hyperlinks and URLs in this section is not allowed unless specified in the Notice of Funding Opportunity.
Full instructions Page R-43

☐ **Facilities & Other Resources *(no page limit)***

Describe how the scientific environment in which the research will be done contributes to the probability of success (e.g., institutional support, physical resources, and intellectual rapport). In describing the scientific environment in which the work will be done, discuss ways in which the proposed studies will benefit from unique features of the scientific environment or subject populations or will employ useful collaborative arrangements. If there are multiple US performance sites, describe the resources available at each site (i.e. subrecipient locations). Describe any special facilities used for working with biohazards or other potentially dangerous substances. For early stage investigators (ESIs), describe institutional investment in the success of the investigator. See NIH's New and Early Stage Investigator Policies.
Full instructions Pages R-43 to R-44

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☐ **Equipment** ***(no page limit)***

List major items of equipment already available for this project and, if appropriate identify location and pertinent capabilities. If there are multiple US performance sites, describe the equipment available at each site (i.e. subrecipient locations).
Full instructions Page R-44

☐ **Other Attachments** ***(no page limit)*** Page R-44

** Very Important – add the **Foreign Justification**. Refer to Pages R-41 to R-42 and the definition of foreign component.

R.230 Project/Performance Site Location(s) Form

This form allows for the collection of multiple performance sites. If you need to add more project/performance site locations than the form allows, enter the information in a separate file and add it to the "Additional Locations" section.

Important Subaward Sites can only be U.S.-based organizations.

Western UEI: CNBKJKNXAJM1
Western Congressional District: 00-000

Full instructions Pages R-45 to R-48

R.240 R&R Senior/Key Person Profile

Unless otherwise specified in an agency announcement, senior/key personnel are the program director/principal investigator (PI/PD) and *other individuals who contribute to the scientific development or execution of the project in a substantive, measurable way whether or not salaries are requested*.
Full Instructions Pages R-49 to R-55

Note: Current & Pending Support attachments are not required for NIH and other PHS agency submissions unless otherwise specified in the NOFO. It may, however, be requested prior to award negotiations.

Also use this section to list any Other Significant Contributors (OSCs), who are those individuals who commit to contribute to the scientific development or execution of the project, but do not commit any specified measurable effort (i.e., person months) to the project. These individuals are typically presented at effort of "zero person months" or "as needed." Individuals with measurable effort may not be listed as Other Significant Contributors (OSCs). OSCs should be listed after all senior/key persons. **A Biographical Sketch Common Form and NIH Biographical Sketch Supplement is required for all senior/key persons and Other Significant Contributors**.

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☐ **"Biographical Sketch" Common Form and NIH Biographical Sketch Supplement** (no hard page limit)
Applicants are required to use Science Experts Network Curriculum Vitae (SciENcv) to complete the Biographical Sketch Common Form and the NIH Biographical Sketch Supplement to produce digitally certified PDF(s) for use in application submission. Page R-52

Reminder: Applicants are required to have an ORCID ID and link it with their eRA Commons profiles.

Resources

- Instructions for Biographical Sketch Common Form (pdf: 01/31/2026)
- NIH Biographical Sketch Supplement
- Common Forms for Biographical Sketch and Current and pending (Other) Support FAQ

R.300 - R&R Budget Form

The R01 Financial Characteristics:

- Generally awarded for 3 – 5 years
- No specific dollar limit unless specified in NOFO

Western Applicants, as part of a foreign entity/organization, must use the Research & Related (R&R) Budget Form, even though the general guidelines indicate the use of the Modular Form for requests less than $250,000 USD per budget period.

Resource: Develop Your Budget

Detailed instructions for each section of the R&R Budget Form on Pages R-56 to R-70

Special Budget Form Notes:

Effort Reporting for Sections A and B on the Form:
Use 'CAL' box for effort reporting: Refer to 'FAQ on Persons Months'.

Section C. Equipment
Item of property exceeding $10,000 USD

Section D. Travel
'Domestic' defined as: Travel destinations in the U.S., Canada, Mexico, and U.S. possessions

Section E. Participant/Trainee Support Costs
Unless specifically stated otherwise in a NOFO, NIH and other PHS agencies applicants should skip Section E. Participant/Trainee Support Costs.

Section H. Indirect Costs (AKA F&A Rate)
Western applications apply an 8% indirect cost rate on all direct costs, excluding equipment, as per:

Special Instructions for Foreign Organizations (Non-domestic [non-U.S. Entities]): Foreign institutions and international organizations may request funds for limited F&A costs (8% of modified total direct costs less equipment) to support the costs of compliance with HHS and NIH requirements including, but not limited to, those related to the protection of human subjects, animal welfare, invention reporting, financial conflict of interest, and research misconduct. Foreign organizations may not include any charge-back of customs and import fees, such as consular fees, customs surtax, value-added taxes (VAT), and other related charges

U.S. Subawards/Consortium/Contractual Costs, Section 5. - List the total funds requested for:

1. all subaward/consortium organization(s) proposed for the project and
2. any other contractual costs proposed for the project.

This line item should include both direct and indirect costs for all U.S. subaward/consortium organizations. NIH policy provides for exclusion of consortium/contractual F&A costs when determining if an applicant is in compliance with a direct cost limitation. However, you must include the full cost of consortium/subawards in this field.

☐ **Budget Justification, Section L. –** no page limits. Values in USD, include exchange rate calculation, note Foreign indirect cost rate, and include a statement why or why not salary is requested for Senior/Key Personnel. Adhere to current NIH salary caps.

See Special Instructions for **Applications Proposing the Use of Human Fetal Tissue**, and for **Applications Submitted with a Data Management and Sharing (DMS) Plan** (see Budgeting for Data Management & Sharing)
Pages R-68 to R-69

R.310 – R&R Subaward Budget Attachment(s) Form

Each U.S. consortium grantee organization that performs a **substantive portion** of the project must complete an R&R Subaward Budget Attachment, including the Budget Justification section.

Per Notice NOT-OD-25-104 **NIH will not issue awards to domestic or foreign entities (new, renewal or non-competing continuation), that include a subaward to a foreign entity**. Therefore, Canadian-led NIH applications can only include subawards to U.S. domestic entities.

Consortium/Contractual F&A Costs: NIH policy provides for the exclusion of consortium/contractual F&A costs when determining if an applicant is in compliance with a direct cost limitation. However, you must include the full cost of the subaward/consortium in the Subawards/Consortium Costs field (R.300 - R&R Budget Form, Section F. Other Direct Costs, Question 5). If a subaward/consortium **is not** performing a substantive portion of the project, they do not need to complete an R&R Subaward Budget Form; however, their costs must be included in the prime grantee's R&R Budget Form. All F&A costs count toward the direct cost limit.

F&A costs for the first $25,000 of each consortium may be included in the modified total direct cost base, when calculating the overall F&A rate, as long as your institution's negotiated F&A rate agreement does not expressly prohibit it.

The R&R Budget Forms do not allow for “empty” budget periods.
Subaward/consortiums organizations should complete all budget periods in the R&R Subaward Budget Form for their subaward budgets, aligning the budget period numbers, start dates, and end dates with the budget periods of the prime grant.

☐ **R&R Subaward Budget Form(s) and Budget Justification(s):** The Subaward Budget Form(s) and Budget Justification(s), must be PDF files. R&R Budget Forms are already PDFs when extracted. Do not alter the format.

Full instruction Pages R-71 to R-73

R.400 - PHS 398 Research Plan Form

☐ **Introduction to Application** *(for resubmission or revision only, 1 page limit)*
NIH allows a thirty-seven month window for resubmission (only one resubmission is allowed for each new, unfunded application). Include an introduction for all resubmissions that summarizes substantial additions, deletions, and changes to the application and responds to the issues and criticism raised in the summary statement. Full instructions Page R-81

☐ **Specific Aims** *(1 page limit)*
State concisely the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will exert on the research field(s) involved. List succinctly the specific objectives of the research proposed, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology. Page R-82

☐ **Research Strategy** *(12 page limit)*
Organize the Research Strategy in the order specified in Pages R-82 to R-85 of the Research application instructions unless otherwise specified in the NOFO. Start each section with the appropriate – Significance, Innovation, Approach.

Pay attention to directions related to applications proposing the involvement of Human Subjects and/or clinical trials, and/or applicants with multiple specific aims.

Renewal Applications: For renewal applications changing from a single PD/PI to multiple PD/PIs, changing the number or makeup of the multiple PD/PIs, the applicant must provide a rationale for

the change and include the required Multiple PD/PI Leadership Plan. A rationale for a change from a multiple PD/PI to a single PD/PI application must also be provided.

Progress Report for Renewal and Revision Applications:
Note that the Progress Report falls within the Research Strategy and is therefore included in the page limits for the Research Strategy.

Full Instructions Pages R-82 to R-85

☐ **Progress Report Publication List** *(renewal only)*
A "Progress Report Publication List" attachment is required only if the type of application is renewal. Page R-86

Other Research Plan Section:

☐ **Vertebrate Animals**
Include a "Vertebrate Animals" attachment if you answered "yes" to the question "Are Vertebrate Animals Used?" on the R.220 – R&R Other Project Information Form.

If live Vertebrate Animals are involved in the project, address each of the following criteria listed below:
1. Description of Procedures
2. Justifications
3. Minimization of Pain and Distress

Full instructions Pages R-86 to R-87

☐ **Select Agent Research**
Include a "Select Agent Research" attachment if your proposed activities involve the use of select agents at any time during the proposed project period, either at the applicant organization or at any performance site.
Address the following three points for each site at which select agent research will take place, be succinct:
1. Identify the select agent(s) to be used in the proposed research.
2. Provide the registration status of all entities where select agent(s) will be used.
3. Provide a description of all facilities where the select agent(s) will be used.

Full instructions Pages R-87 to R-88

☐ **Multiple PD/PI Leadership Plan**
Any applicant who designates multiple PD/PIs (on the R.240 - R&R Senior/Key Person Profile (Expanded) Form) must include a Multiple PD/PI Leadership Plan. Having a subrecipient/subaward aspect does not necessarily result in a Multiple PD/PI application.

When required, the governance and organizational structure of the leadership team and the research project should be described, including communication plans, process for making decisions on scientific direction, and procedure for resolving conflicts.

Note: Including Multiple PD/PIs can have implications for Early Stage Investigators (ESI) and/or New Investigators (NI). FAQ ESI & NI

Full instructions Pages R-88 to R-89

☐ **Consortium/Contractual Arrangements**

Include a "Consortium/Contractual Arrangements" attachment if you have consortiums/contracts in your budget. Explain the programmatic, fiscal, and administrative arrangements to be made between the applicant organization and the consortium organization(s) The Letter of Intent from the Consortium site (signed by authorized official) is uploaded here. Canadian-led applications can only include subawards to U.S. domestic entities. Full instructions Page R-89

☐ **Letters of Support**

Attach all appropriate letters of support, including any letters necessary to demonstrate the support of consortium participants and collaborators such as Senior/Key Personnel and Other Significant Contributors included in the grant application. For consultants, letters should include rate/charge for consulting services and level of effort/number of hours per year anticipated. Use of hyperlinks and URLs in Letters of Support is not allowed unless specified in the funding opportunity. Full instructions Page R-90

☐ **Resource Sharing Plan(s)**

Note: Effective for due dates on or after January 25, 2023, Data Management and Sharing (DMS) Plans are now included in Section 11. Other Plan(s). Plans for Genomic Data Sharing should be provided as part of the Data Management and Sharing Plan.

Full instructions on Pages R-90 to R-91

☐ **Other Plan(s) - DMPs** (*Recommended not to exceed two pages. No hyperlinks*)

For Elements of a Data Management and Sharing Plan and Full instructions see Pages R-91 to R-93

Help and Resources at UWO: Western Libraries offers Research Data Management (RDM) support.

☐ **Authentication of Key Biological and/or Chemical Resources** *(limit 1 page)*

If applicable to the proposed science, briefly describe methods to ensure the identity and validity of key biological and/or chemical resources used in the proposed studies. Full instructions page R-93

☐ **Appendix** *(as applicable, max. 10 PDF attachments)*

Refer to the NOFO to determine whether there are any special appendix instructions for your application. A maximum of 10 PDF attachments is allowed in the appendix. Do not use the appendix to circumvent the page limits of the Research Strategy or any other section of the application for which a page limit applies. A summary sheet listing all of the items included in the Appendix is encouraged but not required. See full instructions for allowable content.

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Full instructions and content guidance Pages R-94 to R-95.

R.500 - PHS Human Subjects and Clinical Trials Information

Complete the PHS Human Subjects and Clinical Trials Information form after you have completed the R.220 - R&R Other Project Information Form.

All applicants must use the PHS Human Subjects and Clinical Trials Information form regardless of your answer to the question “Are human subjects involved?” on the R.220 - R&R Other Project Information Form.

This form accommodates the full spectrum of all types of clinical trials, including, but not limited to, behavioral, exploratory/development, mechanistic, pilot/feasibility, early phase, efficacy, effectiveness, group-randomized, and others.

Read all the instructions in the Funding Opportunity Announcement (FOA) before completing this form to ensure your application meets all IC-specific criteria. If you are proposing a clinical trial, make sure your FOA accepts clinical trials (i.e., ‘clinical trial required’ or ‘clinical trial optional’).

Note: There are no page limits for any attachments in the PHS Human Subjects and Clinical Trials Information form.

For additional requirements and possible attachments read carefully the full instructions on Pages R-96 to R-132.

R. 600 PHS Assignment Request Form

This ASSIST form is optional. Use it only if you wish to communicate specific awarding component assignments or review preferences. There is no requirement that all fields or all sections be completed. You have the flexibility to make a single entry or to provide extensive information using this form.

Full instructions Pages R-133 to R-135

NIH R01 Checklist – Forms I

☐ Cover Letter *(if applicable, generally 1 – 2 pages)*

☐ Project Summary/Abstract *(30 lines of text maximum)*

☐ Project Narrative *(2 or 3 sentences maximum)*

☐ Bibliography & References Cites

☐ Facilities & Other Resources

☐ Equipment

☐ Foreign Justification (Other Attachments section)

☐ *NEW* Biographical Sketch Common Form and NIH Biographical Sketch Supplement for all Sr/Key Personnel (must be developed in and downloaded from SciENcv. ORCID ID must be linked to eRA Commons Personal Profile)

☐ Budget Justification (attached to R&R Budget Form)

☐ Consortium R&R Budget(s) and Budget Justification(s) (*if applicable – must only be with U.S. entities*)

☐ Introduction to Application *(for resubmission or renewal only, 1 page limit)*

☐ Specific Aims *(1 page limit)*

☐ Research Strategy *(12 page limit)*

☐ Progress Report Publications List *(for Renewals)*

☐ Vertebrate Animals *(if vertebrate animals used)*

☐ Select Agent Research *(if application involves the use of select agents)*

☐ Multiple PD/PI Leadership Plan *(if designated multiple PD/PI application)*

☐ Consortium/Contractual Arrangements

☐ Letters of Support

☐ Resource Sharing Plan(s)

☐ Data Management and Sharing Plan (NEW in 2023)

☐ Authentication of Key Biological and/or Chemical Resources *(1 page limit)*

☐ Appendix *(as applicable)*

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☐ Human subjects/human specimens/human data/study record attachments *(as required)*

☐ Assignment Request Form *(optional)*

Appendix A – Additional Items Required for U.S.-based Subcontractors/Subawards

☐ Official organization name, DUNS number, address

☐ Administrative contact information for Institution

☐ Contact information and eRA Commons Credential from Subaward investigator(s)

☐ NIH Biographical Sketch Common Form and NIH Biographical Sketch Supplement for Subaward investigator.

☐ Letter of Intent to collaborate/consortium letter from Authorized (OSP) Official

☐ Letter of Support from collaborating Senior/Key Personnel

☐ COI Disclosure from PI (or evidence that their Institution is in compliance)

☐ Information about Facilities/Equipment/Resources to add to Full application

☐ Subaward site's Budget on R&R Budget Pages and a Budget Justification

☐ Scope of Work/Statement of Work (describes the actual work being completed by the Subawardee)

☐ Subaward entity's Facilities & Administration (F&A) Rate Agreement