NIH R21 Guide – Forms H
Exploratory/Developmental Research 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 Funding Opportunity Announcement (FOA) and the SF424 (R&R) Application Packages – Research Instructions for NIH and Other Agencies, Forms Version H Series (Released October 25, 2022)- due dates on or after January 25, 2023

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: 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. Recommended Fonts: Arial, Georgia, Helvetica, Palatino Linotype.
- 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 funding opportunity announcement (FOA) and form field instructions**. The use of hyperlinks is typically limited to citing relevant publications in biosketches and publication lists. It is highly unusual for a FOA to allow links in Specific Aims, Research Strategy and other page-limited attachments.

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: Natalie Wu, 1593 Western Rd. SSB 5150, London, ON N6G 1G9, nwu28@uwo.ca
SF242 Block 19: Bryan Neff, 1593 Western Rd. SSB 5150, London, ON N6G 1G9, bn_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 new PHS assignment form is used for that purpose. Instead the cover letter should be used to relay information such as:

- Reason for late application
- Changed/correct applications submitted after the due date (required)
- Explanation of why a Subaward isn't active in all periods of the proposed project
- Statements regarding agency approval documents (e.g., requests over $500,000)
- Intent to submit a video as part of the application: (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_2/2.3_application_information_and_processes.htm#Policies)
- Indication that the proposed study will generate large-scale human or non-human genomic data: https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.2_availability_of_research_results_publications__intellectual_property_rights__and_sharing_research_resources.htm#Sharing

- Include a statement in the cover letter if the proposed studies involve human fetal tissue obtained from elective abortions (HFT), regardless of whether or not Human Subjects are involved and/or there are costs associated with the HFT. For further information on HFT policy refer to the NIH Grants Policy Statement, Section 2.3.7.11 Human Fetal Tissue from Elective Abortions, Section 4.1.14 Human Fetal Tissue Research and Section 4.1.14.2 Human Fetal Tissue from Elective Abortions.

Full instructions Pages R-26 and R-27

R.210 – PHS 398 Cover Page Supplement Form

Fill-in required information in ASSIST application, as per Instructions Pages R-33 to R-41.

R.220 – R&R Other Project Information Form

Fill-in required information in ASSIST application, as per Instructions Pages R-33 to R-41.

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 (see exception for Training Applications in the Training-specific instructions). 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 Pages R-38 to R-39

☐ **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-39

☐ **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
Full instructions Pages R-39 to R-40

☐ **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 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-40 to R41

☐ **Equipment**

List major items of equipment already available for this project and, if appropriate identify location and pertinent capabilities. If there are multiple performance sites, describe the equipment available at each site (i.e. subrecipient locations).
Full instructions Page R-41

☐ **Other Attachments (*page no page limit*)** Page R-41

** Very Important – add the **Foreign Justification**. Refer to page R-38 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.
Western UEI: CNBKJKNXAJM1
Western Congressional District: 00-000
Full instructions Pages R-42 to R-45

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, measureable way whether or not salaries are requested*. Consultants should be included in this "Senior/Key Person Profile (Expanded)" Form if they meet this definition.
Full Instructions Pages R-46 to R-55

Note: Current & Pending Support attachments is not required for NIH and other PHS agency submissions unless otherwise specified in the FOA. 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 biosketch is required for all senior/key persons and Other Significant Contributors**.
Biosketch

☐ **Biographical Sketch** *(5 page limit)*
Blank template and instructions found: https://grants.nih.gov/grants/forms/biosketch.htm
Full Instructions Pages R-49 to R-52

R.300 - R&R Budget Form

The R21 Financial Characteristics:

- You may request a project period of up to two years
- The combined budget for direct costs for the two year project period may not exceed $275,000. No more than $200,000 may be requested in any single year.

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.

Detailed instructions for each section of the R&R Budget Form on Pages R-56 to R-69

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 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

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 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.

NEW! 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).
Instructions Pages R-68 to R-69

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

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

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.

If the consortium is a foreign institution or international organization, F&A for the consortium is limited to 8%.

☐ **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-70 to R-72

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-80

☐ **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-81

☐ **Research Strategy** *(6 page limit)*

Organize the Research Strategy in the order specified in Pages R-85 and R-88 of the Research application instructions unless otherwise specified in the FOA. Start each section with the appropriate heading – 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.

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-81 to R-84

☐ **Progress Report Publication List** *(renewal only)*

A "Progress Report Publication List" attachment is required only if the type of application is renewal. Pages R-85

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-85 and R-86

☐ **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. Pages R-87 and R-88

Full instructions Pages R-86 to R-87

☐ **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. Full instructions Pages R-87 and R-88

☐ **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. Full instructions Page R-88

☐ **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. Full instructions Page R-89

☐ **Resource Sharing Plan(s)**

NEW! 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-89 to R-90

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

For Elements of a Data Management and Sharing Plan and Full instructions see Pages R-90 to R-92

☐ **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-92

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

Refer to the FOA 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.

Full instructions and content guidance Pages R-93 to R-94

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').

For additional requirements and possible attachments read carefully the full instructions on Pages R-97 to R-131.

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-132 to R-134

NIH R21 Checklist – Forms H

☐ 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)

☐ Biographical Sketch(s) *(5 page limit)*

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

☐ Consortium R&R Budget(s) and Budget Justification(s) (*if applicable*)

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

☐ Specific Aims *(1 page limit)*

☐ Research Strategy *(6 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

☐ Data Management and Sharing Plan (NEW)

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

☐ Appendix *(as applicable)*

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

☐ Assignment Request Form *(optional)*

Appendix A – Additional Items Required For Subcontractors

☐ Official organization name, UEI credential, address

☐ Administrative contact information for Institution

☐ Contact information from Subaward investigator

☐ NIH biographical sketch 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

☐ Budget on R&R Budget Pages and Budget Justification

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