Western Research

PF5- NIH Collaborative International Research Project

(Parent PF5 Clinical Trial Optional)

PA-26-002

International Project Proposal Checklist

Required Organizational Registrations

[ ] The University of Western Ontario maintains the required **NCAGE**, **System for Award Management (SAM)**, **Unique Entity Identifier (UEI)**, **eRA Commons** registrations and roles needed to apply for and hold NIH funding.

Required for Senior/Key Personnel

- [ ] **Senior/Key Personnel**: All senior/key personnel must complete individual eRA Commons registration, including completing Personal Profile within eRA Commons. International Project PIs must have the PI role on their eRA Commons account.
    - Need to identify "Project Lead" – this senior/key personnel will become the Principal Investigator of the disaggregated award.
- [ ] **Senior/Key Personnel**: Complete ORCID registration.
- [ ] **Senior/Key Personnel**: Link your ORCID account to your eRA Commons account.
- [ ] **Senior/Key Personnel**: Complete Research Security Training (RST) within the 12 months prior to proposal submission.
- [ ] **Senior/Key Personnel**: Complete and provide NIH Common Form Biosketches generated and certified from SciENcv
    - *Note: Within SciENcv investigators **must** link both their ORCID ID and their eRA commons accounts to their SciENcv account to be able to generate NIH Common Form Biosketches.*

International Projects (IP)

Submission pathways to U.S. Lead: The U.S. Lead may request to receive the International Project contents via an emailed package of finalized documents (sent by ORS), or via an invitation to load the material directly into an International Project in the submission platform ASSIST.

Checklist Disclaimer: Thoroughly read the PA-26-002 NOFO and 'MULTI – PROJECT INSTRUCTIONS FOR NIH AND OTHER PHS AGENCIES SF424 (R&R) APPLICATION PACKAGES' for the most detailed instructions on required International Project contents.

Formatting Note: Attachments must follow NIH Formatting Standards.

Each individual International Project component requires the following:

Sequence below mirrors Multi-Project Instructions for NIH and Other PHS Agencies (Application Instructions)

SF424 (R&R) Cover (International Project) – template may be provided by U.S. Lead

- **Applicant Information**: For the International Project, this must be the foreign organization information, not the information for the Overall applicant.
- **Type of Applicant** (optional)
- **Descriptive Title of Applicant's Project**
- **Proposed Project Start/Ending Dates**

PHS 398 Cover Page Supplement (International Project) – template may be provided by U.S. Lead

- Enter Human Embryonic Stem Cells in each relevant component.

Research & Related Other Project Information (International Project) - template may be provided by U.S. Lead

Questions in form:

- Human Subjects: Answer only the 'Are Human Subjects Involved?' and 'Is the Project Exempt from Federal regulations?' questions.
- Vertebrate Animals: Answer only the 'Are Vertebrate Animals Used?' question.
- Activities outside of the United States or Partnerships with international collaborators:
- In Field 6, check "yes", and identify the country for this International Project only.

Attachments:

- [ ] **Project Summary/Abstract:** Refer to M-Application Guide. This section is **limited to 30 lines of text** and must follow the required font and margin specifications (strict enforcement).

- [ ] **Project Narrative**: Include a Project Narrative for the International Project. Follow the instructions in the M Application Guide, focusing on the relevance of the research conducted within the International Project to public health. At most, three sentences.
- [ ] **Bibliography & References Cited**: Attach this information as a PDF file. See the Format Attachments page. Use of hyperlinks and URLs in this section is not allowed unless specified in the Notice of Funding Opportunity.
- [ ] **Facilities & Other Resources**: Applicants must include a Facilities & Other Resources section in the International Project component which highlights the scientific environment in which the work will be done. The section can include a description of logistical support available to address budgetary, regulatory, and other compliance concerns. **No page limit, adhere to formatting standards.**
- [ ] **Equipment**: List major items of equipment already available for this project and, if appropriate, identify the equipment's location and pertinent capabilities. Attach this information as a PDF file. Use of URLs and hyperlinks in this section is not allowed unless specified by the Notice of Funding Opportunity. **No page limit, adhere to formatting standards.**
- **[ ] Other Attachments – Foreign Justification**: In a pdf document file named "ForeignJustification_[site]" without quotations, where "[site]" is a short descriptive name of the foreign organization or country. Describe the special resources or characteristics of the research project (e.g., human subjects, animals, disease, equipment, and techniques), including the reasons why the facilities or other aspects of the proposed project are more appropriate than a domestic setting. **Adhere to standard formatting, no hyperlinks, and no page limit.**

Project /Performance Site Location(s) (International Project) – template may be provided U.S. Lead. ORS can complete this.

Research & Related Senior/Key Person Profile (International Project) – template for UWO Sr/Key Person entries may be provided by U.S. Lead.

ASSIST will default to "Project Lead" for the first individual listed. If you would like to use a different category, then replace "Project Lead" below with a different Category (e.g., Core Lead).

In the Project Director/Principal Investigator section of the form, use Project Role of 'Other' with Category of 'Project Lead' and provide a valid eRA Commons ID in the Credential field. If selected for funding, the Project Lead will become the (Contact) PD/PI on the disaggregated award.

In the additional Senior/Key Profiles section, list Senior/Key persons that are working in the component.

Attachments:

- [ ] Include a single **Biographical Sketch (contains Biographical Sketch Common Form and NIH Biographical Sketch Supplement) for each Senior/Key person** on our foreign component**. Do not flatten this PDF attachment obtained from SciENcv**
- **Current & Pending Other Support document**: Not required at application stage, but will be requested at Just-in-Time stage. Use SciENcv to develop.

Research & Related (R&R) Detailed Budget (International Project)

Budget forms appropriate for the specific component will be included in the application package (i.e. in ASSIST).

Notes:

- The International Project budget must not include any subawards/consortium/contractual costs identified for other foreign (non-U.S.) organizations. Subaward budgets to domestic (U.S.-based) organizations are allowed.
- Include budget information for Data Management and Sharing Costs within the applicable component(s).

Attachments:

- [ ] **UWO's R&R Budget form – specific template required**: The budget being requested is for the organization leading the component.
    - **Indirect Costs (F&A)**: Request the standard **8% indirect cost rate** for the foreign organization
- [ ] **UWO's Budget Justification**: "Budget Justification" attachment is required. Attach only one file. The Data Management and Sharing justification must be clearly labeled as "Data Management and Sharing Justification" within the budget justification attachment followed by the estimated dollar amount (total direct costs). **No page limit, following standard formatting.**

PHS 398 Research Plan (International Project)

Attachments:

- [ ] **Introduction to Application**: "Introduction to Application" *only for Resubmission and Revision applications*, an Introduction to Application is allowed for each component. **One page, adhere to formatting standards.**
- [ ] **Specific Aims**: For the "specific Aims" attachment all instructions in the How to Apply - Application Guide must be followed, with the following additional instructions: List the long-range objectives and goals of the proposed International Project. **One page limit.**
    - Given the broad range of scientific areas covered by this Parent PF5 NOFO, it is anticipated that the size and scope of International Projects may vary considerably between projects and even within a single PF5 application. The Specific Aims of an International Project may be contained within a subset of a Research Project's

Specific Aims or be independent of the Research Project(s) but within the scope of the Overall Aims. The applicant should justify how the aims of each International Project support the Overall PF5 goal and integrate with the other components.

- [ ] **Research Strategy**: For "Research Strategy" all instructions in the How to Apply - Application Guide must be followed, with the following additional instructions:
    - The Significance section should address the significance of the contribution of the foreign organization to the overall collaborative team effort for this project.
    - The Approach section should address the research approach taken by the foreign organization to address the scope of work described in the component's Specific Aims. The applicant should clearly articulate how the experimental and technical approaches undertaken by the foreign organization integrate with the overall goals of the PF5 project.
    - **Six (6) page limit, follow standard formatting.**
- [ ] **Progress Report Publication List**: *Only required/allowed for renewal applications*. Can be included in component or included within Overall Component. No page limit, standard formatting.
- Attachments continued (under Other Research Plan Section)
    - [ ] **Vertebrate Animals**: "Vertebrate Animals" attachment needed if you answered "Yes" to the question "Are Vertebrate Animals Used?" on the M.220 - R&R Other Project Information Form. Follow Application Instructions. **No Page limits, standard formatting**.
    - [ ] **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. **No page limit, standard formatting**.
    - [ ] **Consortium/Contractual Arrangements**: Applicable only if International Project includes a subaward to a U.S. organization.
    - [ ] **Letters of Support**: A letter of support must be provided from UWO's Authorized Representative (via ORS). The AOR must clearly indicate in the letter of support that they understand that, should the application be selected for funding, the foreign organization will fill the role as a recipient organization for the disaggregated award, and therefore will have all the necessary registrations completed, as listed above, prior to award.
    - **Other Plan(s)**: A Data Management and Sharing (DMS) Plan must be provided in the Overall Component, *not in this International Project*. A DMS Plan for the International Project component that addresses data that is generated, managed, and shared from the International Project organization may be requested during the Just-in-Time process.
    - [ ] **Authentication of Key Biological and/or Chemical Resources**: Attach if applicable. **Max. one (1) page suggested**. Standard formatting.
    - [ ] **Appendix**: Only limited items are allowed in the Appendix. Follow all instructions for the How to Apply- Application Guide. **A maximum of 10 PDF attachments is allowed.**

PHS Human Subjects and Clinical Trials Information (International Project)

When involving human subjects research, clinical research, and/or NIH-defined clinical trials follow all instructions for the PHS Human Subjects and Clinical Trials Information form in the How to Apply- Application Guide, with the following additional instructions:

If you answered "Yes" to the question "Are Human Subjects Involved?" on the R&R Other Project Information form, you must include at least one human subjects study record using the Study Record: PHS Human Subjects and Clinical Trials Information form or a Delayed Onset Study record.

Attachments:

- [ ] **Study Record or Delayed Onset Study record**: PHS Human Subjects and Clinical Trials Information. All instructions in the How to Apply- Application Guide must be followed.