NIH Proposal Development Checklist

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# Required Internal Documents

*These items are due to the Office of Research & Sponsored Programs (ORSP) before the grant can be submitted.*

[ ] [Grant/contract transmittal form](https://www.uwlax.edu/globalassets/offices-services/grants/uwl-grant-contract-transmittal-form.docx)

Refer to the [UWL grant submission timeline](https://www.uwlax.edu/globalassets/offices-services/grants/orsp-checklist.pdf) for internal deadlines related to the submission of various application elements for institutional review and approval. Route the form with a final budget and budget justification, and a proposal narrative draft for signatures from your department chair/unit director, dean/division director, and the authorized ORSP representative. If PIs/co-PIs are from multiple UWL departments/offices, signatures are needed from each respective department chair/unit director and dean/division director.

[ ] [Financial conflict of interest (FCOI) training & assessment](https://www.uwlax.edu/globalassets/offices-services/grants/fcoi-basics.pdf)

All UWL investigators need to complete the FCOI training course and assessment in Canvas. Once completed, the training and assessment is valid for 4 years. An assessment score of 80% or more must be obtained. Contact ORSP to have an investigator set up as a student in the FCOI course. Training and assessment must be completed once every 4 years if an investigator has active PHS agency funding or is applying for a PHS agency award. See the [PHS FCOI: Identifying Investigators](https://www.uwlax.edu/globalassets/offices-services/grants/fcoi-investigator-definition.pdf) table for assistance determining who qualifies as an investigator.

Each investigator following UWL’s FCOI policy needs to complete the FCOI training and assessment in Canvas. A score of 80% or more must be obtained on the assessment. Contact ORSP to have an investigator set up as a student in the FCOI course. Training and assessment must be completed once every 4 years if an investigator has an active award from a PHS agency or other agency that follows PHS regulations.

[ ] [Significant financial interest (SFI) disclosure form](https://uwlax.ca1.qualtrics.com/jfe/form/SV_brRodUJK0ubDUSF)

All UWL investigators need to complete this online form prior to the submission of every NIH grant application. The UWL [financial conflict of interest (FCOI) policy summary](https://www.uwlax.edu/globalassets/offices-services/grants/fcoi-basics.pdf) provides an overview of SFIs that need to be disclosed.

# NIH Basics

*Below are resources you should review or ensure you have as you begin the proposal development process.*

[ ] [eRA Commons](https://public.era.nih.gov/commons/commonsInit.do) account

Submitted NIH applications and awards are electronically administered through the eRA Commons system. All senior/key personnel named in the proposal–including those at UWL and other collaborating institutions–will need an individual eRA Commons account. For UWL personnel, contact ORSP for set-up of a new account or re-affiliation of an existing account. Collaborators outside of UWL will need to contact their sponsored research office for account set-up.

[ ] [ASSIST](https://public.era.nih.gov/assist/public/login.era)

NIH applications are developed and submitted electronically via the NIH ASSIST system. You will need an active [eRA Commons](https://public.era.nih.gov/commons/commonsInit.do) account to access ASSIST. Contact ORSP with the Funding Opportunity Announcement (FOA) number (e.g., PAR-18-714 for AREA grants) to request application set-up.

[ ] [Application guide](https://grants.nih.gov/grants/how-to-apply-application-guide.html)

Refer to the [application guide](https://grants.nih.gov/grants/how-to-apply-application-guide.html) to determine the specific requirements for your application and for information on how to complete each component. Most UWL applications will be subject to **both** the [research instructions](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/research-forms-e.pdf) and [general instructions](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf).

[ ] Funding Opportunity Announcement (FOA)/Parent Announcement (PA)

Along with the application guide, the FOA/PA provides guidance specific to the program you are targeting, which may include additional or different guidance from that addressed in the application guide. If the FOA differs from the application guide or research instructions, the FOA supersedes other guidelines. Closely review the list of participating institutes/centers (ICs) in the FOA to ensure the IC(s) you are targeting are eligible for that program.

# Required NIH Proposal Components

*The list is a general guide to common requirements for applications that should be used in conjunction with the* [*application guide*](https://grants.nih.gov/grants/how-to-apply-application-guide.html)*, general instructions, research instructions, and FOA to determine the full requirements for a specific program. NIH provides* [*form templates*](http://grants.nih.gov/grants/forms/format-pages.htm) *for some documents, instructions for* [*formatting attachments*](http://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/format-attachments.htm)*, and* [*page limits*](https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/page-limits.htm)*. Refer to the* [*ASSIST User Guide*](https://era.nih.gov/files/ASSIST_user_guide.pdf) *for instructions on completing forms.*

[ ]  NIH ASSIST forms

See the NIH [ASSIST User Guide](https://era.nih.gov/files/ASSIST_user_guide.pdf) for information on how to complete required forms. In order to access the forms in ASSIST, contact ORSP to request an application be set-up.

[ ] [Budget](http://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/develop-your-budget.htm)

The [UWL budget helper template](https://www.uwlax.edu/globalassets/offices-services/grants/budget_helper_spreadsheet.xlsm) is the recommended starting point, as it automatically calculates required fringe benefits, indirect costs, and a cumulative budget. Alternately, the current UWL fringe benefit and indirect cost rates can be found [here](https://www.uwlax.edu/globalassets/offices-services/grants/fringe_indirect2.pdf). More budgeting resources can be found on the [ORSP website](https://www.uwlax.edu/grants/how-to-apply-for-grants/#tm-budgeting). If subawards are included, a separate budget and budget justification is required for each subrecipient. A detailed annual budget and budget justification is needed for internal review and approval whether the budget submitted to NIH is R&R detailed or modular.

[ ] Budget justification

A general [template](https://www.uwlax.edu/globalassets/offices-services/grants/budget-justification-template.docx) is available on the ORSP website. There are significant differences in justification requirements for R&R detailed budgets and modular budgets. See the [research instructions](https://grants.nih.gov/grants/how-to-apply-application-guide.html) and NIH’s [budget guidance](https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/develop-your-budget.htm).

[ ]  PHS Assignment Request Form (optional)

Applicants may request assignment of an application to a particular review group or NIH institute/center, although the Center for Scientific Review ultimately determines where an application is assigned. The form can also be used to list individuals who should not review an application and identify areas of expertise needed to review an application.

[ ]  Research Plan: Specific Aims

A [template](https://www.uwlax.edu/globalassets/offices-services/grants/nih-specific-aims-template.docx) is available on the ORSP website. Limited to 1 page.

[ ]  Research Plan: Research Strategy

The Research Strategy must include and address the following headings: Significance, Innovation, Approach. Do not duplicate information addressed in other attachments. Limited to 12 pages for R15 proposals.

[ ]  Project Summary/Abstract

A [template](https://www.uwlax.edu/globalassets/offices-services/grants/nih-project-summary-template.docx) is available on the ORSP website. Limited to 30 lines of text.

[ ]  Project Narrative

A [template](https://www.uwlax.edu/globalassets/offices-services/grants/nih-project-narrative-template.docx) is available on the ORSP website. Limited to 3 sentences.

[ ]  Bibliography & References Cited

Include any references cited in the application. You are allowed to cite interim research products, which are subject to specific citation requirements; see the [related FAQs](https://grants.nih.gov/grants/interim_product_faqs.htm). There is no page limit for this document, which is uploaded as a separate file. Follow the citation standards within your academic discipline.

[ ]  Facilities & Other Resources

A [template](https://www.uwlax.edu/globalassets/offices-services/grants/nih-facilities-template.docx) is available on the ORSP website. There is no page limit for this document, but it should be succinct.

[ ]  Equipment

A [template](https://www.uwlax.edu/globalassets/offices-services/grants/nih-equipment-template.docx) is available on the ORSP website. There is no page limit for this document, but it should be succinct.

[ ]  Biographical Sketch

Include one for each senior/key personnel and other significant contributors. Senior/key personnel are “individuals who contribute in a substantive, meaningful way to the scientific development or execution of the project, whether or not salaries are requested.” NIH provides a [template and instructions](http://grants.nih.gov/grants/forms/biosketch.htm). Limited to 5 pages per biographical sketch.

[ ]  Letter of Support: Certification of Institutional Eligibility

The R15 AREA solicitation (PAR-18-714) requires a letter certifying institutional eligibility for the program to be uploaded as a Letter of Support. It must be signed by the Provost, and so plan ahead in requesting this document. Contact ORSP for assistance and a template.

# Potentially Required NIH Proposal Components

## *Projects Involving Live Vertebrate Animals*

[ ]  Care & Use of Vertebrate Animals in Research attachment

Projects involving live vertebrate animals are subject to NIH’s related [requirements](http://grants.nih.gov/grants/olaw/vertebrate_animal_section.htm) and must submit this attachment, which should address (1) description of procedures; (2) justifications; and (3) minimization of pain and distress. Refer to the [research instructions](https://grants.nih.gov/grants/how-to-apply-application-guide.html) for full guidelines.

[ ]  [IACUC Congruence Review](https://grants.nih.gov/grants/olaw/120607_Congruence_slides.pdf)

Projects involving live vertebrate animals are required to undergo IACUC congruency review by the UWL IACUC Coordinator prior to award issuance (i.e., during the Just in Time process) to ensure the approved IACUC protocol is congruent with the grant application. The PI is responsible for initiating the review; to allow for potentially required protocol revisions, it is strongly recommended a PI initiate the process after application scores are received if a high score indicates funding is likely. Consult with ORSP for further guidance.

## *Projects Involving Human Subjects and/or Specimens/Data*

[ ]  Human Subjects and Clinical Trials Information Form and attachments

This form is required for all human subjects research *and* projects involving human specimens and/or data that may or may not qualify as human subjects research. For help determining whether your research is classified as human subjects research, refer to the NIH [Research Involving Private Information or Biological Specimens flowchart](https://grants.nih.gov/grants/policy/hs/PrivateInfoOrBioSpecimensDecisionChart.pdf).

1. ***If you checked “no”*** *to “Are human subjects involved?”* in Other Project Information, **but** the project involves human specimens and/or data:

[ ]  A justification is required explaining why no human subjects are involved. See the [Research Instructions](https://grants.nih.gov/grants/how-to-apply-application-guide.html) for requirements.

1. ***If you checked “yes”***to *“Are human subjects involved?*” in Other Project Information*:*

[ ]  Add a study record for *each* proposed study involving human subjects. Further information is required if study(ies) are [delayed onset study(ies)](https://grants.nih.gov/grants/glossary.htm#DelayedOnsetHumanSubjectStudy). See the [Research Instructions](https://grants.nih.gov/grants/how-to-apply-application-guide.html) for full requirements. Generally, each study record requires the following sections:

[ ]  Basic Information

[ ]  Study Population Characteristics

Required for all human subjects studies unless either or both of the following apply:

* If you selected only Exemption 4 and no other exemptions.
* If you answered “no” to “Does the study involve human participants?”, then only some questions in this section are required. (See [Research Instructions](https://grants.nih.gov/grants/how-to-apply-application-guide.html).)

Examples of attachments required in this section: Inclusion of Women, Minorities, & Children; Recruitment & Retention Plan; Study Timeline.

[ ]  Inclusion Enrollment Report(s)

Required for all human subjects studies unless you select only Exemption 4 and no other exemptions.

[ ]  Protection and Monitoring Plans

Examples of required attachments: Protection of Human Subjects, Data & Safety Monitoring Plan.

[ ]  Protocol Synopsis

Required if you answered “yes” to all questions in the Clinical Trial Questionnaire. Not required if you answered “no” to any question.

[ ]  Other Clinical Trial-related Attachments

Required if you answered “yes” to all questions in the Clinical Trial Questionnaire. Not required if you answered “no” to any question.

[ ]  IRB Congruence Review

Applications for projects involving human subjects are required to undergo IRB congruency review by the UWL IRB Coordinator prior to award issuance (i.e., during the Just in Time process) to ensure the approved IRB protocol is congruent with the grant application. The PI is responsible for initiating the review; to allow for potentially required protocol revisions, it is strongly recommended a PI initiate the process after application scores are received if a high score indicates funding is likely. Consult with ORSP for further guidance.

## *Projects Involving Biological and/or Chemical Resources*

[ ]  Authentication of Key Biological and/or Chemical Resources attachment

This is required for projects involving biological and/or chemical resources that 1) may differ from lab to lab over time; 2) may have qualities/qualifications that could influence research data; and 3) are integral to the proposed research. A 1-page document is required to describe methods to ensure the identify and validity of these resources (e.g., cell lines, specialty chemicals, antibodies, other biologics). Standard laboratory reagents that are not expected to vary do not need to be included (e.g., buffers, other common biologicals or chemicals).

[ ]  [Select Agents](http://www.selectagents.gov/) Research attachment

This document is required if proposed activities use select agents at any time at the applicant organization or any performance site. Select agents are hazardous biological agents and toxins that have been identified by HHS or USDA as having the potential to pose a severe threat to the public, animals, and/or plants. See the Federal Select Agent website for a [full list](https://www.selectagents.gov/SelectAgentsandToxinsList.html). Refer to the [research instructions](https://grants.nih.gov/grants/how-to-apply-application-guide.html) for attachment requirements.

[ ] [Dual use research of concern (DURC)](http://www.phe.gov/s3/dualuse/documents/durc-policy.pdf)

If a project involves the use of one of the [15 agents/toxins](http://www.phe.gov/s3/dualuse/Documents/durc-companion-guide.pdf) (see p. 16 for list) identified by federal regulations, the PI must contact the UWL IBC to receive guidance on ensuring compliance with federal and institutional DURC requirements.

## *Other Supplementary Documents*

[ ]  Bids for substantive funding requests (e.g., equipment, consultants, services)

Attach relevant bids to the end of the budget justification document.

[ ]  Resource Sharing Plan(s)

When applicable, this section should include the following:

* *Data Sharing Plan:* Applications with direct costs of $500,000 or more in any single year are expected to address data sharing unless otherwise instructed by a solicitation; SBIR grantees are subject to alternate guidance. See the [NIH Data Sharing Policy](http://grants.nih.gov/grants/policy/data_sharing/) for more information.
* *Sharing Model Organisms Plan:* This is required for all applications where the development of model organisms is anticipated. See the [NIH Model Organism Sharing Policy](https://grants.nih.gov/grants/policy/model_organism/).
* *Genomic Data Sharing (GDS) Plan:* This is required for projects generating large-scale human or non-human genomic data; see the [NIH GDS policy](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-124.html).

[ ]  Appendix

 As detailed in NIH [NOT-OD-17-098](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-098.html), the appendix may only include:

* Blank data collection forms, blank survey forms and blank questionnaire forms—or screenshots thereof.
* Simple lists of interview questions (For clarification, these blank forms and lists are not and do not include items such as: data, data compilations, lists of variables or acronyms, data analyses, publications, manuals, instructions, descriptions or drawings/figures/diagrams of data collection methods or machines/devices).
* Blank informed consent/assent forms
* Other items only if they are specified in the FOA as allowable Appendix materials

Some FOAs further restrict allowable appendix materials and/or may specify that some materials listed above must be provided in another part of the application.  Applications submitted to those FOAs must follow instructions in the FOA and must not put those items in the Appendix.

[ ]  Other documents required by program solicitation/FOA/PA

# Required Components for Proposals with External Collaborators

*Collaborators are incorporated into an application based on the contribution(s) they will make to a project:*

1. ***Subrecipients*** *make significant contributions to a project’s objectives and have some responsibility for programmatic decision-making. They are included in an application’s budget via subawards.*
2. ***Consultants*** *provide goods and/or services that are ancillary to a project’s objectives. They are included in an application’s budget as consultants.*

*Required proposal components depend upon the type of collaborator(s) included in the application. See the items listed below and review the program solicitation to verify what is allowable and/or required.* ***For UWL PIs/co-PIs, the items listed under “Required Internal Documents” in this checklist are also required prior to submission.***

[ ]  Consortium/Contractual Arrangements

Explain the programmatic, fiscal, and administrative arrangements to be made between the applicant organization and the consortium organization(s). Refer to the [template](https://www.uwlax.edu/globalassets/offices-services/grants/nih-consortium-and-contractual-arrangements-template.docx) on the ORSP website.

[ ]  Letter of Support from Consultants & Collaborators

If consultants and/or collaborators are included in a project, it may be appropriate (or required) to include letters of support confirming their roles. Consultant letters should include the rate/charge and level of effort/number of hours for consulting services.

[ ]  Subrecipient letter of intent (LOI) or other written confirmation of commitment

For projects involving subrecipients, the confirmation should be signed by an authorized representative of the subrecipient’s grants office (or other authorized representative) and should (1) confirm the institution’s commitment to the project; (2) include an attached scope of work, budget, and budget justification; and (3) certify which institution’s federally compliant FCOI policy subrecipient investigators will follow. The signed documentation should be routed to the lead institution’s grants office prior to submission. Contact ORSP for a template.

[ ]  Subrecipient DUNS number

[ ]  Subrecipient scope of work (SOW)

The SOW should provide an overview of the subrecipient’s role in the project, including a description of the work to be performed, objectives to be addressed, methodology, deliverables, milestones, and special requirements (as applicable). Contact ORSP for a template.

[ ]  Subrecipient budget and budget justification

The budget should outline only the requested funds for the subrecipient, including applicable fringe benefits and indirect costs. See the [budget helper spreadsheet](https://www.uwlax.edu/globalassets/offices-services/grants/budget_helper_spreadsheet.xlsm) on the ORSP website for a format. A budget justification [template](https://www.uwlax.edu/globalassets/offices-services/grants/budget-justification-template.docx) is also available on the ORSP website.

[ ]  [Leadership Plan for Projects with Multiple PDs/PIs](http://grants.nih.gov/grants/multi_pi/)

[ ] All collaborating investigators: FCOI policy certification

See the [PHS FCOI: Identifying Investigators](https://www.uwlax.edu/globalassets/offices-services/grants/fcoi-investigator-definition.pdf) table for assistance determining who qualifies as an investigator. This certification should indicate which entity’s FCOI policy an external collaborator will follow (i.e., their institution’s PHS compliant FCOI policy or UWL’s FCOI policy). Collaborators following their own institution’s FCOI policy will be subject to that institution’s requirements and should consult with their sponsored research office for guidance. All UWL investigators are required to follow UWL’s [FCOI policy](https://www.uwlax.edu/grants/financial-conflict-of-interest-fcoi/). For subrecipients, this certification can be included in the LOI.

[ ] Collaborating [investigators](http://www.uwlax.edu/uploadedFiles/Offices-Services/Grants/FCOI_Investigator_Checklist_PHS.pdf) following UWL’s [FCOI policy](https://www.uwlax.edu/grants/financial-conflict-of-interest-fcoi/):

[ ] a. [FCOI training and assessment](https://www.uwlax.edu/globalassets/offices-services/grants/fcoi-basics.pdf)

Each investigator following UWL’s FCOI policy needs to complete the FCOI training and assessment in Canvas. A score of 80% or more must be obtained on the assessment. Contact ORSP to have an investigator set up as a student in the FCOI course. Training and assessment must be completed once every 4 years if an investigator has an active award from a PHS agency or other agency that follows PHS regulations.

[ ] b. [Significant financial interest (SFI) disclosure form](https://uwlax.ca1.qualtrics.com/jfe/form/SV_brRodUJK0ubDUSF)

Each investigator following UWL’s FCOI policy needs to complete the online form. A new form is required for each grant application.