**PHS FINANCIAL CONFLICT OF INTEREST (FCOI)**

* All UNL PIs and Co-I’s have a COI/COC disclosure on file.

**GENERAL FORMATTING**

* No headers, footers, or page numbers in attachments. NIH will add headers, footers, page numbers, bookmarks and a table of contents upon submission.
* Page size is no larger than standard letter paper size (8.5" x 11”).
* All margins are at least 1/2”.
* Font requirements:
  + Font size is at least 11 point 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%).
  + Type density must be no more than 15 characters per linear inch (including characters and spaces).
  + Line spacing is no more than six lines per vertical inch.
  + Text color has 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.
  + Recommended fonts: Arial, Georgia, Helvetica, or Palatino Linotype.
* No hyperlinks or URLs are included unless specifically noted as allowable in the NOFO. When allowed, you must hyperlink the actual URL text rather than hiding the URL behind a specific word or phrase.

**ATTACHMENTS**

* All attachments must be uploaded as PDFs.
* File names cannot contain an ampersand (&).
* All file names must be unique.
* All attachment file names must be 50 characters or less (including spaces).

**R&R COVER**

* For a Resubmission, Renewal, and Revision, enter the application ID from the original proposal (i.e. DK123456 from ID of 1R21DK123456-02) as the Federal Identifier.
* Agency Routing Identifier: applications in response to a NOSI should enter the notice number.
* Employer Identification: 147-0049123A8.
* Cover Letter Attachment: only include if any of the situations below apply and should include project title and funding opportunity title.
  + For late applications, include specific information about timing and nature of the cause of the delay.
  + When submitting a Changed/Corrected Application after the due date, a cover letter is required explaining the reason for late submission of the Changed/Corrected Application (include the original cover letter text as well because it overwrites the original cover letter).
  + Explanation of any subaward budget components not active for all periods of the proposed grant.
  + Statement that any required agency approval documentation is attached, (e.g. approval for $500K+).
  + When intending to submit a video as part of the application, the cover letter must include information about the intent to submit it; if this is not done, the video will not be accepted
  + Include a statement in the cover letter if the proposed studies will generate large-scale human or non-human genomic data as detailed in the NIH Genomic Data Sharing Policy
  + 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.

**OTHER PROJECT INFORMATION**

* Human Assurance # (if applicable): enter 00002258 and do not enter “FWA” before the numbers.
* Animal Welfare Assurance # (if applicable): enter D16-00289.
* Project Summary/Abstract: **REQUIRED**; limited to 30 lines of text.
* Project Narrative: **REQUIRED**; limited to 2-3 sentences; describes the relevance to public health.
* Bibliography & References Cited: **REQUIRED** unless otherwise specified in the NOFO.
* Facilities & Other Resources: **REQUIRED** unless otherwise specified in the NOFO**.** Should indicate ways the organization will support the program, financial or otherwise. Includes any facilities and resources of any foreign performance sites. For early stage investigators (ESIs), describes institutional investment in the success of the investigator.
* Equipment: **REQUIRED**.
* Other Attachments: use only if directed by the NOFO or if the project involves a foreign component.
  + Foreign Justification: required if you check "yes" on question 6. Describe 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. In the body of the text, begin the section with a heading indicating “Foreign Justification” and name the file “Foreign Justification.”

**SITES (project/performance locations)**

* Primary and all subaward sites are listed.
* UEI is included for all sites.

**SR/KEY PERSON PROFILE**

* Make sure organization name is “University of Nebraska-Lincoln” for the PD/PI Contact Info.
* **REQUIRED:** Include the eRA Commons ID for all senior/key personnel listed.
* Degree type and year are completed for all senior/key personnel.
* Bio sketch
  + 5 pages
  + Educational block: undergrad, grad, post doc
  + Personal statement, including up to 4 publications; can list other names used to author research products.
    - As applicable, all applicants may include details on ongoing and completed research projects from the past three years that they want to draw attention to within the personal statement, Section A.
  + Positions, Scientific Appointments, and Honors: in reverse chronological order, list ***all positions and scientific appointments both domestic and foreign, including affiliations with foreign entities or governments. This includes titled academic, professional, or institutional appointments whether or not remuneration is received, and whether full-time, part-time, or voluntary (including adjunct, visiting, or honorary).***
  + Up to 5 contributions to science; for each contribution, can reference up to 4 peer reviewed publications or other research products; limited to ½ page per contribution, including citations.
    - Can provide a URL to list of published work, but it is not required. If provided, it must be a .gov address (e.g. My NCBI My Bibliography).
  + Graphics, figures & tables are not allowed in the bio sketch.

**R&R BUDGET (as applicable)**

* This form must be added through Add Optional Form.
* No salary increases are included in the budget template (base salary increase is okay in the first year for project start dates after July 1).
* All senior/key personnel (PIs, Co-Is, etc.) must have measurable effort (more than zero).
* Salaries are checked against the current NIH salary cap and any cash cost share is routed in NuRamp (see NIH Salary Cap Calculator at <https://research.unl.edu/sponsoredprograms/proposal-preparation-resources/>).
* Start date follows earliest project start date table (see <https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/due-dates.htm>).
* Roles in the budget form match exactly to roles shown in the senior/key personnel profile (e.g. PD/PI).
* The Cognizant Agency should be listed as DHHS, Denise Shirlee, 214-767-3261.
* Budget justification is uploaded and explains any exclusions applied to the F&A base calculation.
* When a DMS plan is required, budget justification includes information for Data Management and Sharing costs even if no costs will be incurred for Data Management and Sharing:
  + DMS justification is clearly labeled as “Data Management and Sharing Justification” followed by the requested dollar amount (if no cost will be incurred, “0” is listed for the requested dollar amount).
  + Brief summary of type and amount of scientific data to be preserved and shared and the name of the established repository(ies) where they will be preserved and shared is listed.
  + General cost categories such as curating data and developing supporting documentation, local data management considerations, preserving and sharing data through established repositories, etc., including an amount for each category and a brief explanation is listed.
  + DMP justification length is no more than half a page (recommended).
* If application proposes the use of Human Fetal Tissue (HFT) obtained from elective abortions, a detailed justification is included that includes the quantity, type(s), and source(s) of the HFT, including the stage of fetal development. This information must be included if costs for the HFT are assigned to the grant or if the HFT is acquired under the grant at no costs. The HFT justification must be clearly labeled in the budget justification attachment.

**R&R SUBAWARD BUDGET (as applicable)**

* This form must be added through Add Optional Form.
* Subs must have a detailed R&R budget if UNL’s budget is R&R.
* Measurable effort must be listed for each sub’s Senior/Key Personnel.
* Roles in the budget form match exactly to roles shown in the senior/key personnel profile (e.g. PD/PI).
* Foreign institution’s F&A is limited to 8% MTDC.
* Cognizant Federal Agency is complete.
* Budget justification is uploaded.

**MODULAR BUDGET (as applicable)**

* This form must be added through Add Optional Form.
* Only allowed for R01, R03, R15, R21, and R34 ($250,000 or less in direct costs per year; this limit does not include consortium/contractual F&A). Cannot use modular if human fetal tissue obtained from elective abortions is included in the proposal.
* No salary increases are included in the budget template (base salary increase is okay in the first year for project start dates after July 1).
* Salaries are checked against the current NIH salary cap and any cash cost share is routed in NuRamp (see NIH Salary Cap Calculator at <https://research.unl.edu/sponsoredprograms/proposal-preparation-resources/>). Effort in personnel justification with no salary budgeted = cost share.
* Start date confirmed against earliest project start date table (see <https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/due-dates.htm>).
* The Cognizant Agency should be listed as DHHS, Denise Shirlee, 214-767-3261.
* The Indirect Cost Rate Agreement Date should be listed as 12/17/2020.
* Personnel justification: no salaries/benefits info included; all personnel are listed, including names, effort, and roles on the project (see here for editable example: <https://research.unl.edu/sponsoredprograms/proposal-preparation-resources/>).
* Consortium justification: includes estimated total costs each year rounded to nearest $1,000; indicate foreign or domestic; only personnel justification without salaries/benefits (see here for editable example: <https://research.unl.edu/sponsoredprograms/proposal-preparation-resources/>).
* Additional narrative justification: included when any of the following are involved (see here for editable example: <https://research.unl.edu/sponsoredprograms/proposal-preparation-resources/>).
  + There are variations in modules except for R21.
  + There are MTDC base exclusions.
  + There is work being conducted off-site involving a foreign study site or off-site F&A rate.
  + The application includes the requirement to submit a Data Management and Sharing (DMS) Plan.
    - DMS justification is clearly labeled as “Data Management and Sharing Justification” followed by the requested dollar amount (if no cost will be incurred, “0” is listed for the requested dollar amount).
    - Brief summary of type and amount of scientific data to be preserved and shared and the name of the established repository(ies) where they will be preserved and shared is listed.
    - General cost categories such as curating data and developing supporting documentation, local data management considerations, preserving and sharing data through established repositories, etc., including an amount for each category and a brief explanation is listed.
    - DMP justification length is no more than half a page (recommended).

**RESEARCH PLAN**

* Introduction to Application: required for Resubmission or Revision; 1 page limit unless specified in the NOFO (R25, K12, T and D Training Grants all have 3 page limit). For resubmissions and renewals: introduction includes rationale for any change involving the number or makeup of PD/PIs.
* Specific Aims: **REQUIRED**; 1 page limit
* Research Strategy: **REQUIRED**; should contain headings of Significance, Innovation, and Approach.
  + If the use of human fetal tissue obtained from elective abortions is included in the proposed application you must include specific information in the Approach section.
  + **R01: 12 page limit**
  + **R03, R21, R35, F31, F32: 6 page limit.**
  + For programs not listed above see page limitations at <https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/page-limits.htm#train>
* Progress Report Publication List: required for Renewal applications only.
* Vertebrate Animals: required if vertebrates are involved. Should cover:
  + Description of Procedures
  + Justifications
  + Minimization of Pain and Distress
  + Note that euthanasia is no longer addressed here.
* Select Agent Research: required if 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.
* Multiple PI/PD Leadership Plan: required only if there is more than one PD/PI listed on the application.
* Consortium/Contractual Arrangements: required if subawards are included; use editable example found at <https://research.unl.edu/sponsoredprograms/proposal-preparation-resources/>.
* Letters of Support: any letters necessary to demonstrate the support of consortium participants and collaborators such as Senior/Key Personnel and Other Significant Contributors.
  + For consultants, letters should include rate/charge for consulting services and level of effort/number of hours per budget period anticipated. In addition, letters ensuring access to core facilities and resources should stipulate whether access will be provided as a fee-for-service.
  + Letters must not contain data/figures/tables/graphs, preliminary data, methods, background and significance details that are expected to be found in Research Strategy section of the application.
* Resource Sharing Plan(s): required only for Sharing Model Organisms and/or Research Tools.
* Other Plan(s): (note if both items below are required, should have a single plan that addresses elements for both).
  + Data Management and Sharing (DMS) Plan (recommended 2 page max): required based on activity codes (see <https://sharing.nih.gov/data-management-and-sharing-policy/about-data-management-and-sharing-policies/research-covered-under-the-data-management-sharing-policy>).

Should address:

* + - Data type
    - Related Tools, Software and/or Code
    - Standards
    - Data Preservation, Access, and Associated Timelines
    - Access, Distribution, or Reuse Considerations
    - Oversight of Data Management and Sharing
  + Genomic Data Sharing: required only if applicable.
* Authentication of Key Biological and/or Chemical Resources: required if Research Strategy proposes key biological and/or chemical resources; must have one page plan describing methods proposed for authenticating key resources.
* Appendix: maximum of 10 PDF attachments allowed; use file names descriptive of content. Summary sheet encouraged, but not required. Applications with appendix materials not specifically listed below or in the NOFO will be withdrawn and not reviewed.
  + Blank data collection forms, blank survey forms, and blank questionnaire forms - or screenshots thereof
  + Simple lists of interview questions
  + Blank informed consent/assent forms
  + Other items only if they are specified in the NOFO as allowable appendix materials

**HUMAN SUBJECTS AND CLINICAL TRIALS**

\*\*\*This form consolidates human subjects, inclusion enrollment report, and clinical trial information.

* Question about the use of human specimens and/or data must be answered. If answer is yes, a justification is required if the use is not considered human subjects research; if answer is no, skip remainder of this form.

**YES to Human Subjects:**

* Study record or delayed onset study for each proposed study involving human subjects is completed.
* Delayed onset studies: a justification is attached. If sIRB policy will apply to the study, the justification must also include information about how the study will comply with the policy.
* Inclusion of Individuals Across the Lifespan
* Inclusion of Women and Minorities
* Recruitment and Retention Plan
* Inclusion Enrollment Report(s)
* Protection of Human Subjects
  + Question on multi-site study is answered; sIRB attachment is no longer required for NIH applications; it is expected you will comply with the policy. sIRB info will now be provided at JIT stage.

**Clinical Trials Only:**

* Study Timeline
* Data Safety Monitoring Plan
* Overall Structure of the Study Team
* Statistical Design and Power
* Answer question about the use of FDA-regulated intervention; if yes, upload required summary describing the availability of study agents and support for the acquisition and administration of the study agent(s).
* Dissemination Plan

**OPTIONAL FORM**

* PHS Assignment Request Form: can complete just one or can complete multiple of the optional fields.
* Awarding Component Assignment Request (optional)
* Study Section Assignment Request (optional)
* Rationale for assignment suggestions (optional)
* List individuals who should not review your application and why (optional)
* Identify scientific areas of expertise needed to review your application (optional).