**Proposal Component Checklist and Narrative Instructions**

National Institutes of Health

Research (“R” Series) Instructions (e.g., R01, R03, R21)

*This document provides a checklist of proposal components for standard NIH Research Grant (R series) proposals (e.g., R01, R03, or R21) on the first and second page, followed by detailed instructions for completing the narrative attachments. While this document provides summarized instructions, complete instructions can be found by reviewing the relevant Funding Opportunity Announcement (FOA) and the* [*SF424 (R&R) Research (R) Instructions – Forms Version I Series.*](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-i/research-forms-i.pdf)

**SF424 (R&R) Form**

* Cover Letter Attachment (if applicable)

**PHS 398 Cover Page Supplement Form**

* Human Fetal Tissue Compliance Assurance (if applicable)
* Human Fetal Tissue Sample IRB Consent Form (if applicable)

**PHS 398 Research Plan Form**

* Introduction to Application (Resubmission or Revision only)
* Specific Aims
* Research Strategy
* Progress Report Publication List (Renewal applications only)
* Vertebrate Animals (if applicable)
* Select Agent Research (if applicable)
* Multiple PI/PD Leadership Plan (if applicable)
* Consortium/Contractual Arrangements (if applicable)
* Letters of Support (if appropriate)
* Resource Sharing Plan(s) (if applicable)
* Other Plans (Data Management and Sharing Plan)
* Authentication of Key Biological and/or Chemical Resources (if applicable)
* Appendix (if applicable)

**R&R Senior/Key Person Profile (Expanded) Form**

* Biographical Sketch(es)

**R&R Other Project Information Form**

* Project Summary/Abstract
* Project Narrative
* Bibliography and References Cited
* Facilities and Other Resources
* Equipment
* Other Attachments (if applicable)

**Project/Performance Site Location(s) Form**

* No attachments are required

**PHS 398 Modular Budget Form *or* the R&R Budget Form**

* Budget justification attachment(s)

**R&R Subaward Budget Attachment(s) Form** (if applicable)

* Only used in conjunction with the R&R Budget Form, not the PHS 398 Modular Budget Form

**PHS Assignment Request Form** (complete if you wish to make specific assignment or review requests)

* No attachments are required

**PHS Human Subjects and Clinical Trials Information Form[[1]](#footnote-2)**

* Inclusion of Individuals Across the Lifespan (required for most human subjects studies)
* Inclusion of Women and Minorities (required for most human subjects studies)
* Recruitment and Retention Plan (required for most human subjects studies)
* Study Timeline (required for clinical trails, optional for other human subjects studies)
* Protection of Human Subjects (required for all human subjects studies)
* Single Institutional Review Board Plan (if applicable; only requested for AHRQ applications, not NIH applications)
* Data and Safety Monitoring Plan (required for clinical trials, optional for other human subjects studies)
* Overall Structure of the Study Team (optional)
* Statistical Design and Power (for clinical trials only)
* FDA-regulated Interventions (if applicable; for clinical trials only)
* Dissemination Plan (for clinical trials only)
* Human Specimens and/or Data Justification (if applicable)
* Other Requested Information (if applicable; renewal or resubmission of a renewal application only)
* Delayed Onset Study(ies) Justification (if applicable)

***Note:*** *Page limits provided throughout are for standard R01, R03, and R21 proposals but may vary for other NIH mechanisms and specific Program Announcements (PAs) or Requests for Application (RFAs).*

**Formatting Instructions for Narrative Attachments**

* Recommend using Arial font. A font size of 11 points or larger must be used. The font must be no more than 15 characters per linear inch (including characters and spaces) and must be no more than six lines per vertical inch.
* Smaller text in figures, graphs, diagrams, and charts is acceptable as long as it is legible.
* Use English and avoid jargon; spell out acronyms the first time it is used in each application section/attachment and note the appropriate abbreviation in parentheses. The abbreviation may be used in the section/attachment thereafter.
* Use at least one-half inch margins (top, bottom, left, and right) for all pages. No applicant-supplied information should appear in the margins, headers, or footers.
* Strongly encouraged to use only a standard, single-column format for the text.
* Hyperlinks and URLs are only allowed when specifically noted in the FOA and form field instructions (e.g., biographical sketches or publication lists). It is highly unusual for a FOA to allow links in the Specific Aims, Research Strategy, and other page-limited attachments. Hyperlinks and URLs may not be used to provide information necessary to application review. 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.
* For additional information on standard formatting requirements, see the NIH [Format Attachments](https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/format-attachments.htm) page.

**Cover Letter Attachment** (if applicable)

* Address the cover letter to the Division of Receipt and Referral.
* Do not use the cover letter to communicate application assignment preferences. The Assignment Request Form is provided for that purpose.
* The cover letter is for internal use only and will not be shared with peer reviewers. The letter should contain any of the following information, as applicable:
1. Application title.
2. Title of FOA (PA or RFA).
3. For late applications, include specific information about the timing and nature of the delay.
4. For changed/corrected applications submitted after the due date, a cover letter is required, and it must explain the reason for late submission of the changed/corrected application. If you already submitted a cover letter with a previous submission and are now submitting a late changed/corrected application, you must include all previous cover letter text in the revised cover letter attachment. The system does not retain any previously submitted cover letters; therefore, you must repeat all information previously submitted in the cover letter as well as any additional information.
5. Explanation of any subaward budget components that are not active for all budget periods of the proposed grant (see R&R Subaward Budget Attachment[s] Form).
6. Statement that you have attached any required agency approval documentation for the type of application submitted. This may include approval for applications that request $500,000 or more, approval for Conference Grant or Cooperative Agreement (R13 or U13), etc. It is recommended that you include the official communication from a NIH official as part of your cover letter attachment.
7. 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, a video will not be accepted.
8. 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.
9. Include a statement 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.

**Human Fetal Tissue Compliance Assurance** (if applicable)

* If the proposed project involves the use of HFT, the applicant must provide a letter, signed by the PD/PI, assuring the HFT donating organization or clinic adheres to the requirements of the informed consent process and documenting that HFT was not obtained or acquired for valuable consideration. The letter must be named “HFTComplianceAssurance.pdf”.

**Human Fetal Tissue Sample IRB Consent Form** (if applicable)

* If the proposed project involves the use of HFT, provide a blank sample of the IRB-approved consent form. The form must be a blank sample and named “HFTSampleIRBConsentForm.pdf”.
* The informed consent for use of HFT from elective abortions requires language that acknowledges informed consent for donation of HFT was obtained by someone other than the person who obtained the informed consent for abortion, that informed consent for donation of HFT occurred after the informed consent for abortion was obtained will not affect the method of abortion, and that no enticements, benefits, or financial incentives were used at any level of the process to incentivize abortion or the donation of HFT. The form must be signed by both the woman and the person who obtains the informed consent.

**Introduction to Application** (for Resubmission or Revision applications only; limited to one page)

* For resubmissions, the introduction must summarize the substantial additions, deletions, and changes to the application. The introduction must also include a response to the issues and criticism raised in the Summary Statement.
	+ Do not markup changes within application attachments (e.g., do not highlight, color, bold or italicize changes in Research Strategy)
	+ *Note: For resubmission 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 in the introduction 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 in the introduction.*
* For revisions, the introduction should describe the nature of the revision and how it will influence the specific aims, research design, and methods of the current grant.
	+ *Note that for Revision applications, the body of the application should contain sufficient information from the original grant application to allow evaluation of the proposed revision in relation to the goals of the original application, and any budgetary changes for the remainder of the project period of the current grant should be discussed in the Budget Justification*
* Use of hyperlinks and URLs in this section is not allowed unless specified in the funding opportunity.

**Specific Aims** (limited to one page)

* 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 aims of the research proposed.
* Use of hyperlinks and URLs in this section is not allowed unless specified in the funding opportunity.
* Do not include figures in the Specific Aims attachment as this can interfere with NIH post-award process to categorize awards in RePORT.

**Research Strategy** (limited to 12 pages for R01s; limited to six pages for R03s and R21s)

* Organize the Research Strategy in the order specified below.
* Start each section with the appropriate heading – Significance, Innovation, and Approach.
* Cite published experimental details in the Research Strategy and provide the full reference in the Bibliography and References Cited document.
* For applications proposing the involvement of human subjects and/or clinical trials, use the Research Strategy to discuss the overall strategy, methodology, and analyses of the proposed research, but do not duplicate information in the PHS Human Subjects and Clinical Trials Information form, which will capture detailed study information. Refer to information in the PHS Human Subjects and Clinical Trials Information form as appropriate in your discussion of the Research Strategy.
* Use of hyperlinks and URLs in this section is not allowed unless specified in the funding opportunity.

**1. Significance**

* Explain the importance of the problem or critical barrier to progress that the proposed project addresses.
* Describe the strengths and weaknesses in the rigor of the prior research (both published and unpublished) that serves as the key support for the proposed project.
* Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.
* Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved.

**2. Innovation**

* Explain how project challenges and seeks to shift current research or clinical practice paradigms.
* Describe any novel theoretical concepts, approaches or methodologies, instrumentation, or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or interventions.
* Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions.

**3. Approach**

* Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims.
* Describe plans to address weaknesses in the rigor of the prior research that serves as the key support for the proposed project.
* Describe the experimental design and methods proposed and how they will achieve robust and unbiased results.
* Include how the data will be collected, analyzed, and interpreted, and reference the *Resource Sharing Plans* and the *Data Management and Sharing (DMS) Plan*, as appropriate (see below).
* Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.
* You also may wish to include a discussion of future directions for your research, as well as a project timeline, in this section.
* If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high-risk aspects of the proposed work.
* For trials that randomize groups or deliver interventions to groups, describe how your methods for analysis and sample size are appropriate for your plans for participant assignment and intervention delivery. These methods can include a group- or cluster-randomized trial or an individually randomized group-treatment trial.
* For studies in vertebrate animals and humans, explain how relevant biological variables, such as sex, are factored into research designs and analyses. For example, strong justification from the scientific literature, preliminary data, or other relevant considerations must be provided for applications proposing to study only one sex.
* Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised. A full discussion on the use of select agents should appear in the Select Agent Research document below.
* If research on Human Embryonic Stem Cells (hESCs) is proposed but an approved cell line from the NIH hESC Registry cannot be chosen, provide a strong justification for why an appropriate cell line cannot be chosen from the registry at this time.
* **If the use of HFT is included in the proposed application:**
	1. **Use the specific heading “Human Fetal Tissue Research Approach.”**
	2. **Describe the proposed characteristics, procurement, and procedures for the research use of HFT. The description should be sufficiently detailed to permit meaningful evaluation by NIH.**
	3. **Justify the use of HFT in the proposed research by indicating the following:**
		1. **Why the research goals cannot be accomplished by using an alternative to HFT;**
		2. **What methods were used (e.g., literature review, preliminary data) to determine that alternatives could not be used;**
		3. **Results from a literature review used to provide justifications;**
		4. **Plans for the treatment of HFT and the disposal of HFT when research is complete;**
		5. **Description of planned written, voluntary, informed consent process for cell/tissue donation, or description and documentation of process if cells/tissue were already obtained.**

Applications proposing HFT that do not address these requirements will be administratively withdrawn.

* ***Preliminary Studies:*** For new applications, include information on the PD/PI’s preliminary studies, data, and/or experience pertinent to this application. Except for Exploratory/Developmental Grants (R21/R33), Small Research Grants (R03), and Academic Research Enhancement Award Grants (R15), preliminary data can be an essential part of a research grant application and help to establish the likelihood of success of the proposed project. Early Stage Investigators should include preliminary data.
* ***Progress Report:*** For renewal/revision applications, provide the beginning and ending dates for the period covered since the last competitive review. Summarize the specific aims of the previous project period and the importance of the findings, and emphasize the progress made toward their achievement. Explain any significant changes to the aims and any new directions, including changes resulting from significant budget reductions. For studies meeting NIH definition for clinical research, discuss previous participant enrollment (e.g., recruitment, retention, inclusion of women, minorities, children, etc.).
	+ Use the Progress Report section to discuss, but not duplicate, information collected elsewhere in the application.
	+ Do not include a list of publications, patents, and other printed materials in the Progress Report. That information should be included in Progress Report Publication List document below.
	+ Note that the Progress Report falls within the Research Strategy and is therefore included in the page limits for the Research Strategy.
	+ 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 here 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 Publication List** (Renewal applications only)

* List the titles and complete references to all appropriate publications, manuscripts accepted for publication, patents, and other printed materials that have resulted from the project since it was last reviewed competitively.
* You are allowed to cite interim research products, which are complete, public research products that are not final such as preprints and preregistered protocols. To cite the interim product, include the Digital Object Identifier and the Object type (e.g., preprint, protocol) in the citation. Also list any information about the document version (e.g., most recent date modified), and if relevant, the date the product was cited.
* When citing articles that fall under the Public Access Policy, were authored or co-authored by the applicant, and arose from NIH support or from Agency for Healthcare Research and Quality (AHRQ) funding provided after February 19, 2016, provide the NIH Manuscript Submission reference number (e.g., NIHMS97531) or the PubMed Central (PMC) reference number (e.g., PMCID234567) for each article. If the PMCID is not yet available because the journal submits articles directly to PMC on behalf of their authors, indicate “PMC Journal – In Process.” NIH maintains a list of such journals.
* Citations that are not covered by the Public Access Policy, but are publicly available in a free, online format may include URLs or PubMed ID (PMID) numbers along with the full reference.
* Use of hyperlinks and active URLs in this section is not allowed unless specified in the funding opportunity.

**Vertebrate Animals** (if applicable)

* **Complete this section if vertebrate animals will be used in your project.**
* **Address each of the following criteria:**
	+ ***Description of Procedures:*** Provide a concise description of the proposed procedures that involve live vertebrate animals in the work outlined in the Research Strategy. Include sufficient detail to allow evaluation of the procedures. Identify the species, strains, ages, sex, and total numbers of animals by species to be used. If dogs or cats are proposed, provide the source of the animals.
	+ ***Justifications:*** Provide justification that the species are appropriate for the proposed research. Explain why the research goals cannot be accomplished using an alternative model (e.g., computational, human, invertebrate, in vitro).
	+ ***Minimization of Pain and Distress:*** Describe the interventions, including analgesia, anesthesia, sedation, palliative care, and humane endpoints, that will be used to minimize discomfort, distress, pain, and injury.
* Identify all project/performance or collaborating site(s) and describe the proposed research activities with vertebrate animals that will be conducted at those sites.
* If applicable, explain when and how animals are expected to be used if plans for the use of animals have not been finalized.

**Select Agent Research** (if applicable)

* Complete this document 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.
* Select agents are defined as hazardous biological agents and toxins that have been identified by Health and Human Services (HHS) or the U.S. Department of Agriculture (USDA) as having the potential to pose a severe threat to public health and safety, to animal and plant health, or to animal and plant products.
* See [SF424 (R&R) Research (R) Instructions – Forms Version I Series](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-i/research-forms-i.pdf) for links to lists of select agents.
* Address the following three points for each site at which select agent research will take place:
* Identify the select agent(s) to be used in the proposed research.
* Provide the registration status of all entities—any government agency (Federal, State, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity—where select agent(s) will be used. If the performance site(s) is a foreign institution, provide name(s) of the country or countries where select agent research will be performed.
* Provide a description of all facilities where the select agent(s) will be used. Describe the procedures that will be used to monitor possession, use, and transfer of select agent(s). Describe plans for appropriate biosafety, biocontainment, and security of the select agent(s). Describe the biocontainment resources available at all performance sites.
* If the activities proposed in the application involve only the use of strains of select agents that have been excluded from the list of select agents and toxins as per 42 CFR 73.3, the select agent requirements do not apply. Use this document to identify the strains of the select agents that will be used and note that they have been excluded from this list. The CDC maintains a list of exclusions, which is available on the Select Agents and Toxins Exclusions website.
* If the strains are not currently excluded from the list of select agents and toxins but you have applied or intend to apply to HHS for an exclusion from the list, indicate the status of your request or your intent to apply for an exclusion and provide a brief justification for the exclusion.

**Multiple PD/PI Leadership Plan** (if applicable)

* For applications designating multiple PD/PIs *only*, a Multiple PD/PI Leadership Plan must be included.
* Describe a rationale for choosing a multiple PD/PI approach.
* Describe the governance and organizational structure of the leadership team and the research project, including communication plans, processes for making decisions on scientific direction, and procedures for resolving conflicts.
* Delineate the roles and administrative, technical, and scientific responsibilities for the project or program for the PD/PIs and other collaborators.
* If budget allocation is planned, delineate the distribution of resources to specific components of the project or the individual PD/PIs.
* *Note: For resubmission or renewal applications changing from a single PD/PI to multiple PD/PIs or changing the number or makeup of the multiple PD/PIs, the Multiple PD/PI Leadership Plan is required.*

**Consortium/Contractual Arrangements** (if applicable)

* 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).
* If consortium/contractual activities represent a significant portion of the overall project, explain why the applicant organization, rather than the ultimate performer of the activities, should be the grantee.

**Letters of Support** (if applicable)

* Attach appropriate letters of support, including those necessary to demonstrate the support of consortium participants and collaborators, such as Senior/Key Personnel and Other Significant Contributors, included in the grant application. Letters are not required for personnel (such as research assistants) not contributing in a substantive, measurable way to the scientific development or execution of the project.
* Letters should stipulate expectations for co-authorship, and whether cell lines, samples, or other resources promised in the letter are freely available to other investigators in the scientific community or will be provided to the particular investigators only.
* For consultants, letters should include rate/charge for consulting services and level of effort/number of hours per budget period anticipated. Letters ensuring access to core facilities and resources should stipulate whether access will be provided as a fee-for-service.
* Material Transfer Agreements may be included in this section.
* Letters must focus on the topics listed above and not contain data/figures/tables/graphs, preliminary data, methods, background and significance details that are expected to be found in the Research Strategy. Letters of Support serve to describe terms of a collaboration or consultation and also are not de facto letters of reference from persons not actively participating in the project. Applications with letters containing such excess information may be withdrawn from the review process.
* Use of hyperlinks and active URLs in this section is not allowed unless specified in the funding opportunity.

**Resource Sharing Plan(s)** (if applicable)

* ***Sharing Model Organisms (if applicable):*** For all projects where the development of model organisms is anticipated, include a description of a specific plan for sharing and distributing unique model organisms or state why such sharing is restricted or not possible.
* ***Research Tools (if applicable):*** When unique research resources will be developed with NIH funds, describe plans to make the resources readily available for research purposes to qualified individuals within the scientific community after the associated research findings have been published or provided to NIH.

**Other Plans (Data Management and Sharing Plan)** (recommend two-page limit)

* Applicants proposing to conduct research that will generate scientific data are subject to the NIH Data Management and Sharing Policy and must attach a Data Management and Sharing (DMS) Plan.
	+ Scientific data is defined as the recorded factual material commonly accepted in the scientific community as of sufficient quality to validate and replicate research findings, regardless of whether the data are used to support scholarly publications. Scientific data includes any data needed to validate and replicate research findings. Scientific data does not include laboratory notebooks, preliminary analyses, completed case report forms, drafts of scientific papers, plans for future research, peer reviews, communications with colleagues, or physical objects such as laboratory specimens.
* Include the following elements in the DMS Plan:
* ***Data Type:*** Briefly describe the scientific data to be managed, preserved, and shared, including a general summary of the types and estimated amount of scientific data to be generated and a description of which scientific data from the project will be preserved and shared as well as the rationale for doing so. Briefly list the metadata, other relevant data, and any associated documentation (e.g., study protocols and data collection instruments) that will be made accessible to facilitate interpretation of the scientific data.
* ***Related Tools, Software and/or Code:*** State whether specialized tools are needed to access or manipulate shared scientific data to support replication or reuse, and name(s) of the needed tool(s) and software. If specialized tools or software are needed, provide the name(s) of the needed tool(s) and software and specify how they can be accessed.
* ***Standards:*** State what common data standards will be applied to the scientific data and associated metadata to enable interoperability of datasets and resources (e.g., data formats, data dictionaries, data identifiers, definitions, unique identifiers, and other data documentation), and provide the name(s) of the data standards that will be applied and describe how these data standards will be applied to the scientific data generated by the research proposed in this project. If applicable, indicate that no consensus standards exist.
* ***Data Preservation, Access, and Associated Timelines:*** Provide plans and timelines for data preservation and access, including the name of the repository(ies) where scientific data and metadata arising from the project will be archived (do not include hyperlinks); how the scientific data will be findable and identifiable (i.e., via a persistent unique identifier or other standard indexing tools); and when (i.e., no later than time of an associated publication or end of the performance period, whichever comes first) the scientific data will be made available to other users (e.g., the larger research community, institutions, and/or the broader public) and for how long.
* ***Access, Distribution, or Reuse Considerations:*** NIH expects that, in drafting Plans, researchers maximize the appropriate sharing of scientific data generated from NIH-funded or conducted research consistent with privacy, security, informed consent, and proprietary issues. Describe and justify any applicable factors affecting subsequent access, distribution, or reuse of scientific data related to informed consent, privacy and confidentiality protections, any restrictions imposed by federal, Tribal, or state laws, regulations, or policies, or existing or anticipated agreements, or any other considerations that may limit the extent of data sharing. State whether access to the scientific data will be controlled (i.e., made available by a data repository only after approval). If generating scientific data derived from humans, describe how the privacy, rights, and confidentiality of human research participants will be protected (e.g., through de-identification, Certificates of Confidentiality, and other protective measures).
* ***Oversight of Data Management and Sharing:*** Describe how compliance with the Plan will be monitored and managed, frequency of oversight, and by whom at the applicant institution (e.g., titles, roles).
* If the research will generate large-scale human or non-human genomic data, provide a plan for sharing of these data as part of the DMS Plan.
	+ State whether data, including genomic summary results, will be made available through controlled or unrestricted access.
	+ For proposed research generating human genomic data within the scope of the GDS Policy, applicants should complete the Data Management and Sharing Plan anticipating sharing according to the assurances of the Institutional Certification.
	+ If there is any element of the Institutional Certification that the institution (in consultation with the IRB) has determined cannot be met, state which element and provide a detailed explanation for why the element cannot be met. In such cases, the data management and sharing plan should describe how genomic data will be shared to the maximal extent possible (for example, sharing data in a summary format).
* Do not include hyperlinks in this attachment.

**Authentication of Key Biological and/or Chemical Resources** (if applicable; a maximum of one page is suggested)

* 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.
* Key biological and/or chemical resources may or may not be generated with NIH funds and: 1) may differ from laboratory to laboratory or over time; 2) may have qualities and/or qualifications that could influence the research data; and 3) are integral to the proposed research. These include, but are not limited to, cell lines, specialty chemicals, antibodies, and other biologics.
* Standard laboratory reagents that are not expected to vary do not need to be included in the plan. Examples are buffers and other common biologicals or chemicals.

**Appendix** (if applicable)

* The only allowable appendix materials are:
	+ Blank data collection forms, blank survey forms, and blank questionnaire forms - or screenshots thereof;
	+ Simple lists of interview questions; and
	+ Blank informed consent/assent forms.
* In your blank forms and lists, 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.
* A maximum of 10 PDF attachments is allowed in the Appendix. If more than 10 appendix attachments are needed, combine the remaining information into attachment #10.
* Use file names for attachments that are descriptive of the content.
* A summary sheet listing all of the items included in the appendix is encouraged but not required. When including a summary sheet, it should be included in the first appendix attachment.

**Biographical Sketch(es)** (limited to five pages per biographical sketch)

* Provide a biographical sketch for the PD/PI(s), each senior/key person, and each other significant contributor. In light of federal agencies’ heightened sensitivity to foreign influence on the United States, make sure the bio lists all affiliations/appointments with any outside entities (including international entities), even if unpaid. A National Institutes of Health [biographical sketch template](https://grants.nih.gov/grants/forms/biosketch.htm) is required[[2]](#footnote-3).

**Project Summary/Abstract** (no longer than 30 lines of text)

* 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).
* Describe the research design and methods for achieving the stated goals.
* Should be informative to other persons working in the same or related fields and understandable to a scientifically literate reader.
* Be sure that the document reflects the key focus of the proposed project so that the application can be appropriately categorized.
* Must not include any proprietary/confidential information or trade secrets.
* Meant to serve as a succinct and accurate description of the proposed work and should be able to stand on its own (separate from the application).
* Avoid describing past accomplishments and the use of the first person.
* If the application is funded, the project summary will be entered into an NIH database and made available on the NIH Research Portfolio Online Reporting Tool (RePORT) and will become public information.
* Use of hyperlinks and URLs in this section is not allowed unless specified in the funding opportunity.
* Unless the funding opportunity states otherwise, only include text (no figures) in this section, as figures can interfere with NIH post-award process to categorize awards in RePORT.

**Project Narrative** (no more than three sentences)

* Describe the relevance of this research to public health. For example, NIH applicants can describe how, in the short- or long-term, the research would contribute to fundamental knowledge about the nature and behavior of living systems and/or the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.
* If the application is funded, this public health relevance statement will be combined with the project summary (above) and will become public information.
* Use of hyperlinks and URLs in this section is not allowed unless specified in the funding opportunity.
* Unless the funding opportunity state otherwise, only include text (no figures) in this section, as figures can interfere with NIH post-award process to categorize awards in RePORT.

**Bibliography and References Cited**

* Should include any references cited in the PHS 398 Research Plan Form and in the PHS Human Subjects and Clinical Trials Information form.
* References should be limited to relevant and current literature.
* When citing articles that fall under the Public Access Policy, were authored or co-authored by the applicant, and arose from NIH support, provide the NIH Manuscript Submission reference number (e.g., NIHMS97531) or the PubMed Central (PMC) reference number (e.g., PMCID234567) for each article. If the PMCID is not yet available because the Journal submits articles directly to PMC on behalf of their authors, indicate “PMC Journal – In Process.” NIH maintains a list of such journals.
* Citations that are not covered by the Public Access Policy, but are publicly available in a free, online format may include URLs or PubMed ID (PMID) numbers along with the full reference. Active hyperlinks in this section are not allowed.
* You are allowed to cite interim research products, which are complete, public research products that are not final such as preprints and preregistered protocols. To cite the interim product, include the Digital Object Identifier and the Object type (e.g., preprint, protocol) in the citation. Also list any information about the document version (e.g., most recent date modified), and if relevant, the date the product was cited.
* Use of hyperlinks and active URLs in this section is not allowed unless specified in the funding opportunity.

**Facilities and Other Resources**

* 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).
* Discuss ways in which the proposed studies will benefit from unique features of the scientific environment or from unique subject populations or how studies will employ useful collaborative arrangements.
* If there are multiple performance sites, describe the resources available at each site.
* Describe any special facilities used for working with biohazards or other potentially dangerous substances. *Note: Information about select agents must be described in the Select Agent Research document of the Research Plan.*
* For Early Stage Investigators (ESIs), describe institutional investment in the success of the investigator. The description may include the following elements:
	+ Resources for classes, travel, or training.
	+ Collegial support such as career enrichment programs, assistance and guidance in the supervision of trainees involved in the ESI’s project, and availability of organized peer groups.
	+ Logistical support such as administrative management and oversight and best practices training.
	+ Financial support such as protected time for research with salary support.
* Use of hyperlinks and URLs in this section is not allowed unless specified in the funding opportunity.

**Equipment**

* List major items of equipment already available for this project and, if appropriate, identify the equipment’s location and pertinent capabilities.
* Use of hyperlinks and URLs in this section is not allowed unless specified in the funding opportunity.

**Other Attachments**

* Attach a file to provide additional information only in accordance with the FOA and/or agency-specific instructions.
* If this project involves activities outside of the United States or partnerships with international collaborators**,** 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.”

**Budget Justification(s) Attachments**

* Consult with departmental grant staff and/or staff in the Office of Sponsored Programs for advice on budget development and completing the appropriate budget justification attachments.
* ***Data Management and Sharing Justification:*** Applications submitted with a Data Management and Sharing Plan must include a brief justification of the proposed activities that will incur costs. This should be clearly labeled as “Data Management and Sharing Justification” and should be no more than half a page.
1. Instructions for completing these attachments are included in a separate document on the Office of Proposal Development’s website, available at: <http://research.unl.edu/proposaldevelopment/proposal-guidelines-templates-and-outlines-boilerplate-language/>. [↑](#footnote-ref-2)
2. Beginning May 25, 2025, NIH will [implement Common Forms](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-24-163.html) and require use of SciENcv and ORCID ID in generation of biosketches. Refer to [Common Forms for Biographical Sketch and Current and Pending (Other) Support](https://grants.nih.gov/policy-and-compliance/changes-coming-2025/common-forms-for-biosketch) for more information. Office of Proposal Development will update this outline and checklist when NIH finalizes the new instructions. [↑](#footnote-ref-3)