**Solicitation Name:** HHS STTR Phase l

**Solicitation Number:** PA-19-270/ PA-19-270

**Proposal Manager:** [Fill in]

**Submission Date:** 5:00 PM Local on September 5, 2019

**Last Updated:** [Fill in]

**Legend:** Forms, Formatting

| Field # | RFP Requirement (Text Extract) | RFP Page, Section, Paragraph | Proposal Volume/  Section, Page, Paragraph | Writing Assigned To | Notes Regarding Compliance | Due Date | Status |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 1. SF 424 (R&R) Application for Federal Assistance   Complete this form first to populate data in other forms. | | | | | | | |
| Field 1. | **Type of Submission**  Applicants should select the box for “Application” in Type of Submission. If you are correcting either system validation errors or application assembly problems that occurred during the submission process, check the box for “Changed/Corrected Application”. Do not use the "Changed/Corrected Application" box to denote a resubmission application. Resubmission applications will be indicated in "Field 8. Type of Application." |  |  |  |  |  |  |
| Field 4.c. | **Previous Grants.gov Tracking ID**  The "Previous Grants.gov Tracking ID" field is required if you checked the "Changed/Corrected Application" box in "Field 1. Type of Submission." A Tracking ID number is of the form, for example, GRANT12345678. |  |  |  |  |  |  |
| Field 5. | **Applicant Information**  This information is for the Applicant Organization, not a specific individual. The small business concern is ALWAYS the applicant organization for an SBIR or STTR award (e.g., ABC Incorporated). |  |  |  |  |  |  |
| Field 7. | **Type of Applicant**  This field is required. For an SBIR/STTR submission, select "R. Small Business." Also note whether the organization is Woman-owned and/or Socially and Economically Disadvantaged.  The applicant organization must certify (through Just-in-Time pre-award procedures) that it will qualify as a small business concern at the time of award. |  |  |  |  |  |  |
| Field 8. | **Type of Application**  Select the type from the following list. Check only one. This field is required. For more information, see NIH [Types of Applications](https://grants.nih.gov/grants/how-to-apply-application-guide/prepare-to-apply-and-register/type-of-applications.htm).   * New: Check this option when submitting an application for the first time or in accordance with other submission policies. See the [NIH Grants Policy Statement, Section 2.3.7.4: Submission of Resubmission Application](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_2/2.3_application_information_and_processes.htm#Policies). * Resubmission: Check this option when submitting a revised (altered or corrected) or amended application. See also the NIH [Application Submission Policies](https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/submission-policies.htm). If your application is both a "New/Revision/Renewal" and a "Resubmission," check only the "Resubmission" box. * Renewal: Check this option if you are requesting additional funding for a period subsequent to that provided by a current award. A renewal application competes with all other applications and must be developed as fully as if the applicant were applying for the first time. * Continuation: The box for "Continuation" is used only for specific FOAs. * Revision: Check this option for competing revisions and non-competing administrative supplements. For more information on competing revisions, see NIH [Competing Revisions](https://grants.nih.gov/grants/competing-revisions.htm). For more information on administrative supplements, see NIH [Administrative Supplements](https://grants.nih.gov/grants/administrative-supplements.htm). |  |  |  |  |  |  |
| **Revision Type**  If Revision, mark appropriate box (es). May select more than one:   * E. Other If “Other” is selected, please specify in the text box provided. * The boxes for options B, C, D, and E will generally not be used and should not be selected unless specifically addressed in a particular FOA. |  |  |  |  |  |  |
| **Submitted to other agencies**  In the field "Is this application being submitted to other agencies?" check "Yes" if one or more of the specific aims submitted in your application is also contained in a similar, identical, or essentially identical application submitted to another federal agency.  Otherwise, check "No."  If you checked "Yes," indicate the agency or agencies to which the application has been submitted. |  |  |  |  |  |  |
| Field 11. | **Descriptive Title of Applicant’s Project**  This field is required. Enter a brief descriptive title of the project.  The descriptive title is limited to 200 characters, including spaces and punctuation.  New Applications: You must have a title different than any other NIH or other PHS Agency project submitted for the same application due date with the same Project Director/Principal Investigator (PD/PI).  Resubmission or Renewal Applications: You should normally have the same title as the previous grant or application; however, if the specific aims of the project have significantly changed, choose a new title.  Revision Applications: You must have the same title as the currently funded grant. |  |  |  |  |  |  |
| Field 12. | **Proposed Project**  *Start Date*: This field is required. Enter the proposed start date of the project. The start date is an estimate, and is typically at least nine months after application submission. The project period should not exceed what is allowed in the FOA.  *Ending Date*: This field is required. Enter the proposed ending date of the project.  Phase I: Routinely, STTR Phase I awards do not exceed one year. |  |  |  |  |  |  |
| Field 13. | **Congressional District of Applicant**  Enter the Congressional District as follows: a 2-character state abbreviation, a hyphen, and a 3-character district number. Examples: CA-005 for California's 5th district, VA-008 for Virginia's 8th district.  If outside the United States, enter 00-000.  For States and U.S. Territories with only a single congressional district, enter "001" for the district number.  For jurisdictions with no representative, enter "099."  For jurisdictions with a nonvoting delegate, enter "098" for the district number. Example: DC-098 or PR-098.  **If you do not know your Congressional District:** Go to [The United States House of Representatives](http://www.house.gov/) website and search for your Congressional District by entering your ZIP+4. If you do not know your ZIP+4, look it up on the [USPS Look Up Zip Code](https://tools.usps.com/go/ZipLookupAction!input.action) website. |  |  |  |  |  |  |
| Field 14. | **Program Director/Principal Investigator (PI) Contact Information**  This information is for the PD/PI. The PD/PI is the individual responsible for the overall scientific and technical direction of the project.  In the eRA Commons profile, the person listed here in "14. Project Director/Principal Investigator Contact Information" must be affiliated with the applicant organization entered in "5. Applicant Information." If you are proposing research at an institute other than the one you are currently at, do not create a separate Commons account with the proposed applicant organization. For additional information on creating affiliations for users in the eRA Commons, see [eRA Account Management System's Online Help.](https://era.nih.gov/erahelp/AMS_NEW/)  **Additional Instructions for SBIR/STTR[[1]](#endnote-1)** |  |  |  |  |  |  |
| Field 15. | **All four fields in "15. Estimated Project Funding" are required.**  **Total Federal Funds Requested**  Enter total federal funds, including Direct Costs, F&A Costs (Indirect Costs), and Fee, requested for the entire project period.  According to statutory guidelines, total funding support (direct costs, indirect costs, fee) normally may not exceed $150,000 for Phase I awards and $1,000,000 for Phase II awards. With appropriate justification from the applicant, Congress will allow awards to exceed these amounts by up to 50% ($225,000 for Phase I and $1,500,000 for Phase II, a hard cap).[[2]](#endnote-2) |  |  |  |  |  |  |
| **Total Non-Federal Funds**  For applications to NIH and other PHS agencies, enter "0" in this field unless cost sharing is a requirement for the specific FOA. |  |  |  |  |  |  |
| **Total Federal & Non-Federal Funds**  Enter the total federal and non-federal Funds requested. The amount in this field will be the same as the amount in the "Total Federal Funds Requested" field unless the specific FOA indicates that cost sharing is a requirement. |  |  |  |  |  |  |
| **Estimated Program Income**  Indicate any program income estimated for this project, if applicable. |  |  |  |  |  |  |
| Field 16. | **Is Application Subject to Review by State Executive Order 12372 Process?**  Applicants should check "No, Program is not covered by E.O. 12372." |  |  |  |  |  |  |
| Field 17. | **Certification**  This field is required.  The list of NIH and other PHS agencies Certifications, Assurances, and other Policies is found in the [NIH Grants Policy Statement, Section 4: Public Policy Requirements, Objectives and Other Appropriation Mandates.](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4_public_policy_requirements__objectives_and_other_appropriation_mandates.htm)  Check "I agree" to provide the required certifications and assurances. |  |  |  |  |  |  |
| Field 18. | **SFLLL or Other Explanatory Documentation (Optional Form)**  If applicable, attach the SFLLL or other explanatory document as per FOA instructions.  If unable to certify compliance with the Certification in the "17. Certification" section above, attach an explanation. Additionally, as applicable, attach the SFLLL (Standard Form LLL, [Disclosure of Lobbying Activities](https://apply07.grants.gov/apply/forms/sample/SFLLL_1_2-V1.2.pdf)) or other documents in this item.  For more information:  See the [NIH Grants Policy Statement, Section 4.1.17: Lobbying Prohibition](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.1_public_policy_requirements_and_objectives.htm#Lobbying), and the NIH [Lobbying Guidance for Grantee Activities](https://grants.nih.gov/policy/lobbying_guidance.htm) page. |  |  |  |  |  |  |
| Field 19. | **Authorized Representative**  The authorized representative is equivalent to the individual with the organizational authority to sign for an application. This individual is otherwise known as the authorized organization representative (AOR) in Grants.gov or the signing official (SO) in eRA Commons. |  |  |  |  |  |  |
| Field 20. | **Pre-application**  Unless specifically noted in a FOA, NIH and other PHS agencies do not use pre-applications. The "Pre-application" attachment field should not be used for any other purpose. |  |  |  |  |  |  |
| Field 21. | **Cover Letter Attachment**  The cover letter is for internal use only and will not be shared with peer reviewers.  **Who must complete the "Cover Letter Attachment:"**  Refer to the "content" list below for items that are permitted, as well as for specific situations in which a cover letter must be included.  A cover letter must not be included with post-award submissions, such as administrative supplements, change of grantee institution, or successor-in-interest.  **Format:**  Attach the cover letter, addressed to the Division of Receipt and Referral, in accordance with the FOA and/or these instructions.  Attach the cover letter in the correct location, **specifically verifying that the cover letter has not been uploaded to the "20. Pre-application" field which is directly above the "21. Cover Letter Attachment" field.** This will ensure the cover letter attachment is kept separate from the assembled application in the eRA Commons and made available only to appropriate staff.  **Content:**  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 (see Late Application policy on NIH's [Application Submission Policies](https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/submission-policies.htm)) 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 applications. If you already submitted a cover letter with a previous submission and are now submitting a late change/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 [G.310 - R&R Subaward Budget Attachment(s) Form](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general/g.310-r&r-subaward-budget-attachment(s)-form.htm)). 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 an 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, the video will not be accepted. See [NIH Grants Policy Statement, Section 2.3.7.7: Post Submission Grant Application Materials](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_2/2.3_application_information_and_processes.htm#Policies) for additional information. 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 (see the [NIH Grants Policy Statement, Section 2.3.7.10: NIH Genomic Data Sharing](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_2/2.3_application_information_and_processes.htm#Policies) and [Section 8.2.3.3: Genomic Data Sharing (GDS) Policy/Policy for Genome-Wide Association Studies (GWAS))](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.2_availability_of_research_results_publications__intellectual_property_rights__and_sharing_research_resources.htm#Sharing). |  |  |  |  |  |  |
| 1. PHS 398 Cover Page Supplement Form   The PHS 398 Cover Page Supplement Form is used for all grant applications except fellowships. This form collects information on human subjects, vertebrate animals, program income, human embryonic stem cells, inventions and patents, and changes of investigator/change of institution. | | | | | | | |
| Field 1. | **Vertebrate Animals Section**  **Are vertebrate animals euthanized?**  You must answer this question if you answered “Yes” to the question “Are Vertebrate Animals Used?” on the B.220 – R&R Other Project Information Form. |  |  |  |  |  |  |
| **If “Yes” to euthanasia: Is method consistent with American Veterinary Medical Association (AVMA) guidelines?**  You must answer this question if you answered “Yes” to the “Are vertebrate animals euthanized?” question above.  **For more information**: See [AVMA Guidelines for the Euthanasia of Animals.](https://www.avma.org/KB/Policies/Pages/Euthanasia-Guidelines.aspx) |  |  |  |  |  |  |
| **If “No” to AVMA guidelines, describe method and provide scientific justification:**  If you answered “No” to the “Is method consistent with AVMA guidelines?” question, you must describe (in 1000 characters or fewer) the method of euthanasia and provide a scientific justification for its use. This justification will be reviewed by Office of Laboratory Animal Welfare (OLAW). |  |  |  |  |  |  |
| Field 2. | **Program Income Section**  **Is program income anticipated during the periods for which the grant support is requested?**  This field is required.  If program income is anticipated during the periods for which grant support is requested, check “Yes,” and complete the rest of the “Program Income” section.  If no program income is anticipated, check “No” and skip the rest of the “Program Income” section. |  |  |  |  |  |  |
| **Budget Period:**  Enter the budget periods for which program income is anticipated. |  |  |  |  |  |  |
| **Anticipated Amount ($):**  Enter the amount of anticipated program income for each budget period listed |  |  |  |  |  |  |
| **Source(s):**  Enter the source of anticipated program income for each budget period listed |  |  |  |  |  |  |
| Field 3. | **Human Embryonic Stem Cells Section**  Use the following instructions to complete the fields in this section.  For additional guidance, see the [NIH Grants Policy Statement, Section 4.1.13: Human Stem Cell Research](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.1_public_policy_requirements_and_objectives.htm#Human). |  |  |  |  |  |  |
| **Does the proposed project involve human embryonic stem cells?**  This field is required.  If the proposed project involves human embryonic stem cells (hESC), check “Yes” and complete the rest of the “Human Embryonic Stem Cells” section.  If the proposed project does not involve hESC, check “No” and skip the rest of the “Human Embryonic Stem Cells” section. |  |  |  |  |  |  |
| **Specific stem cell line cannot be referenced at this time. One from the registry will be used.**  If you will use hESC but a specific line from the NIH [hESC Registry](https://grants.nih.gov/stem_cells/registry/current.htm) cannot be chosen at the time of application submission, check this box. |  |  |  |  |  |  |
| **Cell Line(s):**  List the 4-digit registration number of the specific cell line(s) from the NIH [hESC Registry](https://grants.nih.gov/stem_cells/registry/current.htm) (e.g. 0123). Up to 200 lines can be added. |  |  |  |  |  |  |
| **For more information:**  See NIH’s [Stem Cell Information](https://stemcells.nih.gov/) page for additional information on stem cells, Federal policy statements, and guidelines on federally funded stem cell research. |  |  |  |  |  |  |
| Field 4. | **Inventions and Patents Section (for Renewal applications)**  **Who must complete the “Invention and Patents” section:**  Complete the "Inventions and Patents" section only if you are submitting a renewal application or a resubmission of a renewal application |  |  |  |  |  |  |
| 1. Research & Related Other Project Information Form   The R&R Other Project Information Form is used for all grant applications. This form includes questions on the use of human subjects, vertebrate animals, and environmental impact. This form also has fields to upload an abstract, project narrative, references, information on facilities, and equipment lists. | | | | | | | |
| Field 1. | **Are Human Subjects Involved?**  This field is required.  If activities involving human subjects are planned at any time during the proposed project at any performance site, check “Yes.” Check “Yes” even if the proposed project is exempt from regulations for the Protection of Human Subjects, or if activities involving human subjects are anticipated within the period of award but plans are indefinite.  If activities involving human subjects are not planned at any time during the proposed project at any performance site, select “No” and skip the rest of the "Are Human Subjects Involved" section.[[3]](#endnote-3) |  |  |  |  |  |  |
| **a. If YES to Human Subjects**  Your answers here in question “1.a. If YES to Human Subjects” will populate the corresponding fields in the B.500 – PHS Human Subjects and Clinical Trials Information form.  **Is the Project Exempt from Federal Regulations? Yes/No**  If the project is exempt from federal regulations, check “Yes” and check the appropriate exemption number.  Human subjects research should only be designated as exempt if all of the proposed research projects in an application meet the criteria for exemption.  If the project is not exempt from federal regulations, check “No.”  For more information, see the NIH’s [Exempt Human Subjects Research infographic](https://humansubjects.nih.gov/sites/hs/public_files/exemption_infographic_v6_hs_internet.pdf).  **If yes, check appropriate exemption number 1, 2, 3, 4, 5, 6:** If you selected “Yes” to “Is the Project Exempt from Federal Regulations,” select the appropriate exemption number. **Do not select exemption 7 or 8.**  The categories of research that qualify for exemption are defined in the Common Rule for the Protection of Human Subjects. These regulations can be found at [45 CFR 46](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html).  **Need help determining the appropriate exemption number?** Refer to NIH's Research Involving Human Subjects [Frequently Asked Questions.](https://humansubjects.nih.gov/human-specimens-cell-lines-data)  The Office of Human Research Protections (OHRP) guidance states that appropriate use of exemptions described in 45 CFR 46 should be determined by an authority independent from the investigators (for more information, see [OHRP's Frequently Asked Questions](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/index.html)). Institutions often designate their Institutional Review Board (IRB) to make this determination. Because NIH does not require IRB approval at the time of application, the exemptions designated often represent the opinion of the PD/PI, and the justification provided for the exemption by the PD/PI is evaluated during peer review.  **If no, is the IRB review Pending? Yes/No**  If IRB review is pending, check “Yes.”  Applicants should check “Yes” to the question “Is the IRB review Pending?” even if the IRB review/approval process has not started by the time of submission.  If IRB review is not pending (e.g., if the review is complete), check “No.”  **IRB Approval Date**  Enter the latest IRB approval date (if available). Leave blank if IRB approval is pending.  An IRB approval date is not required at the time of submission when IRB review is pending. This may be requested later in the pre-award cycle as a Just-In-Time requirement. See the [NIH Grants Policy Statement, Section 2.5.1: Just-in-Time Procedures](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_2/2.5_completing_the_pre-award_process.htm#Just-in-) for more information.  **Human Subject Assurance Number**  Enter the approved Federalwide Assurance (FWA) number that the applicant has on file with OHRP. Enter the 8-digit number. Do not enter “FWA” before the number.  Enter “None” if the applicant organization does not have an approved FWA on file with OHRP. In this case, the applicant organization, by the signature in the Certification section on the B.200 -SF424 (R&R) Form, is declaring that it will comply with [45 CFR 46](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/) and proceed to obtain a FWA (see [Office for Human Research Protections](https://www.hhs.gov/ohrp/) website). Do not enter the FWA number of any collaborating institution. |  |  |  |  |  |  |
| Field 2. | **Are Vertebrate Animals Used?**  This field is required.  If activities involving vertebrate animals are planned at any time during the proposed project at any performance site, check “Yes.” Otherwise, check “No” and skip the rest of the “2. Are  Vertebrate Animals Used?” section.  Note that the generation of custom antibodies constitutes an activity involving vertebrate animals.  If animal involvement is anticipated within the period of award but plans are indefinite, check "Yes."  **Additional Instructions for SBIR/STTR:**  If you have answered “Yes” to the “Are Vertebrate Animals Used?” question, you must also provide an explanation and anticipated timing of animal use in B.400 -  PHS 398 Research Plan Form, Vertebrate Animals. This attachment must be submitted and reviewed prior to the involvement of animals in any research studies. |  |  |  |  |  |  |
| **a. If YES to Vertebrate Animals**  **Is the IACUC review Pending?**  If an Institutional Animal Care and Use Committee (IACUC) review is pending, check "Yes."  Applicants should check “Yes” to the "Is the IACUC review Pending?" question even if the IACUC review/approval process has not started by the time of submission.  **IACUC Approval Date**  Enter the latest IACUC approval date (if available). Leave blank if IACUC approval is pending. IACUC approval must have been granted within three years of the application submission date to be valid.  An IACUC approval date is not required at the time of submission. NIH does not require verification of review and approval of the proposed research by the IACUC before peer review of the application. However, this information is required under the [NIH Grants Policy Statement Section 2.5.1: Just-in-Time Procedures](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_2/2.5_completing_the_pre-award_process.htm#Just-in-).  **Animal Welfare Assurance Number**  Enter the federally approved assurance number, if available.  Enter “None” if the applicant organization does not have an Office of Laboratory Animal Welfare (OLAW)-approved Animal Welfare Assurance.  **Do not enter the Animal Welfare Assurance number for a Project/Performance Site of a collaborating institution.**  When an applicant organization does not have an Animal Welfare Assurance number, the authorized organization representative’s signature on the application constitutes declaration that the applicant organization will submit an Animal Welfare Assurance when requested by OLAW.  If the animal work will be conducted at an institution with an Animal Welfare Assurance and the applicant organization does not have the following:   * an animal care and use program; * facilities to house animals and conduct research on site; and * ACUC;   then, the applicant must obtain an Inter-institutional Assurance from OLAW prior to an award. |  |  |  |  |  |  |
| Field 3 | **Is proprietary/privileged information included in the application?**  This field is required.  Patentable ideas; trade secrets; or privileged, confidential commercial, or financial information should be included in applications only when such information is necessary to convey an understanding of the proposed project.  If the application includes such information, check “Yes” and clearly mark each line or paragraph on the pages containing the proprietary/privileged information with a statement similar to: “The following contains proprietary/privileged information that (name of applicant) requests not be released to persons outside the government, except for purposes of review and evaluation.” This statement can be included at the top of each page as applicable.  If a grant is awarded as a result of or in connection with the submission of this application, the government shall have the right to use or disclose the information to the extent authorized by law. Although the grantee institution and the PD/PI will be consulted about any such disclosure, the NIH and other PHS agencies will make the final determination. Any indication by the applicant that the application contains proprietary or privileged information does not automatically shield the information from release in response to a Freedom of Information Act (FOIA) request should the application result in an award (see [45 CFR 5](https://www.ecfr.gov/cgi-bin/text-idx?SID=422fdceea76050e59217165c8f15e124&mc=true&node=pt45.1.5&rgn=div5)). Additionally, if an applicant fails to identify proprietary information at the time of submission as instructed here, a significant substantive justification will be required to withhold the information if requested under FOIA. |  |  |  |  |  |  |
| Field 4 | **Environmental Questions**  Question 4 pertains to the environmental impact of the proposed research. |  |  |  |  |  |  |
| **a. Does this Project Have an Actual or Potential Impact - positive or negative - on the environment?**  This field is required.  Indicate whether or not this project has an actual or potential impact on the environment.  Most NIH research grants are not expected to individually or cumulatively have a significant effect on the environment, and NIH has established several categorical exclusions allowing most applicants to answer “No” unless a specific FOA indicates that the National Environmental Policy Act (NEPA) applies. However, if an applicant expects that the proposed project will have an actual or potential impact on the environment, or if any part of the proposed research and/or project includes one or more of the following scenarios, check “Yes.”   1. The potential environmental impacts of the proposed research may be of greater scope or size than other actions included within a category. 2. The proposed research threatens to violate a federal, state, or local law established for the protection of the environment or for public health and safety. 3. Potential effects of the proposed research are unique or highly uncertain. 4. Use of especially hazardous substances or processes is proposed for which adequate and accepted controls and safeguards are unknown or not available. 5. The proposed research may overload existing waste treatment plants due to new loads (volume, chemicals, toxicity, additional hazardous wasted, etc.). 6. The proposed research may have a possible impact on endangered or threatened species. 7. The proposed research may introduce new sources of hazardous/toxic wastes or require storage of wastes pending new technology for safe disposal. 8. The proposed research may introduce new sources of radiation or radioactive materials. 9. Substantial and reasonable controversy exists about the environmental effects of the proposed research. |  |  |  |  |  |  |
| **b. If yes, please explain**  Your entry is limited to 55 characters. |  |  |  |  |  |  |
| **c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed? Yes/No**  This field is required if you answered “Yes” to Question 4.a. Check “Yes” or “No.” |  |  |  |  |  |  |
| **d. If yes, please explain:**  Your entry is limited to 55 characters. |  |  |  |  |  |  |
| Field 5. | **Is the research performance site designated, or eligible to be designated, as a historic place?**  This field is required.  If any research performance site is designated, or eligible to be designated, as a historic place, check the “Yes” box. Otherwise, check “No.” |  |  |  |  |  |  |
| **a. If yes, please explain:**  Your entry is limited to 55 characters. |  |  |  |  |  |  |
| Field 6. | **Does this project involve activities outside of the United States or partnerships with international collaborators?**  This field is required. Indicate whether this project involves activities outside of the United States or partnerships with international collaborators. Check “Yes” or “No.”  If you have checked “Yes” to Question 6, you must include a “Foreign Justification” attachment in Field 12, Other Attachments. 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.” |  |  |  |  |  |  |
| **a. If yes, identify countries**  Enter the countries with which international cooperative activities are planned. You may use abbreviations. Your entry is limited to 55 characters. |  |  |  |  |  |  |
| **b. Optional Explanation**  This field is optional. Your entry is limited to 55 characters. |  |  |  |  |  |  |
| Field 7. | **Project Summary/Abstract**  The "Project Summary/Abstract" attachment is required.  The project summary is a succinct and accurate description of the proposed work and should be able to stand on its own (separate from the application). This section should be informative to other persons working in the same or related fields and understandable to a scientifically literate reader. Avoid both descriptions of past accomplishments and the use of the first person. Please be concise. |  |  |  |  |  |  |
| **Format:**  This section is limited to 30 lines of text, and must follow the required [font and margin specifications](https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/format-attachments.htm). A summary which exceeds this length will be flagged as an error by the Agency upon submission. You will need to take corrective action before the application can be accepted.  Attach this information as a PDF file. See the [Format Attachments](https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/format-attachments.htm) page. |  |  |  |  |  |  |
| **Content:**  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. Be sure that the project summary reflects the key focus of the proposed project so that the application can be appropriately categorized.  Do not include proprietary, confidential information or trade secrets in the project summary. 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](https://report.nih.gov/)) and will become public information.  Note that the "Project Summary/Abstract" attachment is not same as the "Research Strategy" attachment. |  |  |  |  |  |  |
| Field 8. | **Project Narrative**  The "Project Narrative" attachment is required.  **Content:**  Describe the relevance of this research to public health in, at most, three sentences. 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. |  |  |  |  |  |  |
| Field 9 | **Bibliography & References Cited**  **Who must complete the “Bibliography & References Cited” attachment:**  The “Bibliography & References Cited” attachment is required unless otherwise noted in the FOA.  **Format:**  Attach this information as a PDF file. See the [Format Attachments](https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/format-attachments.htm) page.  **Content:**  See the following instructions for which references to include in the “Bibliography and References Cited” attachment.  **Additional Instructions for SBIR/STTR:**  The “Bibliography & References Cited” attachment should include any references cited in B.400 - PHS 398 Research Plan Form and in the B.500 - PHS Human Subjects and Clinical Trials Information form.  The references should be limited to relevant and current literature. While there is not a page limitation, it is important to be concise and to select only those literature references pertinent to the proposed research.  You are allowed to cite interim research products. Note: interim research products have specific citation requirements. See related [Frequently Asked Questions](https://grants.nih.gov/grants/interim_product_faqs.htm) for more information. |  |  |  |  |  |  |
| Field 10 | **Facilities & Other Resources**  **Format:**  The “Facilities & Other Resources” attachment is required unless otherwise specified in the FOA.  **Content:**  Describe how the scientific environment in which the research will be done contributes to the probability of success (e.g., institutional support, physical resources, and intellectual rapport). In describing the scientific environment in which the work will be done, discuss ways in which the proposed studies will benefit from unique features of the scientific environment or 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 and any other potentially dangerous substances. **Note: Information about select agents must be described in the Research Plan, Select Agent Research.**  For early stage investigators (ESIs), describe institutional investment in the success of the investigator. See NIH's [New and Early Stage Investigator Policies](https://grants.nih.gov/policy/early-investigators/index.htm). Your 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 with 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.   **Additional Instructions for SBIR/STTR:**  The research to be performed by the applicant small business concern and its collaborators must be in United States facilities that are available to and under the control of each party for the conduct of each party’s portion of the proposed project. Foreign sites must be approved by the funding officer. |  |  |  |  |  |  |
| Field 11 | **Equipment**  The “Equipment” attachment is required.  **Format:**  Attach this information as a PDF file.  **Content:**  List major items of equipment already available for this project and, if appropriate, identify the equipment's location and pertinent capabilities. |  |  |  |  |  |  |
| Field 12 | **Other Attachments**  Attach a file to provide additional information only in accordance with the FOA and/or agency-specific instructions.  If applicable, attach a “Foreign Justification” here. (See Question 6 above).  **Additional Instructions for SBIR/STTR:**  **SBA Company registry (for both SBIR and STTR):**  All applicants to the SBIR and STTR programs are required to attach proof of registration with the SBA Company Registry in Question 12. Other Attachments. You will receive a unique SBC Control ID and SBA Registry file (in PDF format) when you complete your SBC Company Registration. This is the file you must attach in Question 12. Other Attachments. Applicants who have previously registered must also attach proof of registration. |  |  |  |  |  |  |
| 1. Project/Performance Site Location(s) Form: [MANDATORY]    The Project/Performance Site Location(s) Form is used for all grant applications. It is used to report the primary location and any other locations at which the project will be performed.  Using the Project/Performance Site Location(s) Form:  This form allows for the collection of multiple performance sites. If you need to add more project/performance site locations than the form allows, enter the information in a separate file and add it to the “Additional Locations” section. | | | | | | | |
| Project/Performance Site Primary Location | Generally, the primary location should be that of the applicant organization or identified as offsite in accordance with the conditions of the applicant organization’s negotiated Facilities and Administrative (F&A) agreement. This information must agree with the F&A information on the budget form of the application.  Provide an explanation of resources available from each project/performance site on the "Facilities and Resources" attachment of the B.220 - R&R Other Project Information Form.  If the proposed project involves human subjects or live vertebrate animals, it is up to the applicant organization to ensure that all sites meet certain criteria:  **Human Subjects:** If a project/performance site is engaged in research involving human subjects, the applicant organization is responsible for ensuring that the project/performance site operates under an appropriate Federal Wide Assurance for the protection of human subjects and complies with [45 CFR 46](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html) and other NIH human subject related policies described in the [NIH Grants Policy Statement, Section 4.1.15: Human Subjects Protections.](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.1_public_policy_requirements_and_objectives.htm#Human3)  **Vertebrate Animals:** For research involving live vertebrate animals, the applicant organization must ensure that all project/performance sites hold an Office of Laboratory Animal Welfare (OLAW)-approved Animal Welfare Assurance. If the animal work will be conducted at an institution with an Animal Welfare Assurance and the applicant organization does not have the following:   * an animal care and use program; * facilities to house animals and conduct research on site; and * an IACUC;   then applicant must obtain an Inter-institutional Assurance from OLAW prior to an award.  **Additional Instructions for SBIR/STTR:**  Describe any consortium/contractual arrangements in the "Consortium/Contractual Arrangements" attachment in B.400 – PHS 398 Research Plan Form.  One of the performance sites indicated must be that of the applicant small business concern (SBC).[[4]](#endnote-4) |  |  |  |  |  |  |
| Project/Performance Site Location 1 | Use this “Project/Performance Site Location 1” block to provide information on performance sites in addition to the Primary Performance Site listed above, if applicable. Include any VA facilities and foreign sites. |  |  |  |  |  |  |
| Additional Location(s) | If you need to add more project/performance site locations than the form allows, enter the information in a separate file and add it to the “Additional Locations” section.  A format page for Additional Performance Sites can be found on NIH's [Additional Performance Site Format Page.](https://grants.nih.gov/grants/forms/additional-performance-site.htm) |  |  |  |  |  |  |
| 1. R&R Senior/Key Person Profile (Expanded) Form: [MANDATORY]   The R&R Senior/Key Person Profile (Expanded) Form is used for all grant applications, and allows the collection of data for all senior/key persons associated with the project. Some information for the PD/PI may be prepopulated from the SF424 (R&R) form. See instructions in B.200 - SF 424 (R&R) Form if these fields are empty.  Using the R&R Senior/Key Person Profile (Expanded) Form  This form allows for the data collection for a PD/PI and up to 99 other senior/key individuals (including any multi-PD/PIs). After the first 100 individuals have been entered, use the “Additional Senior/Key Person Profiles Format Page” to attach any remaining data.  To ensure proper performance of this form, save your work frequently.  Who qualifies as a Senior/Key Person?  Unless otherwise specified in a FOA, senior/key personnel are defined as all individuals who contribute in a substantive, meaningful way to the scientific development or execution of the project, whether or not salaries are requested. Consultants should be included in this “Senior/Key Person Profile (Expanded)” Form if they meet this definition.  List individuals that meet the definition of senior/key regardless of what organization they work for. | | | | | | | |
| Profile - Project Director/Principal Investigator | Enter data in this “Profile – Project Director/Principal Investigator” section for the Project Director/Principal Investigator (PD/PI).  The PD/PI must have an eRA Commons account with the PI role, and the account must be affiliated with the applicant organization. If you are proposing research at an institute other than the one you are currently at, do not create a separate Commons account with the proposed applicant organization. For information on eRA Commons account administration, see the [eRA Account Management System’s Online Help](https://era.nih.gov/erahelp/AMS_NEW/#Manage_Account/Affiliate_Account.htm?Highlight=affiliation).  **Special Instructions for Multiple PD/PIs:** When submitting an application involving multiple PD/PIs, list the “Contact” PD/PI in this field. List all additional PD/PIs in the Senior/Key Person section(s) below.  **Additional Instructions for SBIR/STTR:**  **STTR Applications:** The STTR applicant organization must officially affiliate the PD/PI with the small business concern (SBC) in the eRA Commons if the PD/PI is not an employee of the SBC. For additional information on creating user affiliations in the eRA Commons, see the [eRA Account Management System’s Online Help](https://era.nih.gov/erahelp/AMS_NEW/#Manage_Account/Affiliate_Account.htm?Highlight=affiliation).  **Credential, e.g., agency login:** This field is required. Enter the assigned eRA Commons username for the project’s PD/PI. The eRA Commons username must hold the PI role and be affiliated with the applicant organization. Applications will not pass agency validation requirements without a valid eRA Commons username.  **Special Instructions for Multiple PD/PI:** The Commons username must be provided for all individuals assigned the Project Role of PD/PI on the application.  **Project Role:** Enter "PD/PI" for the Project Role for the PD/PI.  **Other Project Role Category:** Skip the “Other Project Role Category” field, as no other role can be added to the PD/PI role.  **Attach Biographical Sketch** Provide a biographical sketch for each PD/PI. See instructions below on how to complete a biographical sketch.  **Attach Current & Pending Support**: Do not use this attachment upload for NIH and other PHS agency submissions unless otherwise specified in the FOA.  While this information is not required at the time of application submission, it may be requested later in the pre-award cycle. If and when this occurs, refer to the [NIH Grants Policy Statement, Section 2.5.1: Just-in-Time Procedures.](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_2/2.5_completing_the_pre-award_process.htm) |  |  |  |  |  |  |
| Instructions for a Biographical Sketch | These instructions apply to Research (R), Career Development (K), Training (T), Fellowship (F), Multi-project (M), and SBIR/STTR (B).  **Who must complete the “Biographical Sketch” section:** All senior/key personnel and [other significant contributors (OSCs)](https://grants.nih.gov/grants/glossary.htm#OtherSignificantContributors(OSCs)) must include biographical sketches (biosketches).  **Format:** Use the sample format on the [Biographical Sketch Format Page](https://grants.nih.gov/grants/forms/biosketch.htm) to prepare this section for all grant applications.  Figures, tables (other than those included in the provided format pages), or graphics are not allowed in the biosketch. Do not embed or attach files (e.g. video, graphics, sound, data).  The biosketch may not exceed five pages per person. This five-page limit includes the table at the top of the first page.  Attach this information as a PDF file. See the [Format Attachments](https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/format-attachments.htm) page.  **Content:** Note that the instructions here follow the format of [Biographical Sketch Format Page](https://grants.nih.gov/grants/forms/biosketch.htm).[[5]](#endnote-5)  **eRA Commons User Name:**  If the individual is registered in the [eRA Commons](https://public.era.nih.gov/commons/public/login.do?TYPE=33554433&REALMOID=06-1edb031f-46c7-44b3-b803-60b537de74d2&GUID=&SMAUTHREASON=0&METHOD=GET&SMAGENTNAME=-SM-938PYmoLVb4VrDeXo04LZUDVDvc%2b3899ByInEAjuSUvWNIGfB2zRpWiCivYGCogG&TARGET=-SM-HTTP%3a%2f%2fpublic%2eera%2enih%2egov%2fcommons), fill in the eRA Commons User Name in the “eRA Commons User Name” field of the Biosketch Format Page.  The “eRA Commons User Name” field is required for the PD/PI (including career development and fellowship applicants), primary sponsors of fellowship applicants, all mentors of candidates for mentored career development awards, and candidates for diversity and reentry research supplements.  The “eRA Commons User Name” field is optional for other project personnel.  **The eRA Commons User Name should match the information provided in the Credential field of the R&R Senior/Key Person Profile (Expanded) Form in your grant application.** |  |  |  |  |  |  |
| Profile – Senior/Key Person 1 | Enter data in this “Profile – Senior/Key Person 1” section to provide information on a senior/key person (other than the PD/PI listed above), if applicable.  **Format:** List all senior/key person profiles, followed by other significant contributors (OSC) profiles.  **Content – Who to include in the “Profile – Senior/Key Person” section:**  **Senior/Key Persons:** Fill in a separate “Profile – Senior/Key Person” block for each [senior/key personnel](https://grants.nih.gov/grants/glossary.htm#Senior/KeyPersonnel). Those with a postdoctoral role should be included if they meet the NIH Glossary definition of [senior/key personnel](https://grants.nih.gov/grants/glossary.htm#Senior/KeyPersonnel). A biosketch is required for all senior/key persons.  **Other Significant Contributors:** Also use the “Profile – Senior/Key Person” section to list any [other significant contributors (OSCs)](https://grants.nih.gov/grants/glossary.htm#OtherSignificantContributors(OSCs)). Consultants should be included if they meet the NIH Glossary definition of [OSC](https://grants.nih.gov/grants/glossary.htm#OtherSignificantContributors(OSCs)). OSCs should be listed **after** all other senior/key persons.  A biosketch is required for all OSCs. The biosketch should highlight the OSC’s accomplishments as a scientist. Reviewers assess these pages during peer review. For more information on review criteria, see the [Review Criteria at a Glance](https://grants.nih.gov/grants/peer/guidelines_general/Review_Criteria_at_a_glance.pdf) document. Although Other Support information is required as a just-in-time submission, Other Support information will NOT be required or accepted for OSCs since considerations of overlap do not apply to these individuals.  Should the level of involvement increase for an individual listed as an OSC, thus requiring measurable effort on the award, the individual must be redesignated as “senior/key personnel.” This change must be made before any compensation is charged to the project.  **For more information:** For more information, refer to these NIH Senior/Key Personnel [Frequently Asked Questions](https://grants.nih.gov/grants/policy/senior_key_personnel_faqs.htm).  **Project Role:** Select a project role. Use "Other (Specify)" if the desired category is not available.  **Special Instructions for Multiple PD/PIs:** All PD/PIs must be assigned the “PD/PI” role, even those at organizations other than the applicant organization. The role of “Co-PD/PI” is not currently used by NIH or other PHS agencies to designate a multiple PD/PI application. In order to avoid confusion, do not use the role of “Co-PD/PI.”  **Note on OSCs:** For OSCs, enter “Other (Specify)” for the “Project Role” field, and enter “Other Significant Contributor” in the “Other Project Role Category” field.  **Other Project Role Category:** Complete this field (e.g., Engineer, Chemist, Sponsor, Mentor) if you selected “Other Professional” or “Other (Specify)” in the “Project Role” field. |  |  |  |  |  |  |
| Additional Senior/Key Person Profile(s) | If you need to add more Senior/Key Person Profiles than the form allows, enter the information in a separate file and attach it as a PDF.  A format page for Additional Senior/Key Person Profiles can be found at NIH's [Additional Senior/Key Person Form](https://grants.nih.gov/grants/forms/additional-senior-key-person-profile.htm) page. |  |  |  |  |  |  |
| 1. R&R Budget Form   The R&R Budget Form is used in the majority of applications; however, it is important to refer to your specific FOA for guidance on which budget form(s) are allowed for your application.  Some application forms packages include two optional budget forms — (1) the R&R Budget Form and, (2) PHS 398 Modular Budget Form. Include only one of these forms, but not both, in your application. | | | | | | | |
|  | **Who should use the R&R Budget Form?**  There are two primary types of Budget Forms: detailed R&R and PHS 398 modular. Generally, you must use the R&R Budget Form if you are applying for more than $250,000 per budget period in direct costs, and you must use the Modular Budget Form if you are applying for less than $250,000. However, some grant mechanisms or programs (e.g., training grants) may require other budget forms to be used. Refer to your FOA and to the following instructions for guidance on which Budget Form to use.  **Note:** The terms “detailed budget” and “R&R Budget” are used interchangeably.  **Note on Subawards/Consortiums:** If you have a subaward/consortium, you must use the R&R Subaward Budget Attachment(s) Form in conjunction with the R&R Budget Form. The prime must extract the R&R Subaward Budget Attachment(s) from the R&R Subaward Budget Attachment(s) Form and send the extracted file to the subaward/consortium. The consortium should complete the R&R Subaward Budget Attachment, following the instructions here and in B.310 – R&R Subaward Budget Attachment(s) Form.  **For more information:** For more information on how to prepare your budget, see NIH's [Develop Your Budget](https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/develop-your-budget.htm) page.  **Using the R&R Budget Form:** The location of the R&R Budget Form may vary with the type of submission (e.g., under an “Optional Forms” tab).  You must complete a separate detailed budget for each budget period requested. The form will generate a cumulative budget for the total project period. If no funds are requested for a required field, enter “0.”  You must round to the nearest whole dollar amount in all dollar fields. |  |  |  |  |  |  |
| Introductory Fields | **Budget Type:** This field is required. Check the appropriate box for your budget type, following these guidelines:   * **Project:** The budget being requested is for the primary applicant organization. * **Subaward/Consortium:** The budget being requested is for subaward/consortium organization(s). Note, separate budgets are required only for subaward/consortium organizations that perform a substantive portion of the project. For subawards/consortiums that do not perform a substantive portion of the project, then you must include their costs in Field F5. Subawards/Consortium/Contractual Costs and in the prime’s Section L. Budget Justification.   If you are preparing an application that includes a subaward/consortium that performs a substantive portion of the project, in addition to completing this form, see also the instructions for B.310 - R&R Subaward Budget Attachment(s) Form. |  |  |  |  |  |  |
| A. Senior/Key Person | **Who to include in A. Senior/Key Person:**  Include the names of senior/key persons at the applicant organization, (or organization leading the component of a multi-project application), who are involved on the project in a particular budget period. Include all collaborating investigators and other individuals who meet the senior/key person definition if they are from the applicant organization.  Consultants designated as senior/key persons in the Senior/Key Person Profile Form can be included in the "A. Senior/Key Person" section only if they are also employees of the applicant organization. Otherwise, consultant costs should be included in Consultant Services in Question F of this form.  **Who *not* to include in A. Senior/Key Person:**  Do not list details of collaborators at other institutions here, as they will be provided in the Subaward Budget for each subaward/consortium organization.  Personnel listed as other significant contributors who are not committing any specific measurable effort to the project should not be included in the Personnel section (sections "A. Senior/Key Person" and "B. Other Personnel") since no associated salary and/or fringe benefits can be requested for their contribution.  **Base Salary ($):** Enter the annual compensation paid by the employer for the senior/key person. This includes all activities such as research, teaching, patient care, and other. An applicant organization may choose to leave this blank; however, NIH or other PHS Agency staff will request this information prior to award.  **Months (Cal./Acad./Sum.):** NIH and other PHS agencies use the concept of “person months” as a metric for determining percent of effort. For more information about calculating person months, see NIH's [Frequently Asked Questions on Person Months](https://grants.nih.gov/grants/policy/person_months_faqs.htm). Identify the number of months the senior/key person will devote to the project in the applicable box (i.e., calendar, academic, summer).  Use either calendar months OR a combination of academic and summer months. Measurable effort is required for every senior/key person entry.  For an explanation of "measurable effort," see the NIH Senior/Key Personnel [Frequently Asked Questions](https://grants.nih.gov/grants/policy/senior_key_personnel_faqs.htm).  If effort does not change throughout the year, it is OK to use only the calendar months column.  However, you may use both the academic and summer months columns if your institutional business process requires noting each separately even if effort remains constant. If effort varies between academic and summer months, leave the calendar months column blank and use only the academic and summer months columns.  If your institution does not use a 9-month academic year or a 3-month summer period, indicate your institution’s definition of these in Section L. Budget Justification.  **Requested Salary ($)**: This field is required. Regardless of the number of months being devoted to the project, indicate the salary being requested for this budget period for the senior/key person.  **Fringe Benefits ($):** Enter the amount of requested fringe benefits, if applicable, for the senior/key person.  **Funds Requested ($):** This field is automatically calculated and will reflect the total requested salary and fringe benefits for the senior/key person.  **Project Role:** This field is required. Identify the project role of each senior/key person. Roles should correspond to the roles included on the B.240 - R&R Senior/Key Person Profile (Expanded) Form. Note that there must be at least one PD/PI per budget period.  **Additional Instructions for SBIR/STTR:**  **STTR:** If the budget type is “project,” you do not have to list a PD/PI; list the PD/PI in the Subaward/Consortium budget.  **Additional Senior/Key Persons:** If you are requesting funds for more senior/key persons than the form allows, you must include an attachment listing the additional senior/key person(s) in this “Additional Senior/Key Persons” field. Use the same format as the budget form and include all the information identified in this section. |  |  |  |  |  |  |
| B. Other Personnel | **Number of Personnel:**  For each project role category, identify the number of personnel proposed.  **Administrative, Secretarial, and Clerical Support Salaries:** In most circumstances, the salaries of administrative, secretarial, or clerical staff at educational institutions and nonprofit organizations are included as part of indirect costs (Section H. Indirect Costs). However, examples of situations where direct charging of administrative or clerical staff salaries may be appropriate may be found at: [45 CFR 75.403](https://www.ecfr.gov/cgi-bin/text-idx?SID=22e841b836b64c2a679a9038cd8d7767&mc=true&node=se45.1.75_1403&rgn=div8).  Inclusion of such costs may be appropriate only if all of the following conditions are met:   1. Administrative or clerical services are integral to a project or activity; 2. Individuals involved can be specifically identified with the project or activity; 3. Such costs are explicitly included in the budget or have prior written approval of the federal awarding agency; and 4. The costs are not also recovered as indirect costs.   Requests for direct charging for secretarial/clerical personnel (i.e., administrative and clerical staff) must be appropriately justified in Section L. Budget Justification. For all individuals classified as administrative/secretarial/clerical, provide a justification (in the Budget Justification) documenting how they meet all four conditions. NIH ICs may request additional information for these positions in order to assess allowability.  **Post Doctoral and Graduate Students:** For all postdoctoral associates and graduate students not already named in "Section A. Senior/Key Person," individually list names, roles (e.g., postdoctoral associates or graduate student), associated months, and requested salary and fringe benefits in Section L. Budget Justification.  **Project Role:** List any additional project role(s) (e.g., engineer, IT professionals, etc.) in the blank(s) provided. Identify the number of each personnel proposed.  You may have up to six named roles. If you have more than six, you must combine project roles here and add an explanation about the named roles in Section L. Budget Justification.  Do not include consultants in this section. Consultants are included below in Section F. Other Direct Costs.  **All other requirements from Field A. apply.** |  |  |  |  |  |  |
| C. Equipment Description | The “C. Equipment Description” section is for you to list items and dollar amount for each item exceeding $5,000 (unless the organization has established lower levels).  **Equipment Item:** Equipment is defined as an item of property that has an acquisition cost of $5,000 or more (unless the organization has established lower levels) and an expected service life of more than one year.  List each item of equipment separately and justify each in Section L. Budget Justification. Allowable items ordinarily will be limited to research equipment not already available for the conduct of the work.  **Funds Requested:** This information is required. List the estimated cost of each item, including shipping and any maintenance costs and agreements.  **Additional Equipment:** If you're requesting funds for more equipment than the form allows, you must include an attachment listing the additional equipment items in this “Additional Equipment” field. Enter the information in a separate file and attach it as a PDF. List each additional item and the funds requested for each individual item. The dollar amount for each item should exceed $5,000 (unless the organization has established lower levels).  **Total funds requested for all equipment listed in the attached file:** If you have attached a file with additional equipment, enter the total funds requested for all the equipment listed in the attachment. |  |  |  |  |  |  |
| D. Travel | **Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions):** Enter the total funds requested for domestic travel. Domestic travel includes destinations in the U.S., Canada, Mexico, and U.S. possessions. In Section L. Budget Justification, include the purpose, destination, dates of travel (if known), and the number of individuals for each trip. If the dates of travel are not known, specify the estimated length of trip (e.g., 3 days).  **Foreign Travel Costs:** Identify the total funds requested for foreign travel. Foreign travel includes any destination outside of the U.S., Canada, Mexico, or U.S. possessions. In Section L. Budget Justification, include the purpose, destination, dates of travel (if known), and the number of individuals for each trip. If the dates of travel are not known, specify the estimated length of trip (e.g., 3 days). |  |  |  |  |  |  |
| E. Participant/Trainee Support Costs | Unless specifically stated otherwise in a FOA, NIH and other PHS agencies applicants should skip Section E. |  |  |  |  |  |  |
| F. Other Direct Costs | **1. Materials and Supplies:** List the total funds requested for materials and supplies. In Section L. Budget Justification, indicate general categories such as glassware, chemicals, animal costs, etc., including an amount for each category. Categories with amounts less than $1,000 are not required to be itemized.  **2. Publication Costs:** List the total funds requested for publication costs. The proposal budget may request funds for the costs of documenting, preparing, publishing, or otherwise making available to others, the findings and products of the work conducted under the award. Include supporting information in Section L. Budget Justification.  **3. Consultant Services:** List the total funds requested for all consultant services. Identify the following items in Section L. Budget Justification, as applicable:   * each consultant, the services he/she will perform, total number of days, travel costs, and the total estimated costs; * the names and organizational affiliations of all consultants, other than those involved in consortium/contractual arrangements; * consulting physicians in connection with patient care; and * persons who are confirmed to serve on external monitoring boards or advisory committees to the project. Describe the services to be performed.   **4. Automatic Data Processing (ADP)/Computer Services:** List the total funds requested for ADP/computer services. The cost of computer services, including computer-based retrieval of scientific, technical, and education information may be requested. In Section L. Budget Justification, include the established computer service rates at the proposing organization, if applicable.  **5. Subawards/Consortium/Contractual Costs:** List the total funds requested for:   1. all subaward/consortium organization(s) proposed for the project and 2. any other contractual costs proposed for the project.   This line item should include both direct and indirect costs for all subaward/consortium organizations.  Contractual costs for support services, such as laboratory testing of biological materials, clinical services, or data processing, are occasionally sufficiently high to warrant a categorical breakdown of costs. When this is the case, provide detailed information as part of Section L. Budget Justification.  NIH policy provides for exclusion of consortium/contractual F&A costs when determining if an applicant is in compliance with a direct cost limitation. However, you must include the full cost of consortium/subawards in this field. See the [NIH Grants Policy Statement, Section 2.3.7.1: Applications that Include Consortium/Contractual F&A Costs](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_2/2.3_application_information_and_processes.htm#Policies) for policy related to the exclusion of consortium/subaward amounts in determining whether an applicant is in compliance with a direct cost limitation.  **6. Equipment or Facility Rental/User Fees:** List the total funds requested for equipment or facility rental/user fees. In Section L. Budget Justification, identify and justify each rental user fee.  **7. Alterations and Renovations:** List the total funds requested for alterations and renovations (A&R). In Section L. Budget Justification, itemize by category and justify the costs of alterations and renovations, including repairs, painting, and removal or installation of partitions, shielding, or air conditioning. Where applicable, provide the square footage and costs.  Under certain circumstances the public policy requirements that apply to construction activities may also apply to A&R activities. Refer to the [NIH Grants Policy Statement, Section 10.10: Construction Grants – Public Policy Requirements and Objectives](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_10/10.10_public_policy_requirements.htm) for more information.  **8-10 Other:** Add descriptions for any “other” direct costs not requested above. Use Section L. Budget Justification to further itemize and justify.  List funds requested for each of the items in lines "8-10 Other.” Use lines 8-10 for costs such as patient care and tuition remission. If requesting patient care costs, request inpatient and outpatient costs separately, using lines 8 and 9.  Lines "8-10 Other" may also be used to request direct costs related to the use of single Institutional Review Board (sIRB) for multi-site human subjects research. For more information on charging direct and indirect costs for single IRB activities, see the [Scenarios to Illustrate the Use of Direct and Indirect Costs for Single IRB Review under the NIH Policy on the Use of a Single IRB for Multi-Site Research](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-109.html). **Note:** If you intend to request an exception to the sIRB policy based on compelling justification, do not account for this exception in your proposed budget. The proposed budget must reflect all necessary sIRB costs without an exception (i.e. applicants should not assume that an exception will be granted when considering what sIRB costs to include in the budget). See the [FAQs](https://osp.od.nih.gov/clinical-research/nih-policy-on-the-use-of-a-single-irb-for-multi-site-research-faqs-on-costs/) on Costs of the NIH Policy on the Use of a Single IRB for Multi-Site Research for more information.  **Additional Instructions for SBIR/STTR:**  **Special Instructions for Technical Assistance Costs:** NIH offers distinct technical assistance programs to SBIR and STTR Phase I and Phase II awardees. These programs offer specialized, strategic business training and provide access to a vast network of industry experts. If you wish to utilize your own technical assistance provider, you are required to include this as a consultant in your budget and to provide a detailed budget justification. You may request up to $5,000 for assistance. Reimbursement is limited to services received that comply with 15 U.S.C. § 638(q):  To provide small business concerns engaged in SBIR or STTR projects with technical assistance services, such as access to a network of scientists and engineers engaged in a wide range of technologies, or access to technical and business literature available through on-line data bases, for the purpose of assisting such concerns in:   * making better technical decisions concerning such projects; * solving technical problems which arise during the conduct of such projects; * minimizing technical risks associated with such projects; and * developing and commercializing new commercial products and processes resulting from such projects.   To request technical assistance from your own provider:   * Label the requested cost of up to $5,000 “Technical Assistance” on one of the lines from 8-10. * Include a detailed description of the services your vendor will provide in the Budget Justification. |  |  |  |  |  |  |
| H. Indirect Costs | Indirect costs (Facilities & Administrative [F&A] costs) are defined as costs that are incurred by a grantee for common or joint objectives and that, therefore, cannot be identified specifically with a particular project or program. See the NIH Glossary's definition of [Indirect Costs](https://grants.nih.gov/grants/glossary.htm#FacilitiesandAdministrative(F&A)Costs(orindirectcosts)).  **For more information:** You are encouraged to visit the following Defense Finance and Accounting Services (DFAS) Websites or call DFAS staff at 301-496-2444 for guidance: [Main DFAS](https://oamp.od.nih.gov/dfas) website, DFAS [Frequently Asked Questions](https://oamp.od.nih.gov/dfas/faq). The following website has a listing of unallowable and unallocable costs and the related Federal Acquisition Regulation (FAR) citation for each[: NIH Office of Management's Unallowable/Unallocable Costs](https://oamp.od.nih.gov/dfas/indirect-cost-branch/indirect-cost-submission/unallowableunallocable-costs).  Refer to the [NIH Grants Policy Statement, Section 7.4: Reimbursement of Facilities and Administrative Costs](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_7/7.4_reimbursement_of_facilities_and_administrative_costs.htm) for more information.  **Additional Instructions for SBIR/STTR:** In accordance with the Small Business Innovation Development Act of 1982 and the Small Business Technology Transfer Act of 1992, irrespective of the time period in which the costs are incurred, no SBIR/STTR funds can be used to “support” any commercialization (Phase III activities). “Support” in this case includes both direct and indirect costs.  The Small Business Administration’s SBIR and STTR Program Policy Directives defined terms:  SBIR agencies must establish an SBIR Program by reserving, in each fiscal year, not less than 3.2 percent (FY 2017) of its extramural budget for awards to SBCs for R/R&D. “R&D activities” include any activities directed toward reducing the technical risk of the technology.   * Commercialization. The process of developing marketable products or services and producing and delivering products or services for sale (whether by the originating party or by others) to government or commercial markets. * Phase III is the period during which Phase II innovation moves from the laboratory into the marketplace. No SBIR funds support this phase. The small business must find funding in the private sector or other non-SBIR federal agency funding.   Based on this position, when NIH is negotiating indirect costs with SBIR/STTR grantees/contractors, we are disallowing all indirect costs applicable to commercialization activities related to SBIR/STTR awards.  **Commercialization cost categories:** Below is a list of cost categories NIH considers to be commercialization.   * marketing and sales; * market research; * business development/product development/market plans; * legal fees; * travel and other costs relating to license agreements and partnerships; and * labor costs for the Marketing Director and Director of Business Development, as well as sales and marketing staff who are grantee/contractor employees or contractors hired for those purposes.   **Indirect Cost Type:** Enter the type of indirect cost (e.g., Salary & Wages, Modified Total Direct Costs, etc.) and whether the cost is off-site. If more than one rate or base is involved for a given type of indirect cost, then list them as separate entries. If you do not have a current indirect (F&A) rate(s) approved by a federal agency, indicate “None--will negotiate” and include information for a proposed rate. Use Section L. Budget Justification if additional space is needed.  **Indirect Cost Rate (%)[[6]](#endnote-6):** Enter the most recent indirect cost rate(s) established with the cognizant federal office, or in the case of for-profit organizations, the rate(s) established with the appropriate agency. This field should be entered using a rate such as “55.5.”  **Cognizant Federal Agency:** Enter the name of the cognizant Federal Agency and the name and phone number of the individual responsible for negotiating your rate (your point of contact). If no cognizant agency is known, enter “None.” |  |  |  |  |  |  |
| I. Total Direct and Indirect Costs | This total will be automatically populated from the sum of Total Direct Costs (from Section G. Direct Cost) and the Total Indirect Costs (from Section H. Indirect Costs).  **Additional Instructions for SBIR/STTR:**  **Award Limits:** According to statutory guidelines, total funding support (direct costs, indirect costs, fee) normally may not exceed $150,000 for Phase I awards and $1,000,000 for Phase II awards. |  |  |  |  |  |  |
| J. Fee | Do not include a fee in your budget, unless the FOA specifically allows inclusion of a “fee.” If a fee is allowable, enter the requested fee.  **Additional Instructions for SBIR/STTR:** A reasonable fee, not to exceed 7% of total costs (direct and indirect) for each Phase (I and II) of the project, is available with SBIR/STTR awards. The fee is intended to be a reasonable profit factor available to for-profit organizations, consistent with normal profit margins provided to profit-making firms for research and development work.  *Example:*  $70,000 direct costs (includes all third party costs) + $28,000 F&A costs (40% \* 70,000) = $98,000.  Maximum allowable fee = 7% \* $98,000 = $6,860 fee.  Total Award = $104,860.  Explain the basis and the amount requested for the fee in Section L. Budget Justification.  The amount requested for the fee should be based on the following guidelines:   * it must be consistent with that paid under contracts by the PHS for similar research conducted under similar conditions of risk; * it must take into account the complexity and innovativeness of the research to be conducted under the SBIR/STTR project; and * it must recognize the extent of the expenditures for the grant project for equipment and for performance by other than the grantee organization through consultant and subaward agreements.   The fee is not a direct or indirect "cost" item and may be used by the small business concern for any purpose, including additional effort under the SBIR/STTR award. The fee applies solely to the small business concern receiving the award and not to any other participant in the project. However, the grantee may pay a profit/fee to a contractor providing routine goods or services in accordance with normal commercial practice.  Note: The electronic system automatically rounds up. If you get an error “The fee must be less than 7%,” try using 6.99% as the rate. |  |  |  |  |  |  |
| L. Budget Justification | The “Budget Justification” attachment is required. Attach only one file.  Use the Budget Justification to provide the additional information requested in each budget category identified above and any other information the applicant wishes to submit to support the budget request. If you have a quote(s), you may include it here. The following budget categories must be justified, where applicable: equipment, travel, participant/trainee support, and other direct cost categories.  If your application includes a subaward/consortium budget, a separate Budget Justification must be submitted. See B.310 - R&R Subaward Budget Attachment(s) Form. |  |  |  |  |  |  |
| 1. R&R Subaward Budget Attachment(s) Form:   The R&R Subaward Budget Attachment(s) Form is used for applications with a subaward or consortium.  This form is required only when the prime grantee is submitting an R&R Budget Form and has subaward/consortium budgets.  Applicants using the Modular Budget Form should see B.320 - Modular Budget Form for instructions concerning information on consortium budgets. | | | | | | | |
|  | **Who should use the R&R Subaward Budget Attachment(s) Form?**  The R&R Subaward Budget Attachment(s) Form is required if you have a subaward/consortium and are using the B.300 - R&R Budget Form.  Do not use this form if you are using the PHS Modular Budget Form or if you do not have a subaward/consortium.  Each consortium grantee organization that performs a substantive portion of the project must complete an R&R Subaward Budget Attachment, including the Budget Justification section.  C**onsortium/Contractual F&A Costs:**  **Additional Instructions for SBIR/STTR:** These instructions on Consortium/Contractual F&A Costs do not apply.  **Using the R&R Subaward Budget Attachment(s) Form:** The location of the R&R Subaward Budget Attachment(s) Form may vary with the type of submission (e.g., under an “Optional Forms” tab).  The steps needed to include a subaward budget in your application vary by submission method. If submitting using Grants.gov downloadable forms, the prime applicant can extract a copy of the R&R Budget Form from the R&R Subaward Budget Attachment(s) Form and send the extracted file to the consortium for completion. After the consortium completes the R&R Budget Form, following the instructions here and in B.300 – R&R Budget Form, the prime grantee must then upload the R&R Budget Form to the R&R Subaward Budget Attachment(s) Form.  For all submission methods, the R&R Budget Form with a "Budget Type" of Subaward/Consortium is used to collect subaward budget data. However, ASSIST and other system-to-system solutions may present a different interface than the R&R Subaward Budget Attachment Form shown here.  This form accommodates a set number of separate subaward budgets. If you need to add more subaward budgets than the form allows, include the remaining budgets as part of Budget Justification in B.300 – R&R Budget Form.  Regardless of how many subaward budgets you include, the sum of all subaward budgets (those attached within the R&R Subaward Budget Attachment(s) Form and those provided as part of the project budget’s Budget Justification), must be included in B.300 - R&R Budget Form, Section F. Other Direct Costs, Question 5. Subawards/Consortium/Contractual Costs of the project budget.  **Format:** All attachments, including all Subaward Budget Forms and Budget Justifications, must be PDF files. The R&R Budget Forms are already PDFs when extracted. Do not alter the format.  **Content:** On this R&R Subaward Budget Attachment(s) Form, you will attach the R&R Subaward Budget files for your application. Each consortium should complete the Subaward Budget(s) in accordance with the B.300 - R&R Budget Form instructions.  **Submitting Subaward Budgets that are not Active for all Periods of the Prime Grant:** The R&R Budget Forms do not allow for “empty” budget periods.  The budget period numbers and dates should be the same in all the R&R Subaward Budget Forms included in the R&R Subaward Budget Attachment(s) Form.  The R&R Subaward Budget Forms include several required fields which must be completed (even for inactive periods) in order to successfully submit the application. Provide the following information for inactive budget periods in subaward/consortium budgets:   * Organization DUNS * Budget Type = Subaward/Consortium * Budget Period Start/End Dates (align with budget periods and dates of the prime budget) * In Question "A: Senior/Key Person," provide a single entry including the following:   + PD/PI or subaward lead First and Last names   + Project Role (may default to PD/PI; can be adjusted as needed)   + Calendar Months = .01 (smallest amount effort allowed in the field)   + Requested Salary = $0   + Fringe Benefits = $0 * Explanation of the inactive budget periods in the Budget Justification of the subaward/consortium's R&R Subaward Budget Form   **STTR**  **Phase I and Phase II**: At least 40% of the work must be performed by the SBC and at least 30% of the work must be performed by the single partnering research institution. The basis for determining the percentage of work to be performed by each of the cooperative parties will be the total of the requested costs (direct and F&A/indirect, and fee) attributable to each party, unless otherwise described and justified in [B.400 - PHS 398 Research Plan Form, Consortium/Contractual Arrangements](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/sbir-sttr-forms-e.pdf#page=99&zoom=100,0,238).  The single “partnering” research institution must provide a letter to the applicant SBC certifying that at least 30% of the work of the STTR project will be performed by the research institution. The SBC will include this letter as an attachment upload in [B.400 - PHS 398 Research Plan Form, Consortium/Contractual Arrangements](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/sbir-sttr-forms-e.pdf#page=99&zoom=100,0,238).  In addition, an SBC must negotiate a written agreement between the small business and the research institution allocating intellectual property rights to carry out follow-on research, development, or commercialization. See the [STTR Model Agreement](https://sbir.nih.gov/sites/default/files/STTRModelAgreement.doc) for the Allocation of Rights. This agreement is required to receive support under the STTR program but is NOT submitted with the application. A copy of the Agreement must be furnished upon request of the NIH awarding component.  **STTR only**: If more than one subaward is included in the STTR application, identify the single, partnering research institution (RI) on the RI Subaward Budget Justification page |  |  |  |  |  |  |
| 1. PHS 398 Research Plan Form:   The PHS 398 Research Plan form is used only for research, multi-project, and SBIR/STTR applications.  This form includes fields to upload several attachments, including the Specific Aims and Research Strategy.  The Research Plan, together with the rest of your application, should include sufficient information needed for evaluation of the project, independent of any other documents (e.g., previous application). Be specific and informative, and avoid redundancies. | | | | | | | |
|  | Your application should represent a sound approach to the investigation of an important biomedical research, behavioral research, technological, engineering, or scientific question, and be worthy of support under the stated criteria of the FOA. It should be self-contained and written with the care and thoroughness accorded to papers for publication.  Review the application carefully to ensure you have included information essential for evaluation. The scientific and technical merit of the proposed research is the primary concern for all research supported by the National Institutes of Health (NIH) and other PHS agencies.  Read all the instructions in the FOA before completing this form to ensure that your application meets all IC-specific criteria.  **Who should use the PHS 398 Research Plan Form:**  Use the PHS 398 Research Plan Form only if you are submitting a research, multi-project, or SBIR/STTR application.  **Additional Instructions for SBIR/STTR:** You are strongly encouraged to contact agency program staff for pre-application guidance and/or for more specific information on the research topics described in the solicitation.  The applicant small business must not propose market research, patent applications, or litigation. The research proposed in this application may, however, be carried out through construction and evaluation of a laboratory prototype, where necessary.  **Applicants must follow all policies and requirements related to formatting, page limits, and proprietary information. See the following pages for more information:**   * [Format Attachments](https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/format-attachments.htm) * [Page Limits](https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/page-limits.htm) * [NIH Grants Policy Statement, Section 2.3.11.2: Confidentiality of Information](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_2/2.3_application_information_and_processes.htm#Availabi) * [NIH Grants Policy Statement, Section 2.3.11.2.2: The Freedom of Information Act](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_2/2.3_application_information_and_processes.htm#Availabi) |  |  |  |  |  |  |
| 2. Specific Aims | **Who must complete the "Specific Aims" attachment:**  The “Specific Aims” attachment is required unless otherwise specified in the FOA.  **Format:**  Follow the page limits for the introduction in the [NIH Table of Page Limits](https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/page-limits.htm) unless otherwise specified in the FOA.  Attach this information as a PDF file. See NIH's [Format Attachments](https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/format-attachments.htm) page.  **Content:** 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 have on the research field(s) involved.  List succinctly the specific objectives of the research proposed (e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology).  **Additional Instructions for SBIR/STTR:**  **Phase I Applications:** State the specific objectives of the Phase I research and development effort, including the technical questions you will try to answer to determine the Phase I feasibility of the proposed approach and the impact that the results of the proposed research will exert on the research field(s) involved. State concisely and realistically what the proposed research is intended to accomplish in terms of its potential for technological innovation and commercial application. Define the proposed product, process or service to ultimately be developed. Include milestones for each of the aims as these will be used in the evaluation process.  **Phase II, Phase IIB, and CRP Applications:** State the specific objectives of the Phase II research and development effort including the impact that the results of the proposed research will exert on the research field(s). State concisely and realistically what the proposed research is intended to accomplish in terms of its potential for technological innovation and commercial application. Define the proposed product, process, or service to ultimately be developed. Include milestones for each of the aims as these will be used in the evaluation process.  **Fast-Track Applications:** Create a heading titled “Phase I Specific Aims” and follow the instructions above for “Phase I Applications.” Next, create a heading titled “Phase II Specific Aims” and follow the instructions above for “Phase II Applications.” Note that the page limit applies to both phases in combination, not to each phase individually. |  |  |  |  |  |  |
| 3. Research Strategy | **Who must complete the "Research Strategy" attachment:**  The “Research Strategy” attachment is required.  **Format:** Follow the page limits for the Research Strategy in the [NIH Table of Page Limits](https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/page-limits.htm), unless otherwise specified in the FOA. Although multiple sections of information are required in the Research Strategy as detailed below, the page limit applies to the entirety of the single "Research Strategy" attachment.  Attach this information as a PDF file. See NIH's [Format Attachments](https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/format-attachments.htm) page.  **Content:** Organize the Research Strategy in the specified order and use the instructions provided below unless otherwise specified in the FOA. Start each section with the appropriate heading – Significance, Innovation, Approach.  Cite published experimental details in the Research Strategy attachment and provide the full reference in B.220 - R&R Other Project Information Form, Bibliography and Reference Cited.  **Note for Applications Proposing the Involvement of Human Subjects and/or Clinical Trials:**   * Use the Research Strategy section to discuss the overall strategy, methodology, and analyses of your proposed research, but do not duplicate information collected in the PHS Human Subjects and Clinical Trials Information form. * The PHS Human Subjects and Clinical Trials Information form will capture detailed study information, including eligibility criteria; inclusion of women, minorities, and children; protection and monitoring plans; and statistical design and power. * You are encouraged to refer to information in the PHS Human Subjects and Clinical Trials Information form as appropriate in your discussion of the Research Strategy (e.g., see Question 2.4 Inclusion of Women, Minorities, and Children).   **Note for Applicants with Multiple Specific Aims:** You may address the Significance, Innovation, and Approach either for each Specific Aim individually or for all of the Specific Aims collectively.   1. **Significance**    * Explain the importance of the problem or critical barrier to progress that the proposed project addresses.    * Describe the scientific premise for the proposed project, including consideration of the strengths and weaknesses of published research or preliminary data crucial to the support of your application.    * Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.   **Additional Instructions for SBIR/STTR:** Explain the project’s potential to lead to a marketable product, process, or service.  **Phase II, CRP, Fast-Track, and Phase IIB Competing Renewals:** Explain how the commercialization plan demonstrates a high probability of commercialization.   1. **Innovation**    * Explain how the application 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. 2. **Approach**    * Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Describe the experimental design and methods proposed and how they will achieve robust and unbiased results. Unless addressed separately in the Resource Sharing Plan, include how the data will be collected, analyzed, and interpreted, as well as any resource sharing plans as appropriate.    * 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 clusterrandomized trial or an individually randomized group-treatment trial. Additional information is available at the [Research Methods Resources](https://researchmethodsresources.nih.gov/) webpage.    * Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.    * 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.    * Explain how relevant biological variables, such as sex, are factored into research designs and analyses for studies in vertebrate animals and humans. 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. Refer to the NIH Guide Notice on [Sex as a Biological Variable in NIH-funded Research](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-102.html) for additional information.    * Point out any procedures, situations, or materials that may be hazardous to personnel and the precautions to be exercised. A full discussion on the use of select agents should appear in the Select Agent Research attachment below.    * If research on Human Embryonic Stem Cells (hESCs) is proposed but an approved cell line from the NIH [hESC Registry](https://grants.nih.gov/stem_cells/registry/current.htm) cannot be chosen, provide a strong justification for why an appropriate cell line cannot be chosen from the registry at this time.   **Additional Instructions for SBIR/STTR:** Provide a tentative sequence or timetable for the project.  **As applicable, also include the following information as part of the Research Strategy, keeping within the three sections (Significance, Innovation, and Approach) listed above.**  **Preliminary Studies for New Applications:**  For new applications, include information on preliminary studies. Discuss 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 (AREA) Grants (R15), preliminary data can be an essential part of a research grant application and can help to establish the likelihood of success of the proposed project. Early stage investigators should include preliminary data.  **Additional Instructions for SBIR/STTR:**  **Phase I Applications:** Preliminary data are not required for Phase I Applications; however, such results may assist reviewers in assessing the likelihood of success of the proposed project and may be included in the Research Strategy attachment. |  |  |  |  |  |  |
| 4. Progress Report Publication List | **Who must complete the “Progress Report Publication List” attachment:**  A “Progress Report Publication List” attachment is required only if the type of application is renewal. |  |  |  |  |  |  |
| 5. Vertebrate Animals | **Who must complete the “Vertebrate Animals” attachment:**  Include a “Vertebrate Animals” attachment if you answered “Yes” to the question “Are Vertebrate Animals Used?” on the B.220 - R&R Other Project Information Form.  **Format:** Attach this information as a PDF file. See NIH's [Format Attachments](https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/format-attachments.htm) page. Do not use this attachment to circumvent the page limits of the Research Strategy.  **Content:** If live vertebrate animals are involved in the project, address each of the following criteria:   1. **Description of Procedures:** Provide a concise description of the proposed procedures to be used that involve live vertebrate animals in the work outlined in the “Research Strategy” attachment. The description must 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 in the proposed work. If dogs or cats are proposed, provide the source of the animals. 2. **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). 3. **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.   Each of the criteria must be addressed. Failure to adequately address the criteria may negatively affect the application’s impact score. In addition to the 3 criteria above, you should also:   * Identify all project performance (or collaborating) sites and describe the proposed research activities with vertebrate animals that will be conducted at those sites. * Explain when and how animals are expected to be used if plans for the use of animals have not been finalized.   **See the following pages for more information**:   * NIH’s [Office of Laboratory Animal Welfare](https://grants.nih.gov/grants/olaw/olaw.htm) website * NIH's [Vertebrate Animals Section Worksheet](https://grants.nih.gov/grants/olaw/VASchecklist.pdf) * See the [NIH Grants Policy Statement, Section 4.1.1: Animal Welfare Requirements](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.1_public_policy_requirements_and_objectives.htm#Animal) (an applicable Animal Welfare Assurance will be required if the grantee institution does not have one) |  |  |  |  |  |  |
| 6. Select Agent Research | **Who must complete the “Select Agent Research” attachment:**  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.  **Format:** Attach this information as a PDF file. See NIH's [Format Attachments](https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/format-attachments.htm) page. Do not use this attachment to circumvent the page limits of the Research Strategy.  **For more information:** Select agents are hazardous biological agents and toxins that have been identified by 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. The Centers for Disease control and Prevention (CDC) and the Animal APHIS Select Agent Programs jointly maintain a list of these agents. See the [Federal Select Agent Program](https://www.selectagents.gov/) website.  See also the [NIH Grants Policy Statement, Section 4.1.24.1.1: Select Agents](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.1_public_policy_requirements_and_objectives.htm#Public).  **Content:**  **Excluded select agents:** If the activities proposed in the application involve only the use of a strain(s) of select agents which has been excluded from the list of select agents and toxins as per [42 CFR 73.3](https://www.ecfr.gov/cgi-bin/retrieveECFR?r=PART&n=42y1.0.1.6.61#se42.1.73_13), the select agent requirements do not apply. Use this “Select Agent Research” attachment to identify the strain(s) of the select agent that will be used and note that it has been excluded from this list. The CDC maintains a list of exclusions, which is available on the [Select Agents and Toxins Exclusions](https://www.selectagents.gov/SelectAgentsandToxinsExclusions.html) website.  **Applying for a select agent to be excluded:** If the strain(s) is 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, use this section to indicate the status of your request or your intent to apply for an exclusion and provide a brief justification for the exclusion.  **All applicants proposing to use select agents:** Address the following three points for each site at which select agent research will take place. Although no specific page limitation applies to this section, be succinct.   1. Identify the select agent(s) to be used in the proposed research. 2. Provide the registration status of all entities\* where select agent(s) will be used.    * If the performance site(s) is a foreign institution, provide the name(s) of the country or countries where select agent research will be performed.    * \*An “entity” is defined in 42 CFR 73.1 as “any government agency (Federal, State, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity.” 3. 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. |  |  |  |  |  |  |
| 7. Multiple PD/PI Leadership Plan | **Who must complete the “Multiple PD/PI Leadership Plan” attachment:**  Any applicant who designates multiple PD/PIs (on the B.240 - R&R Senior/Key Person Profile (Expanded) Form) must include a Multiple PD/PI Leadership Plan. For applications designating multiple PD/PIs, all such individuals must be assigned the PD/PI role on the B.240 - R&R Senior/Key Profile (Expanded) Form, even those at organizations other than the applicant organization.  Do not submit a Multiple PD/PI Leadership Plan if you are not submitting a multiple PD/PI application.  **Format:** Attach this information as a PDF file. See NIH's [Format Attachments](https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/format-attachments.htm) page.  **Content:** A rationale for choosing a multiple PD/PI approach should be described. The governance and organizational structure of the leadership team and the research project should be described, including communication plans, processes for making decisions on scientific direction, and procedures for resolving conflicts. The roles and administrative, technical, and scientific responsibilities for the project or program should be delineated for the PD/PIs and other collaborators.  If budget allocation is planned, the distribution of resources to specific components of the project or the individual PD/PIs should be delineated in the Multiple PD/PI Leadership Plan. In the event of an award, the requested allocations may be reflected in a footnote on the Notice of Grant Award.  **For more information:** For background information on the multiple PD/PI initiative, see NIH's [Multiple Principal Investigators](https://grants.nih.gov/grants/multi_pi/index.htm) page. |  |  |  |  |  |  |
| 8. Consortium/Contractual Arrangements | **Who must complete the “Consortium/Contractual Arrangements” attachment:**  Include a “Consortium/Contractual Arrangements” attachment if you have consortiums/contracts in your budget.  **Format:** Attach this information as a PDF file. See NIH's [Format Attachments](https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/format-attachments.htm) page.  **Content:** 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.  **STTR: Phase I, Phase II and Phase IIB STTR Applications:** At least 40% of the work must be performed by the SBC and at least 30% of the work must be performed by the single partnering research institution. The basis for determining the percentage of work to be performed by each of the cooperative parties will be the total of the requested costs (direct, F&A/indirect, and fee) attributable to each party, unless otherwise described and justified in this attachment. Certification showing the cooperative R&D arrangement between the SBC and the research institution will be requested prior to an award. The single partnering research institution must certify at the time of application that at least 30% of the work of the STTR project will be performed by the research institution. This 30% requirement applies to the single collaborating organization identified as the “research institution.” The requisite signature, printed name, title, and date of signature of the duly authorized representative of the research institution affirming certifications made by the research institution must be included in a letter stating:  “The small business concern and the research institution certify jointly that: (1) the proposed STTR project will be conducted jointly by the small business concern and the research institution in which not less than 40 percent of the work will be performed by the small business concern and not less than 30 percent of the work will be performed by the research institution (“cooperative research and development”); (2) the proposed STTR project is a cooperative research or research and development effort to be conducted jointly by the small business concern and the research institution in which not less than 40 percent of the work will be performed by the small business concern and not less than 30 percent of the work will be performed by the research institution (“performance of research and analytical work”); and (3) regardless of the proportion of the proposed project to be performed by each party, the small business concern will be the primary party that will exercise management direction and control of the performance of the project. If the research institution is a contractor-operated Federally Funded Research and Development Center (FFRDC), the duly authorized representative of the contractor-operated Federally funded research and development center certifies, additionally, that it: “(4) is free from organizational conflicts of interests relative to the STTR program; (5) did not use privileged information gained through work performed for an STTR agency or private access to STTR agency personnel in the development of this STTR grant application; and (6) used outside peer review, as appropriate, to evaluate the proposed project and its performance therein.”  The applicant SBC should convert the letter from the partnering research institution into a PDF attachment, and include it as part of this attachment.  **Fast-Track STTR Applications**: Create two separate sections entitled “Phase I Consortium/Contractual Arrangements” and “Phase II Consortium/Contractual Arrangements,” and complete the sections following the instructions provided above for each phase. |  |  |  |  |  |  |
| 9. Letters of Support | **Format:** Combine all letters of support into a single PDF file and attach this information here. Do not place these letters in the Appendix.  Follow the attachment guidelines on NIH's [Format Attachments](https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/format-attachments.htm) page.  **Content:** Attach a file with all letters of support, including any letters necessary to demonstrate the support of consortium participants and collaborators such as Senior/Key Personnel and Other Significant Contributors included in the grant application.  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. In addition, letters ensuring access to core facilities and resources should stipulate whether access will be provided as a fee-for-service.  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.  Do not include consultant biographical sketches in the “Letters of Support” attachment, as consultant biosketches should be in the “Biographical Sketch” section (see exception for SBIR/STTR Applications in the SBIR/STTR-specific instructions).[[7]](#endnote-7)  The single “partnering” research institution must provide a letter to the applicant small business concern certifying that at least 30% of the work of the STTR project will be performed by the research institution. |  |  |  |  |  |  |
| 10. Resource Sharing Plan(s) | **Format:** Attach this information as a PDF file. See NIH's [Format Attachments](https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/format-attachments.htm) page.  **Content:**  **Data Sharing Plan:** Investigators seeking $500,000 or more in direct costs (exclusive of consortium F&A) in any budget period are expected to include a brief 1-paragraph description of how final research data will be shared, or explain why data-sharing is not possible (for example human subject concerns, the Small Business Innovation Development Act provisions, etc.). Specific FOAs may require that all applications include this information regardless of the dollar level. Applicants are encouraged to read the FOA carefully and discuss their data-sharing plan with their program contact at the time they negotiate an agreement with the Institute/Center (IC) staff to accept assignment of their application. **For more information**, see the NIH [Data Sharing Policy](https://grants.nih.gov/grants/policy/data_sharing/) or the [NIH Grants Policy Statement, Section 2.3.7.10: NIH Genomic Data Sharing](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_2/2.3_application_information_and_processes.htm#Policies) and [Section 8.2.3.3: Genomic Data Sharing (GDS) Policy/ Policy for Genome-Wide Association Studies (GWAS)](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.2_availability_of_research_results_publications__intellectual_property_rights__and_sharing_research_resources.htm#Sharing).  **Sharing Model Organisms:** Regardless of the amount requested, all applications where the development of model organisms is anticipated are expected to include a description of a specific plan for sharing and distributing unique model organisms or state why such sharing is restricted or not possible. **For more information**, see the [NIH Grants Policy Statement, Section 8.2.3.2: Sharing Model Organisms](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.2_availability_of_research_results_publications__intellectual_property_rights__and_sharing_research_resources.htm#Sharing).  **Genomic Data Sharing (GDS):** Applicants seeking funding for research that generates largescale human or non-human genomic data are expected to provide a plan for sharing of these data. Examples of large-scale genomic data include genome-wide association studies (GWAS), single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, epigenomic, and gene expression data. Supplemental Information to the NIH GDS provides examples of genomic research projects that are subject to the Policy. **For more information** see the [NIH GDS Policy,](https://osp.od.nih.gov/scientific-sharing/policies/) the [NIH Grants Policy Statement, Section 8.2.3.3: Genomic Data Sharing (GDS) Policy/ Policy for Genome-Wide Association Studies (GWAS)](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.2_availability_of_research_results_publications__intellectual_property_rights__and_sharing_research_resources.htm#Sharing), and the [GDS](https://osp.od.nih.gov/scientific-sharing/genomic-data-sharing/) website.  **Note on GDS:** For proposed studies generating human genomic data under the scope of the [GDS Policy](https://osp.od.nih.gov/scientific-sharing/policies/), an institutional certification may be submitted at the time of application submission, but it is not required at that time. The institutional certification, however, will be requested as Just-in-Time (JIT) information prior to award. The institutional certification, or in some cases, a provisional institutional certification, must be submitted and accepted before the award can be issued.  **For more information:** NIH considers the sharing of unique research resources developed through NIH-sponsored research an important means to enhance the value and further the advancement of the research. When resources have been developed with NIH funds, and the associated research findings published or provided to NIH, it is important that they be made readily available for research purposes to qualified individuals within the scientific community. See the [NIH Grants Policy Statement, Section 8.2.3: Sharing Research Resources](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.2_availability_of_research_results_publications__intellectual_property_rights__and_sharing_research_resources.htm#Sharing). |  |  |  |  |  |  |
| 11. Authentication of Key Biological and/or Chemical Resources | **Format:**  Attach this information as a PDF file. See NIH's [Format Attachments](https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/format-attachments.htm) page.  **Content:** 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. A maximum of one page is suggested.  **For more Information:** Key biological and/or chemical resources are characterized as follows.   * 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. * See NIH's page on Rigor and Reproducibility for more information. |  |  |  |  |  |  |
| 12. Appendix | The appendix policy will be changing, effective January 25, 2018. **For applications submitted for due dates on or before January 24, 2018:**  Refer to the FOA to determine whether there are any special appendix instructions for your application.  **Additional Instructions for SBIR/STTR:**  **Phase I SBIR/STTR Applications:** Do not include appendices unless specifically solicited by NIH. |  |  |  |  |  |  |
| 1. SBIR/STTR Information Form:   NIH, CDC, FDA, and ACF SBIR/STTR grant applicants must complete and submit the SBIR/STTR Information Form in conjunction with the other SF424 (R&R) forms and PHS 398 forms. | | | | | | | |
| Introductory Fields | **Phase I Letter of Intent Number:**  Leave blank. This field is not applicable for any HHS (NIH, CDC, FDA) submissions.  **Agency Topic/Subtopic:**  Leave blank. This field is not applicable for all HHS (NIH, CDC, FDA) submissions |  |  |  |  |  |  |
| 6. Disclosure Permission Statement | A selection is required.  If this application does not result in an award, is the Government permitted to disclose the title of your proposed project, and the name, address, telephone number, and e-mail address of the official signing for the applicant organization to state-level economic development organizations that may be interested in contacting you for further information (e.g., possible collaborations, investment), check “Yes.” Otherwise check “No.”  Your response will not affect any peer review or funding decisions |  |  |  |  |  |  |
| 7. Commercialization Plan | **Who must complete the "Commercialization Plan" section:**  If you are submitting a Phase II, Direct Phase II, Phase IIB, Phase I/Phase II Fast-Track, or Commercialization Readiness Program Application, you must include a "Commercialization Plan" attachment. |  |  |  |  |  |  |
| 1. PHS Human Subjects and Clinical Trials Information Form:   The PHS Human Subjects and Clinical Trials Information form is used to collect information on human subjects research, clinical research, and/or clinical trials, including study population characteristics, protection and monitoring plans, and a protocol synopsis.  This form accommodates the full spectrum of all types of clinical trials, including, but not limited to, behavioral, exploratory/development, mechanistic, pilot/feasibility, early phase, efficacy, effectiveness, group-randomized, and others.  Read all the instructions in the Funding Opportunity Announcement (FOA) before completing this form to ensure your application meets all IC-specific criteria. If you are proposing a clinical trial, make sure your FOA accepts clinical trials (i.e., ‘clinical trial required’ or ‘clinical trial optional’).  The PHS Human Subjects and Clinical Trials Information form, together with the rest of your application, should include sufficient information for the evaluation of the project, independent of any other documents (e.g., previous application). Be specific, describe each study clearly, and avoid redundancies. Be especially careful to avoid redundancies with your research strategy. | | | | | | | |
|  | **Who should use the PHS Human Subjects and Clinical Trials Information form:**  All applicants must use the PHS Human Subjects and Clinical Trials Information form regardless of your answer to the question “Are human subjects involved?” on the B.220 - R&R Other Project Information Form.  If you answered “Yes” to the question “Are human subjects involved?” on the B.220 - R&R Other Project Information Form, see the “If Yes to Human Subjects” section for instructions.  If you answered “No” to the question “Are human subjects involved?” on the B.220 - R&R Other Project Information Form, see the “If No to Human Subjects” section for instructions.  **Note for studies involving only the secondary use of identifiable biospecimens or data:** For studies where the only involvement of human subjects is the use of identifiable biospecimens or data originally collected for another purpose, complete the PHS Human Subjects and Clinical Trials Information form with information specific to the current study and not the original collection unless the information associated with the original collection is pertinent to the proposed study. If information about the original collection is necessary, provide context and clearly distinguish between the current study and historical information.  **Using the PHS Human Subjects and Clinical Trials Information form:** Follow instructions on the PHS Human Subjects and Clinical Trials Information form that are specific to your answer to the “Are Human Subjects Involved?” question on the B.220 - R&R Other Project Information Form. The PHS Human Subjects and Clinical Trials Information form allows you to add study record(s) and/or delayed onset study(ies), as applicable.  Within each Study Record: PHS Human Subjects and Clinical Trials Information, you will add detailed information at the study level. Add a separate [study record](https://grants.nih.gov/grants/glossary.htm#StudyRecord) for each protocol involving human subjects proposed in your application. Do not duplicate studies within your application. Each [study](https://grants.nih.gov/grants/glossary.htm#Study) within the application should be unique and should have a unique study title. Each study record is divided into numbered sections:   * Section 1 - Basic Information * Section 2 – Study Population Characteristics (includes Inclusion Enrollment Report) * Section 3 – Protection and Monitoring Plans * Section 4 – Protocol Synopsis * Section 5 – Other Clinical Trial-related Attachments   **Note:** The PHS Human Subjects and Clinical Trials Information form will capture detailed information at the study level. Although you are encouraged to refer to information in the PHS Human Subjects and Clinical Trials Information form in your discussion of the Research Strategy, do not duplicate information between the Research Strategy attachment and the PHS Human Subjects and Clinical Trials Information form.  The PHS Human Subjects and Clinical Trials Information form is dynamic and may eliminate sections that are not relevant to your application. The dynamic form behavior may not be enabled on all submission methods.  **Applicants must follow all policies and requirements related to formatting, proprietary information, human subjects, and clinical trials. See the following pages for more information:**  [Format Attachments](https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/format-attachments.htm)  [Rules for Text Fields](https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/rules-for-text-fields.htm)  [NIH Grants Policy Statement, Section 2.3.11.2: Confidentiality of Information](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_2/2.3_application_information_and_processes.htm#Availabi)  [NIH Grants Policy Statement, Section 2.3.11.2.2: The Freedom of Information Act](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_2/2.3_application_information_and_processes.htm#Availabi)  [Research Involving Human Subjects](https://humansubjects.nih.gov/)  [NIH's Clinical Trials](https://grants.nih.gov/policy/clinical-trials.htm) website  **Note:** There are no page limits for any attachments in the PHS Human Subjects and Clinical Trials Information form. |  |  |  |  |  |  |
| PHS Human Subjects and Clinical Trials Information | Applicants must complete the human subjects questions on the B.220 - R&R Other Project Information Form prior to completing this form.  **Are Human Subjects Involved? Yes/No** This field is pre-populated from the B.220 - R&R Other Project Information Form. If the value in this field appears to be incorrect, you may correct it by adjusting it on the B.220 - R&R Other Project Information Form.  **Is the Project Exempt from Federal regulations? Yes/No** This field is pre-populated from the B.220 - R&R Other Project Information Form. If the value in this field appears to be incorrect, you may correct it by adjusting it on the B.220 - R&R Other Project Information Form.  **Exemption number: 1, 2, 3, 4, 5, 6, 7, 8** This field is pre-populated from the B.220 - R&R Other Project Information Form. If the value in this field appears to be incorrect, you may correct it by adjusting it on the B.220 – R&R Other Project Information Form. **You should not have selected exemption 7 or 8, as these are not yet being used.**  **Note:** If you change your answer to the “Are Human Subjects Involved” question on the B.220 - R&R Other Project Information Form after you have started entering information into the PHS Human Subjects and Clinical Trials Information form, your data in the PHS Human Subjects and Clinical Trials Information form may be lost. |  |  |  |  |  |  |
| Other Information | For all other guidance on completing this form see the [SBIR/STTR Instructions for NIH and Other PHS Agencies](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/sbir-sttr-forms-e.pdf) guide pp.110 |  |  |  |  |  |  |
| 1. PHS Assignment Request Form:   The PHS Assignment Request Form may be used to communicate specific application assignment and review requests to the Division of Receipt and Referral (DRR) and to Scientific Review Officers (SROs).  This information will not be part of your assembled application, and it will neither be made available to program staff nor provided to reviewers. It is used specifically to convey additional, optional information about your preference(s) for assignment and review of your application to DRR and SROs.  This information was previously collected in the Cover Letter Attachment, but must now be provided in the PHS Assignment Request Form. | | | | | | | |
|  | **Completing the PHS Assignment Request Form:**  This form is optional. Use it only if you wish to make specific assignment or review requests. There is no requirement that all fields or all sections be completed. You have the flexibility to enter a single request or to provide extensive information using this form.  **Note on Application Assignments:**  The Division of Receipt and Referral (DRR), Center for Scientific Review (CSR) is responsible for assigning applications to awarding components such as NIH Institutes/Centers (ICs) and other PHS agencies for funding consideration. DRR also assigns applications to NIH Scientific Review Groups (SRGs) and Special Emphasis Panels (SEPs). |  |  |  |  |  |  |

1. **For Single PD/PI Applications**: Name the one person responsible to the applicant small business concern (SBC) for the scientific and technical direction of the project in the "14. PD/PI Contact Information" section.

   **For Multiple PD/PI Applications**: Name the contact PD/PI here in "14. PD/PI Contact Information." The Contact PD/PI (as designated here in "14. PD/PI Contact Information") must be listed first in the G.240 - R&R Senior/Key Person Profile (Expanded) Form and must be affiliated with the applicant organization in the PD/PI's eRA Commons profile.

   NIH and PHS staff conduct official business only with the named PD/PIs and organizational/institutional officials.

   A revision/supplemental application must have the same contact PD/PI as the currently funded grant.

   **SBIR**

   **Phase I, Phase II, and CRP**: The primary employment of the PD/PI must be with the SBC at the time of award and during the conduct of the proposed project. Primary employment means that more than one half (greater than 50%) of the PD/PI's time is spent in the employ of the SBC. Primary employment with an SBC precludes full-time employment at another organization. Occasionally, deviations from this requirement may occur. Such deviations must be approved in writing by the grants management officer after consultation with the NIH SBIR/STTR Program Coordinator.

   **Phase I, Phase II, and CRP Multiple PD/PI applications**: The PD/PI listed here in "14. PD/PI Contact Information" must be affiliated with the applicant SBC organization submitting the application and will serve as the contact PD/PI. The primary employment of the "Contact PD/PI" must be with the SBC at the time of award and during the conduct of the proposed project. As noted above, occasionally, deviations from this requirement may occur. Such deviations must be approved in writing by the grants management officer after consultation with the NIH SBIR/STTR Program Coordinator.

   **PD/PI Definition**: As defined in 42 CFR 52, the PD/PI(s) is or are the "â€¦individual(s) judged by the applicant organization to have the appropriate level of authority and responsibility to direct the project or program supported by the grant and who is or are responsible for the scientific and technical direction of the project." When the proposed PD/PI clearly does not have sufficient qualifications to assume this role, the application is not likely to receive a favorable evaluation.

   **Verification of PD/PI Eligibility**: If the application has the likelihood for funding, the awarding component will require documentation to verify the eligibility of the PD/PI, if at the time of submission of the application, the PD/PI meets any of the following criteria:

   is a less-than-full-time employee of the SBC;

   is concurrently employed by another organization;

   gives the appearance of being concurrently employed by another organization, whether for a paid or unpaid position.

   If the PD/PI is employed or appears to be employed by an organization other than the applicant organization in any capacity (such as Research Fellow, Consultant, Adjunct Professor, Clinical Professor, Clinical Research Professor, or Associate), a letter must be provided by each employing organization confirming that, if an SBIR grant is awarded to the applicant SBC, the PD/PI is or will become a less-than-half-time employee of such organization and will remain so for the duration of the SBIR project. If the PD/PI is employed by a university, such a letter must be provided by the Dean's office or equivalent; for other organizations, the letter must be signed by a corporate official.

   This requirement applies also to those individuals engaged currently as the PD/PI on an active SBIR project. All current employment and all other appointments of the PD/PI must be identified in his or her "Biographical Sketch" required as part of the application. Be certain that correct beginning and ending dates are indicated for each employment record listed.

   **STTR**

   **Phase I and Phase II**: The primary employment of the principal investigator must be with the SBC or the research institution at the time of award and during the conduct of the proposed project. Primary employment means that more than one half (greater than 50%) of the PD/PI's time is spent in the employ of the SBC or the research institution. Primary employment with an SBC or research institution precludes full-time employment at another organization. An SBC may replace the principal investigator on an STTR Phase I or Phase II award, subject to approval in writing by the Funding Agreement Officer. For purposes of the STTR Program, personnel obtained through a Professional Employer Organization or other similar personnel leasing company may be considered employees of the awardee. This is consistent with SBA's size regulations, 13 CFR 121.106-Small Business Size Regulations.

   **For Multiple PD/PI Applications**: The PD/PI listed here in "14. PD/PI Contact Information" must be affiliated with the applicant SBC submitting the application and will serve as the Contact PD/PI. The Contact PD/PI may be from either the SBC or the single partnering research institution.

   **Note**: the Contact PD/PI must have a formal appointment with or commitment to the SBC, which must be in the form of an official relationship between the parties, but need not include a salary or other form of remuneration.

   **PD/PI Eligibility**: The PD/PI must commit a minimum of 10% (1.2 calendar months) effort to the project and must have a formal appointment with or commitment to the applicant SBC, which is characterized by an official relationship between the SBC and that individual. Such a relationship does not necessarily involve a salary or other form of remuneration. In all cases, however, the PD/PI's official relationship with the grantee must entail sufficient opportunity for the PD/PI to carry out his or her responsibilities for the overall scientific and technical direction of the project. Although documentation (e.g., consortium and contractual arrangements) describing the official relationship of the PD/PI with the applicant SBC should NOT be submitted with the grant application, a copy must be furnished upon the request of the NIH awarding component.

   Following is guidance for such documentation (describing the official relationship of the PD/PI with the applicant SBC), which is required prior to award. The letter should be prepared on the letterhead of the independent PD/PI and addressed to the SBC. One page is recommended. At a minimum, the letter should (1) verify the PD/PI's commitment to the project; (2) refer to the specific project by name; and (3) specify what assets or services the PI will contribute (e.g. expertise, number of hours/percent effort) as well as the PD/PI's remuneration. The letter should also indicate that the PD/PI and the SBC have reached an agreement on proprietary interests (e.g., intellectual property).

   Signatures of the authorized organization representative (AOR or signing official) for the applicant organization on the Authorized Representative section and the signature of the duly authorized representative of the research institution certifies, among other things, that the PD/PI has a formal relationship with/commitment to the SBC when the PD/PI is an employee of the Research Institute.

   The following are examples of situations describing the official relationship of the PD/PI with the applicant small business organization:

   PD/PI with a full-time, university appointment may also have appointments with other organizations (with or without salary) and still appropriately consider his or her commitment to the university to be "full-time," consistent with the personnel policies and procedures of the university applied on a routine basis. The PD/PI's commitment to the university and other organizations (including the applicant SBC) cannot exceed 100% of his or her total professional effort.

   PD/PI with a full-time, 12-month appointment with an SBC would be considered to have a commitment to the applicant organization of 100% of his or her total professional effort.

   PD/PI who has a part-time appointment with an SBC and has concurrent commitments or appointments with organizations in addition to the small business concern would deem each commitment as a portion of 100% of his or her total professional effort.

   As responsible stewards of funds, the NIH is concerned that the PD/PI has the time available to carry out the proposed STTR research activities. Therefore, it should be clear in the application that the time proposed for the PD/PI on a particular project is reasonable and it should be clear that the PD/PI has sufficient time (minimum 10% effort, which is 1.2 calendar months) from among his or her total professional commitments to devote to this project. [↑](#endnote-ref-1)
2. As written in the statute and under appropriate circumstances, NIH can apply for a waiver from SBA to issue an award exceeding $225,000 for Phase I or $1,500,000 for Phase II, if this hard cap will interfere with NIH's ability to meet its mission. Award waivers from the SBA are not guaranteed and may delay the release of funds. Applicants are strongly encouraged to contact NIH program officials prior to submitting any award in excess of the guidelines. In all cases, applicants should propose a budget that is reasonable and appropriate for completion of the research project. Note: CDC, FDA, and ACF do not make awards above these statutory guidelines. [↑](#endnote-ref-2)
3. Whether you answer “Yes” or “No” to the “Are Human Subjects Involved?” question here, your answer will populate the relevant field in the B.500 – PHS Human Subjects and Clinical Trials Information form. Follow the B.500 – PHS Human Subjects and Clinical Trials Information form instructions to complete the relevant questions in that form.

   **Need help determining whether your application includes human subjects?** Check out the NIH [Research Involving Human Subjects](https://humansubjects.nih.gov/) website for information, including an [Infopath Questionnaire](https://humansubjects.nih.gov/questionnaire) designed to walk applicants through the decision process.

   **Note on the use of human specimens or data:** Applications involving the use of human specimens or data may or may not be considered to be research involving human subjects, depending on the details of the materials to be used. If you check “No” to “Are Human Subjects Involved?” but your application proposes using human specimens or data, you will be required to provide a clear justification about why this use does not constitute human subjects research. Follow the B.500 – PHS Human Subjects and Clinical Trials Information form instructions.

   **For more information on human biospecimens or data:** Refer to the NIH page on [Frequently Asked Questions on Human Specimens, Cell Lines, or Data](https://humansubjects.nih.gov/human-specimens-cell-lines-data) and the [Research Involving Private Information or Biological Specimens](https://grants.nih.gov/grants/policy/hs/PrivateInfoOrBioSpecimensDecisionChart.pdf) flowchart. [↑](#endnote-ref-3)
4. **Phase I, Phase II, and CRP Applications:** The research or R&D project activity must be performed in the United States. However, based on a rare and unique circumstance (for example, if a supply or material or the study design [e.g., patient population] is not available in the United States), NIH may allow that particular portion of the research or R&D work to be performed or obtained in a foreign sponsorship country. Investigators must thoroughly justify the use of these sites in the application. These rare and unique situations will be considered on a case-by-case basis, and they should be discussed with NIH staff prior to submission of the application. Approval by the funding officer for such specific condition(s) must be in writing prior to issuance of an award. Whenever possible, non-SBIR/STTR funds should be used for other work outside of the United States that is necessary to the overall completion of the project.

   The research and analytical work performed by the grantee organization is to be conducted in research space occupied by, available to, and under the control of the SBIR/STTR grantee for the conduct of its portion of the proposed project. However, when required by the project activity, access to special facilities or equipment in another organization is permitted, as in cases where the SBIR/STTR awardee has entered into a subcontractual agreement with another institution for a specific, limited portion of the research project.

   Whenever a proposed SBIR/STTR project is to be conducted in facilities other than those of the applicant organization, the awarding component will request that the SBC provide a letter from the organization stating that leasing/rental arrangements have been negotiated for appropriate research space. This letter must be signed by an authorized official of the organization whose facilities are to be used for the SBIR/STTR project and must certify that the SBC (grantee organization) will have access to and control over the research space. In addition, the letter must include a description of the facilities and, if appropriate, equipment that will be leased/rented to the grantee organization. If the letter is included with the application, it is excluded from the page limitations. Attach this letter to the B.400 - PHS 398 Research Plan Form, Consortium/Contractual Arrangements.

   **“I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization”**: Do not check the box for “I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization” unless otherwise specified by the FOA. [↑](#endnote-ref-4)
5. Biographical Sketch Format Requirements

   **A. Personal Statement**

   Briefly describe why you are well-suited for your role(s) in this project. Relevant factors may include: aspects of your training; your previous experimental work on this specific topic or related topics; your technical expertise; your collaborators or scientific environment; and/or your past performance in this or related fields.

   You may cite up to four publications or research products that highlight your experience and qualifications for this project. Research products can include, but are not limited to, audio or video products; conference proceedings such as meeting abstracts, posters, or other presentations; patents; data and research materials; databases; educational aids or curricula; instruments or equipment; models; protocols; and software or netware.

   You are allowed to cite interim research products. **Note:** interim research products have specific citation requirements. See related [Frequently Asked Questions](https://grants.nih.gov/grants/interim_product_faqs.htm) for more information.

   **Note the following additional instructions for ALL applicants/candidates:**

   If you wish to explain factors that affected your past productivity, such as family care responsibilities, illness, disability, or military service, you may address them in this “A. Personal Statement” section.

   Indicate whether you have published or created research products under another name.

   You may mention specific contributions to science that are not included in Section C. Do not present or expand on materials that should be described in other sections of this Biosketch or application.

   Figures, tables, or graphics are not allowed.

   **Note the following instructions for specific subsets of applicants/candidates:**

   For institutional research training, institutional career development, or research education grant applications, faculty who are not senior/key persons are encouraged, but not required, to complete the "A. Personal Statement" section.

   Applicants for dissertation research awards should, in addition to addressing the points noted above, also include a description of their career goals, their intended career trajectory, and their interest in the specific areas of research designated in the FOA.

   Candidates for research supplements to promote diversity in health-related research should, in addition to addressing the points noted above, also include a description of their general scientific achievements and/or interests, specific research objectives, and career goals. Indicate any current source(s) of educational funding.

   **B. Positions and Honors**

   List in chronological order the positions you’ve held that are relevant to this application, concluding with your present position. High school students and undergraduates may include any previous positions. For individuals who are not currently located at the applicant organization, include the expected position at the applicant organization and the expected start date.

   List any relevant academic and professional achievements and honors. In particular:

   Students, postdoctorates, and junior faculty should include scholarships, traineeships, fellowships, and development awards, as applicable.

   Clinicians should include information on any clinical licensures and specialty board certifications that they have achieved.

   **C. Contributions to Science**

   **Who should complete the “Contributions to Science” section:**

   All senior/key persons should complete the “Contributions to Science” section except candidates for research supplements to promote diversity in health-related research who are high school students, undergraduates, and post-baccalaureates.

   **Format:** Briefly describe up to five of your most significant contributions to science. The description of each contribution should be no longer than one half page, including citations.

   While all applicants may describe up to five contributions, graduate students and postdoctorates may wish to consider highlighting two or three they consider most significant.

   **Content:** For each contribution, indicate the following:

   the historical background that frames the scientific problem;

   the central finding(s);

   the influence of the finding(s) on the progress of science or the application of those finding(s) to health or technology; and

   your specific role in the described work.

   For each contribution, you may cite up to four publications or research products that are relevant to the contribution. If you are not the author of the product, indicate what your role or contribution was. Note that while you may mention manuscripts that have not yet been accepted for publication as part of your contribution, you may cite only published papers to support each contribution. Research products can include audio or video products (see the [NIH Grants Policy Statement, Section 2.3.7.7: Post-Submission Grant Application Materials](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_2/2.3_application_information_and_processes.htm#Policies)); conference proceedings such as meeting abstracts, posters, or other presentations; patents; data and research materials; databases; educational aids or curricula; instruments or equipment; models; protocols; and software or netware.

   You are allowed to cite interim research products. Note: interim research products have specific citation requirements. See related [Frequently Asked Questions](https://grants.nih.gov/grants/interim_product_faqs.htm) for more information.

   You may provide a URL to a full list of your published work. This URL must be to a Federal Government website (a .gov suffix). NIH recommends using [My Bibliography](https://www.ncbi.nlm.nih.gov/books/NBK53595/). Providing a URL to a list of published work is not required.

   Descriptions of contributions may include a mention of research products under development, such as manuscripts that have not yet been accepted for publication. These contributions do not have to be related to the project proposed in this application.

   **D. Additional Information: Research Support and/or Scholastic Performance**

   **Note the following instructions for specific subsets of applicants/candidates:**

   High school students are not required to complete Section D. Additional Information: Research Support and/or Scholastic Performance.

   Career development award applicants should complete the "Research Support" section but skip the “Scholastic Performance” section.

   Generally, the following types of applicants can skip the “Research Support” section and must complete only the “Scholastic Performance” section. However, when these applicants also have Research Support, they may complete both sections.

   applicants for predoctoral and postdoctoral fellowships

   applicants to dissertation research grants

   candidates for research supplements to promote diversity in health-related research from the undergraduate through postdoctoral levels

   **Research Support**

   These instructions apply to all applicants who are completing the “Research Support” section.

   List ongoing and completed research projects from the past three years that you want to draw attention to. Briefly indicate the overall goals of the projects and your responsibilities. Do not include the number of person months or direct costs.

   Do not confuse “Research Support” with “Other Support.” Other Support information is not collected at the time of application submission.

   **Research Support:** As part of the Biosketch section of the application, “Research Support” highlights your accomplishments, and those of your colleagues, as scientists. This information will be used by the reviewers in the assessment of each your qualifications for a specific role in the proposed project, as well as to evaluate the overall qualifications of the research team.

   [Other Support:](https://grants.nih.gov/grants/glossary.htm#OtherSupport) NIH staff may request complete and up-to-date “other support” information from you as part of Just-in-Time information collection.

   **Scholastic Performance**

   **Predoctoral applicants/candidates (including undergraduates and post-baccalaureates):** List by institution and year **all** undergraduate and graduate courses, with grades. In addition, explain any grading system used if it differs from a 1-100 scale; an A, B, C, D, F system; or a 0-4.0 scale. Also indicate the levels required for a passing grade.

   **Postdoctoral applicants:** List by institution and year **all** graduate scientific and/or professional courses with grades. In addition, explain any grading system used if it differs from a 1-100 scale; an A, B, C, D, F system; or a 0-4.0 scale. Also indicate the levels required for a passing grade. [↑](#endnote-ref-5)
6. **Additional Instructions for SBIR/STTR:**

   **If you have an indirect cost rate:** If the applicant small business concern has a currently effective negotiated indirect cost rate with a federal agency, that rate should be used when calculating proposed indirect costs. However, these rates must be adjusted for independent [self-sponsored] research and development expenses, which are not allowable by HHS.

   If applicable, indicate your organization’s most recent indirect cost rate established with NIH’s Division of Financial Advisory Services (DFAS) or with another federal agency. If your applicant organization is in the process of negotiating or renegotiating a rate, use that rate in the application.

   **If you don’t have an indirect cost rate:** If the applicant organization does not have a current negotiated rate, it should develop a provisional rate for application purposes. Follow the guidelines below.

   **SBIR and STTR Phase I Applicants:** If your organization does not have a currently effective negotiated indirect cost rate with a federal agency, then propose estimated F&A costs at a rate not to exceed 40% of the total direct costs. If awarded at a rate of 40% or less of total direct costs, the rate used to charge actual F&A costs to projects cannot exceed the awarded rate. NIH will not negotiate F&A rates for Phase I awards.

   **SBIR and STTR Phase II and CRP Applicants:** SBIR and STTR applicants who propose in the application an F&A rate of 40 percent of total direct costs or less will not be required to provide further justification at the time of award, and F&A costs will be awarded at the requested rate. However, DFAS will retain the authority to require well-documented proposals for F&A rates on an ad hoc basis. If the applicant SBC has a currently effective negotiated indirect cost rate(s) with a federal agency, such rate(s) should be used when calculating proposed F&A costs for an NIH application. (However, the rates(s) must be adjusted for IR&D expenses, which are not allowable under HHS awards.) SBCs are reminded that only actual F&A costs may be charged to projects. If awarded at a rate of 40 percent or less of total direct costs, the rate used to charge actual F&A costs to projects cannot exceed the awarded rate unless the SBC negotiates an indirect cost rate(s) with DFAS. DFAS will negotiate F&A/IDC rates for SBCs receiving Phase II awards if the requested rate is greater than 40 percent of total direct costs. For more detailed information, see NIH Guide Notice on the [Negotiation of F&A/Indirect Costs for Phase II SBIR/STTR Grants](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-038.html). [↑](#endnote-ref-6)
7. **Additional Instructions for SBIR/STTR:**

   Involvement of consultants and collaborators in the planning and research stages of the project is permitted. With the application, include letters from each individual and/or collaborator confirming their role(s) in the project. The letter(s) should be prepared on the consultant or collaborator’s letterhead and addressed to the SBC. One page is recommended.

   At a minimum, each consultant and collaborator letter should (1) verify their commitment to the project; (2) refer to the specific project by name, acknowledging the PD/PI as the lead on the project; and (3) specify what services/tasks the consultant or collaborator will contribute (e.g. expertise, number of hours/ percent of effort, summary of tasks to be completed). For consultants, the letter should also include the rate/charge for consulting services. Also include biographical sketches for each consultant.

   Letters of interest from potential commercial partners or investors and letters of commitment of funds or other resources that will enhance the likelihood of commercialization should be placed following the letters of support for consultants and collaborators.

   **STTR only:** The single “partnering” research institution must provide a letter to the applicant small business concern certifying that at least 30% of the work of the STTR project will be performed by the research institution. [↑](#endnote-ref-7)