## READ THIS FIRST

## How to use this template:

This template is formatted based on the instructions provided in the “Research Instructions for NIH and Other PHS Agencies” and best-practices recommended by SciCom.

Underneath each section heading in this template are the instructions (in **blue** **text**) for that section—keep the section headings (in **black text**), but delete THIS PAGE and any instructions (in **blue** **text**) in your final documents. **A blank version of this template, without instructions, can be found after the annotated version.**

Note that most proposal components will be submitted as individual PDFs; here, components are compiled into this single document for your convenience. Refer to the NIH [**Format Attachments**](http://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/format-attachments.htm) page for information about overall formatting of your submission.

PROJECT SUMMARY/ABSTRACT

[start text here]

**INSTRUCTIONS—See R-grant** [**SF 424 (R&R) FORMS-I instructions**](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-i/research-forms-i.pdf)**, p. R-39**

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 others 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**](http://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/format-attachments.htm)[**specifications**](http://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/format-attachments.htm). A summary that exceeds the 30-line limit will be flagged as an error by the Agency upon submission. Use of hyperlinks and URLs in this section is not allowed unless specified in the Notice of Funding Opportunity.

**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](http://report.nih.gov/)**) and will become public information.

Note that the "Project Summary/Abstract" attachment is not the same as the "Research Strategy" attachment.

PROJECT NARRATIVE

[start text here]

**INSTRUCTIONS—See R-grant** [**SF 424 (R&R) FORMS-I instructions**](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-i/research-forms-i.pdf)**, p. R-40**

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. Use of hyperlinks and URLs in this section is not allowed unless specified in the Notice of Funding Opportunity. If the application is funded, this public health relevance statement will be combined with the project summary (above) and will become public information.

SPECIFIC AIMS

**INSTRUCTIONS—See R-grant** [**SF 424 (R&R) FORMS-I instructions**](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-i/research-forms-i.pdf)**, p. R-83**

The Specific Aims page is limited to 1 page.Hyperlinks and URLs may not be used in this section unless specified as allowed in the funding opportunity.

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).

Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved.

[**NOTE: FIGURES ARE NO LONGER PERMITTED ON THE SPECIFIC AIMS PAGE**](https://grants.nih.gov/grants-process/write-application/how-to-apply-application-guide/format-attachments#figures-(e.g.,-images,-graphics,-charts,-graphs,-and-tables))

**Below is SciCom’s suggested flow/layout for your Specific Aims page.**

[start text here]

Describe the overarching public health problem and/or gap in knowledge that your proposal will address.

Present preliminary data, an overview of the approach, and your overarching hypothesis.

**Aim 1: State your aim**

Briefly describe the experimental design.

**Aim 2: State your aim**

Briefly describe the experimental design.

(Continue for as many aims as you have…)

Close by describing the expected outcomes and impact of your work, should your aims be completed successfully. Relate this to the overarching problem identified at the beginning, and to the field in general.

RESEARCH STRATEGY

**INSTRUCTIONS—See R-grant** [**SF 424 (R&R) FORMS-I instructions**](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-i/research-forms-i.pdf)**, p. R-83**

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 NOFO. 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.

Hyperlinks and URLs may not be used in this section unless specified as allowed in the funding opportunity.

Organize the Research Strategy in the specified order and use the instructions provided below unless otherwise specified in the NOFO. 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 R.220 - R&R Other Project Information Form, Bibliography and Reference Cited.

**Note for Applications Proposing the Involvement of Human Subjects and/or Clinical Trials:**

* Do not duplicate information in the Research Strategy and the PHS Human Subjects and Clinical Trials Information form. Use the Research Strategy attachment to discuss the overall strategy, methodology, and analyses of your proposed research. Use the PHS Human Subjects and Clinical Trials Information form to provide detailed information for human subjects studies and clinical trials.
* The PHS Human Subjects and Clinical Trials Information form will capture detailed study information, including eligibility criteria; inclusion of women, minorities, and individuals across the lifespan; 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 and Minorities).

**Note for Applicants with Multiple Specific Aims:**

You may address the Significance, Innovation, and Approach either for each Specific Aim individually or for all the Specific Aims collectively.

# Significance

[start text here]

* Explain the importance of the problem or critical barrier to progress that the proposed project addresses.
* Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.
* Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved.

## Rigor of the Prior Research

[start text here]

Describe the strengths and weaknesses in the [rigor](https://grants.nih.gov/grants/glossary.htm#ScientificRigor) of the prior research (both published and unpublished) that serves as the key support for the proposed project.

# Innovation

[start text here]

* 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.

# Approach

* Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Describe plans to address weaknesses in the rigor of the prior research that serves as the key support for the proposed project. Describe the experimental design and methods proposed and how they will achieve robust and unbiased results. Include how the data will be collected, analyzed, and interpreted, and reference any Resource Sharing Plans and the Data Management and Sharing (DMS) Plan, as appropriate. Resources and tools for rigorous experimental design can be found at the [**Enhancing Reproducibility through Rigor and Transparency**](https://grants.nih.gov/policy/reproducibility/index.htm) website.
* For trials that randomize groups or deliver interventions to groups, describe how your methods for analysis and sample size are appropriate for your plans for participant assignment and intervention delivery. These methods can include a group- or cluster- randomized trial or an individually randomized group-treatment trial. 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**](http://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.

**SciCom suggests using the headings below to organize and present the required information.**

## Overall Strategy and Rationale

[start text here]

## Robust and Unbiased Results

[start text here]

## Preliminary Studies

**You may place this information within the Research Strategy (i.e., Significance, Innovation, or Approach) where it makes the most sense for your application. Most often it is included as a subsection here and/or under the individual aims (note that it can be included for one, some, or all aims).**

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.

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.

[start text here]

## Aim 1. [restatement of specific aim]

**Rationale/Hypothesis.** [start text here]

**Preliminary Studies.** [start text here]

**Experimental Design and Methodology.** [start text here]

**Statistical Analyses.** [start text here]

**Expected Results and Benchmarks for Success.** [start text here]

**Potential Problems and Alternative Strategies.** [start text here]

## Aim 2. [restatement of specific aim]

**Rationale/Hypothesis.** [start text here]

**Preliminary Studies.** [start text here]

**Experimental Design and Methodology.** [start text here]

**Statistical Analyses.** [start text here]

**Expected Results and Benchmarks for Success.** [start text here]

**Potential Problems and Alternative Strategies.** [start text here]

# Project Timeline

Consider presenting your proposed timeline as a Gannt chart.

[start text here]

# Impact

You may want to summarize the potential impact of the results (similar to the end of the Specific Aims page) and future research directions.

BIBLIOGRAPHY AND REFERENCES CITED

[start text here]

**INSTRUCTIONS—See R-grant** [**SF424 (R&R) FORMS-I instructions**](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-i/research-forms-i.pdf)**, p. R-40**

**Format:** See the [Format Attachments](http://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/format-attachments.htm) page. Use of hyperlinks and URLs in this section is not allowed unless specified in the Notice of Funding Opportunity.

See the following instructions for which references to include in the “Bibliography and References Cited” attachment.

The “Bibliography & References Cited” attachment should include any references cited in **R.400 - PHS 398 Research Plan Form** and in the **R.500 - PHS Human Subjects and Clinical Trials Information** form.

When citing articles that fall under the Public Access Policy, were authored or co-authored by the applicant, and arose from NIH support, provide the NIH Manuscript Submission reference number (e.g., NIHMS97531) or the PubMed Central (PMC) reference number (e.g., PMCID234567) for each article. If the PMCID is not yet available because the Journal submits articles directly to PMC on behalf of their authors, indicate “PMC Journal – In Process.” NIH maintains a [**list of such journals**](http://publicaccess.nih.gov/submit_process_journals.htm).

Citations that are not covered by the Public Access Policy, but are publicly available in a free, online format may include URLs or PubMed ID (PMID) numbers along with the full reference. Active hyperlinks in this section are not allowed. 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 [**Interim Research Product FAQ**](https://grants.nih.gov/faqs%23/interim-research-product.htm) for more information.

VERTEBRATE ANIMALS

**INSTRUCTIONS—See R-grant** [**SF424 (R&R) FORMS-I instructions**](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-i/research-forms-i.pdf)**, p. R-87**

# Description of Procedures

[start text here]

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.

# Justifications

[start text here]

Provide justification that the species are appropriate for the proposed research. Explain why the research goals cannot be accomplished using an alternative model (e.g. computational, human, invertebrate, in vitro).

# Minimization of Pain and Distress

[start text here]

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://olaw.nih.gov/) website
* NIH's [**Vertebrate Animals Section Worksheet**](https://olaw.nih.gov/sites/default/files/VASchecklist.pdf)
* See the [**NIH Grants Policy Statement, Section 4.1.1: Animal Welfare Requirements**](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.1.1_animal_welfare_requirements.htm)(an applicable Animal Welfare Assurance will be required if the recipient organization does not have one)

SELECT AGENT RESEARCH

[start text here]

**INSTRUCTIONS—See R-grant** [**SF424 (R&R) FORMS-I instructions**](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-i/research-forms-i.pdf)**, p. R-88**

See also the [**NIH Grants Policy Statement, Section 4.1.24.1.1: Select Agents**](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.1.24_public_health_security.htm#Select).

**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/current/title-42/part-73), 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**](https://www.selectagents.gov/sat/exclusions/index.htm)[**Agents and Toxins Exclusions**](https://www.selectagents.gov/sat/exclusions/index.htm) 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 organization, 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**](https://www.ecfr.gov/current/title-42/part-73) as “any government agency (Federal, State, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity.”

1. 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.

MULTIPLE PD/PI LEADERSHIP PLAN

[start text here]

**INSTRUCTIONS—See R-grant** [**SF424 (R&R) FORMS-I instructions**](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-i/research-forms-i.pdf)**, p. R-89**

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.

**Resubmission Applications:** For resubmission applications changing from a single PD/PI to multiple PD/PIs, changing the number or makeup of the multiple PD/PIs, the applicant must provide a rationale for the change in the introduction and include the required Multiple PD/PI Leadership Plan.

**Renewal Applications:** For renewal applications changing from a single PD/PI to multiple PD/PIs, changing the number or makeup of the multiple PD/PIs, the applicant must provide a rationale for the change in the progress report within the research strategy and include the required Multiple PD/PI Leadership Plan.

CONSORTIUM/CONTRACTUAL ARRANGEMENTS

[start text here]

**INSTRUCTIONS—See R-grant** [**SF424 (R&R) FORMS-I instructions**](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-i/research-forms-i.pdf)**, p. R-90**

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 recipient.

Refer to the [**NIH Grants Policy Statement, Section 15: Consortium Agreements**](http://grants.nih.gov/grants/policy/nihgps/HTML5/section_15/15.1_general.htm)for more information.

LETTERS OF SUPPORT

[start text here]

**INSTRUCTIONS—See R-grant** [**SF424 (R&R) FORMS-I instructions**](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-i/research-forms-i.pdf)**, p. R-90**

Use of hyperlinks and URLs in Letters of Support is not allowed unless specified in the funding opportunity.

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.

Material Transfer Agreements may be included in this section.

Letters must focus on the topics listed above and not contain data / figures / tables / graphs, preliminary data, methods, background and significance details that are expected to be found in Research Strategy section of the application. Letters of Support serve to describe terms of a collaboration or consultation and also are not de facto letters of reference from persons not actively participating in the project. Applications with letters containing such excess information may be withdrawn from the review process.

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.

RESOURCE SHARING PLAN(S)

**INSTRUCTIONS—See R-grant** [**SF424 (R&R) FORMS-I instructions**](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-i/research-forms-i.pdf)**, p. R-91**

##### **Note: Effective for due dates on or after January 25, 2023, Data Management and Sharing (DMS) Plans are now included in Section 11. Other Plan(s). Plans for Genomic Data Sharing should be provided as part of the Data Management and Sharing Plan.**

# Sharing Model Organisms

[start text here]

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**](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.2.3_sharing_research_resources.htm#Sharing2)[**Model Organisms**](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.2.3_sharing_research_resources.htm#Sharing2)**.**

# Research Tools

[start text here]

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. For more information, see the [**Research Tools Policy on the NIH Scientific Data Sharing Website**](https://sharing.nih.gov/other-sharing-policies/research-tools-policy) **and the** [**NIH Grants Policy**](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.2.3_sharing_research_resources.htm)[**Statement, Section 8.2.3: Sharing Research Resources**](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.2.3_sharing_research_resources.htm)**.**

**DATA MANAGEMENT AND SHARING PLAN**

If any of the proposed research in the application involves the generation of scientific data, this application is subject to the NIH Policy for Data Management and Sharing and requires submission of a Data Management and Sharing Plan. If the proposed research in the application will generate large-scale genomic data, the Genomic Data Sharing Policy also applies and should be addressed in this Plan. Refer to the detailed instructions in the application guide for developing this plan as well as to additional guidance on [sharing.nih.gov](https://sharing.nih.gov/). The Plan is recommended not to exceed two pages. Text in italics should be deleted. There is no “form page” for the Data Management and Sharing Plan. The DMS Plan may be provided in the *format* shown below.

Public reporting burden for this collection of information is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering, and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0001 and 0925-0002). Do not return the completed form to this address.

**Element 1: Data Type**

1. **Types and amount of scientific data expected to be generated in the project:**

*Summarize the types and estimated amount of scientific data expected to be generated in the project,*

1. **Scientific data that will be preserved and shared, and the rationale for doing so:**

*Describe which scientific data from the project will be preserved and shared and provide the rationale for this decision.*

1. **Metadata, other relevant data, and associated documentation:**

*Briefly list the metadata, other relevant data, and any associated documentation (e.g., study protocols and data collection instruments) that will be made accessible to facilitate interpretation of the scientific data.*

**Element 2: Related Tools, Software and/or Code:**

*State whether specialized tools, software, and/or code are needed to access or manipulate shared scientific data, and if so, provide the name(s) of the needed tool(s) and software and specify how they can be accessed.*

**Element 3: Standards:**

*State what common data standards will be applied to the scientific data and associated metadata to enable interoperability of datasets and resources, and provide the name(s) of the data standards that will be applied and describe how these data standards will be applied to the scientific data generated by the research proposed in this project. If applicable, indicate that no consensus standards exist.*

**Element 4: Data Preservation, Access, and Associated Timelines**

1. **Repository where scientific data and metadata will be archived:**

*Provide the name of the repository(ies) where scientific data and metadata arising from the project will be archived;* *see* [*Selecting a Data Repository*](https://sharing.nih.gov/data-management-and-sharing-policy/sharing-scientific-data/selecting-a-data-repository)*).*

1. **How scientific data will be findable and identifiable:**

*Describe how the scientific data will be findable and identifiable, i.e., via a persistent unique identifier or other standard indexing tools.*

1. **When and how long the scientific data will be made available:**

*Describe when the scientific data will be made available to other users (i.e., no later than time of an associated publication or end of the performance period, whichever comes first) and for how long data will be available.*

**Element 5: Access, Distribution, or Reuse Considerations**

1. **Factors affecting subsequent access, distribution, or reuse of scientific data:***NIH expects that in drafting Plans, researchers maximize the appropriate sharing of scientific data. Describe and justify any applicable factors or data use limitations affecting subsequent access, distribution, or reuse of scientific data related to informed consent, privacy and confidentiality protections, and any other considerations that may limit the extent of data sharing. See* [*Frequently Asked Questions*](https://sharing.nih.gov/faqs#/data-management-and-sharing-policy.htm) *for examples of justifiable reasons for limiting sharing of data.*
2. **Whether access to scientific data will be controlled:***State whether access to the scientific data will be controlled (i.e., made available by a data repository only after approval).)*

1. **Protections for privacy, rights, and confidentiality of human research participants:**

*If generating scientific data derived from humans, describe how the privacy, rights, and confidentiality of human research participants will be protected (e.g., through de-identification, Certificates of Confidentiality, and other protective measures).*

**Element 6: Oversight of Data Management and Sharing:**

*Describe how compliance with this Plan will be monitored and managed, frequency of oversight, and by whom at your institution (e.g., titles, roles).*

AUTHENTICATION OF KEY BIOLOGICAL AND/OR CHEMICAL RESOURCES

[start text here]

**INSTRUCTIONS—See R-grant** [**SF424 (R&R) FORMS-I instructions**](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-i/research-forms-i.pdf)**, p. R-94**

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.

Key biological and/or chemical resources are characterized as follows.

* Key biological and/or chemical resources may or may not have been 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**](https://grants.nih.gov/policy-and-compliance/policy-topics/reproducibility) for more information.

**A BLANK VERSION OF THE ENTIRE TEMPLATE CAN BE FOUND BELOW**

PROJECT SUMMARY/ABSTRACT

[start text here]

PROJECT NARRATIVE

[start text here]

SPECIFIC AIMS

*The blue text and boxes are meant to help you construct your Aims page.* ***They should be deleted in the final version.***

Describe the overarching public health problem and/or gap in knowledge that your proposal will address.

Present preliminary data, an overview of the approach, and you overarching hypothesis.

**Aim 1: State your aim**

Briefly describe the experimental design.

**Aim 2: State your aim**

Briefly describe the experimental design.

(Continue for as many aims as you have…)

Close by describing the expected outcomes and impact of your work, should your aims be completed successfully.

RESEARCH STRATEGY

# Significance

[start text here]

## Rigor of the Prior Research

[start text here]

# Innovation

[start text here]

# Approach

## Overall Strategy and Rationale

[start text here]

## Robust and Unbiased Results

[start text here]

## Preliminary Studies

[start text here]

## Aim 1. [restatement of specific aim]

**Rationale/Hypothesis.** [start text here]

**Preliminary Studies.** [start text here]

**Experimental Design and Methodology.** [start text here]

**Statistical Analyses.** [start text here]

**Expected Results and Benchmarks for Success.** [start text here]

**Potential Problems and Alternative Strategies.** [start text here]

## Aim 2. [restatement of specific aim]

**Rationale/Hypothesis.** [start text here]

**Preliminary Studies.** [start text here]

**Experimental Design and Methodology.** [start text here]

**Statistical Analyses.** [start text here]

**Expected Results and Benchmarks for Success.** [start text here]

**Potential Problems and Alternative Strategies.** [start text here]

# Project Timeline

[start text here]

# Impact

[start text here]

BIBLIOGRAPHY AND REFERENCES CITED

[start text here]

VERTEBRATE ANIMALS

# Description of Procedures

[start text here]

# Justifications

[start text here]

# Minimization of Pain and Distress

[start text here]

SELECT AGENT RESEARCH

[start text here]

MULTIPLE PD/PI LEADERSHIP PLAN

[start text here]

CONSORTIUM/CONTRACTUAL ARRANGEMENTS

[start text here]

LETTERS OF SUPPORT

[start text here]

RESOURCE SHARING PLAN(S)

# Sharing Model Organisms

[start text here]

# Research Tools

[start text here]

**DATA MANAGEMENT AND SHARING PLAN**

If any of the proposed research in the application involves the generation of scientific data, this application is subject to the NIH Policy for Data Management and Sharing and requires submission of a Data Management and Sharing Plan. If the proposed research in the application will generate large-scale genomic data, the Genomic Data Sharing Policy also applies and should be addressed in this Plan. Refer to the detailed instructions in the application guide for developing this plan as well as to additional guidance on [sharing.nih.gov](https://sharing.nih.gov/). The Plan is recommended not to exceed two pages. Text in italics should be deleted. There is no “form page” for the Data Management and Sharing Plan. The DMS Plan may be provided in the *format* shown below.

Public reporting burden for this collection of information is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering, and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0001 and 0925-0002). Do not return the completed form to this address.

**Element 1: Data Type**

1. **Types and amount of scientific data expected to be generated in the project:**

*Summarize the types and estimated amount of scientific data expected to be generated in the project,*

1. **Scientific data that will be preserved and shared, and the rationale for doing so:**

*Describe which scientific data from the project will be preserved and shared and provide the rationale for this decision.*

1. **Metadata, other relevant data, and associated documentation:**

*Briefly list the metadata, other relevant data, and any associated documentation (e.g., study protocols and data collection instruments) that will be made accessible to facilitate interpretation of the scientific data.*

**Element 2: Related Tools, Software and/or Code:**

*State whether specialized tools, software, and/or code are needed to access or manipulate shared scientific data, and if so, provide the name(s) of the needed tool(s) and software and specify how they can be accessed.*

**Element 3: Standards:**

*State what common data standards will be applied to the scientific data and associated metadata to enable interoperability of datasets and resources, and provide the name(s) of the data standards that will be applied and describe how these data standards will be applied to the scientific data generated by the research proposed in this project. If applicable, indicate that no consensus standards exist.*

**Element 4: Data Preservation, Access, and Associated Timelines**

1. **Repository where scientific data and metadata will be archived:**

*Provide the name of the repository(ies) where scientific data and metadata arising from the project will be archived; see* [*Selecting a Data Repository*](https://sharing.nih.gov/data-management-and-sharing-policy/sharing-scientific-data/selecting-a-data-repository)*).*

1. **How scientific data will be findable and identifiable:**

*Describe how the scientific data will be findable and identifiable, i.e., via a persistent unique identifier or other standard indexing tools.*

1. **When and how long the scientific data will be made available:**

*Describe when the scientific data will be made available to other users (i.e., no later than time of an associated publication or end of the performance period, whichever comes first) and for how long data will be available.*

**Element 5: Access, Distribution, or Reuse Considerations**

1. **Factors affecting subsequent access, distribution, or reuse of scientific data:***NIH expects that in drafting Plans, researchers maximize the appropriate sharing of scientific data. Describe and justify any applicable factors or data use limitations affecting subsequent access, distribution, or reuse of scientific data related to informed consent, privacy and confidentiality protections, and any other considerations that may limit the extent of data sharing. See* [*Frequently Asked Questions*](https://sharing.nih.gov/faqs#/data-management-and-sharing-policy.htm) *for examples of justifiable reasons for limiting sharing of data.*
2. **Whether access to scientific data will be controlled:***State whether access to the scientific data will be controlled (i.e., made available by a data repository only after approval).)*

1. **Protections for privacy, rights, and confidentiality of human research participants:**

*If generating scientific data derived from humans, describe how the privacy, rights, and confidentiality of human research participants will be protected (e.g., through de-identification, Certificates of Confidentiality, and other protective measures).*

**Element 6: Oversight of Data Management and Sharing:**

*Describe how compliance with this Plan will be monitored and managed, frequency of oversight, and by whom at your institution (e.g., titles, roles).*

AUTHENTICATION OF KEY BIOLOGICAL AND/OR CHEMICAL RESOURCES

[start text here]