Project Narrative

[start text here]

Project summary/abstract

[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 problem and/or gap in knowledge that your proposal will address.

Present preliminary data, and 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]

**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]

**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]

Bibliography and References Cited

[start text here]

Vertebrate Animals

Include a “Vertebrate Animals” attachment if you answered “Yes” to the question “Are Vertebrate Animals Used?” on the R.220 - R&R Other Project Information Form. Do not use this attachment to circumvent the page limits of the Research Strategy.

Do not use the Vertebrate Animals section to circumvent the page limits of the Research Strategy. Each of the criteria below must be addressed. Failure to adequately address the criteria may negatively affect the application’s impact score. In addition to the criteria below, you should also:

* Explain when and how animals are expected to be used if plans for the use of animals have not been finalized.

See the following for more information: [NIH Office of Laboratory Animal Welfare website](https://olaw.nih.gov/) and [NIH Worksheet for Applications Involving Animals](https://olaw.nih.gov/sites/default/files/VASchecklist.pdf).

# 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" section. 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.

[start text here]

# 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).

[start text here]

# Minimization of Pain and Distress

Describe the interventions including analgesia, anesthesia, sedation, palliative care and humane endpoints to minimize discomfort, distress, pain, and injury.

[start text here]

# Project/Performance or Collaborating Site(s)

# Identify all project performance (or collaborating) sites and describe the proposed research activities with vertebrate animals that will be conducted at those sites.

[start text here]

Resource Sharing Plan(s)

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.

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 [NIH Grants Policy Statement, Section 8.2.3.4 Sharing Model Organisms](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.2.3_sharing_research_resources.htm#Sharing2).

Model organisms include but are not restricted to mammalian models, such as the mouse and rat; and non-mammalian models, such as budding yeast, social amoebae, round worm, fruit fly, zebra fish, and frog. Research resources to be shared include genetically modified or mutant organisms, sperm, embryos, protocols for genetic and phenotypic screens, mutagenesis protocols, and genetic and phenotypic data for all mutant strains. This expectation is for all applications where the development of model organisms is anticipated, regardless of funding amount.

[start text here]

Research Tools

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 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).

[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.

[start text here]

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.

[start text here]

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.

[start text here]

**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.**

[start text here]

**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.**

[start text here]

**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)).

[start text here]

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.

[start text here]

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.

[start text here]

**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.

[start text here]

1. **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).**

[start text here]

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).

[start text here]

**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).

[start text here]

Authentication of Key Biological and/or Chemical Resources

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. No more than 1 page is suggested.

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](https://grants.nih.gov/policy/reproducibility/index.htm) for more information.

[start text here]

Multiple PD/PI Leadership Plan

Do not submit a leadership plan if you are not submitting a Multiple PD/PI application.

For applications designating multiple PD/PIs, a leadership plan must be included. For applications designating multiple PD/PIs, all such individuals must be assigned the PD/PI role on the Senior/Key Profile form, even those at organizations other than the applicant organization.

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 leadership plan. In the event of an award, the requested allocations may be reflected in a footnote on the Notice of Grant Award.

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.

[start text here]

Consortium/Contractual Arrangements

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.

The signature of the Authorized Organization Representative in R.200 - SF 424 (R&R), Authorized Representative signifies that the applicant and all proposed consortium participants understand and agree to the following statement: *The appropriate programmatic and administrative personnel of each organization involved in this grant application are aware of the agency’s consortium agreement policy and are prepared to establish the necessary inter-organizational agreement(s) consistent with that policy.*

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

[start text here]

Letters of Support

Attach all appropriate 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 are not required for personnel (such as research assistants) not contributing in a substantive, measurable way to the scientific development or execution of the project.

Letters should stipulate expectations for co-authorship, and whether cell lines, samples or other resources promised in the letter are freely available to other investigators in the scientific community or will be provided to the particular investigators only.

For consultants, letters should include rate/charge for consulting services and level of effort/number of hours per year anticipated. In addition, letters ensuring access to core facilities and resources should stipulate whether access will be provided as a fee-for-service.

Do not place these letters in the Appendix. Consultant biographical sketches should be in the Biographical Sketch section.

[start text here]