R61/R33 Checklist

Principal Investigator(s)	
Proposal Title	
RFA/PA/FOA#	
Grant Administrator	
Grant Submission Deadline	
COM Deadline / 10 business days prior	
***OSP Deadline / 5 business days prior**	

Arial 11 point font, 1/2 inch margins minimum

When saving the individual files this naming convention should be used:
Last Name_Mechanism_Application Section Example: Jones_R01_Abstract

Section of Application	Format Restrictions	Notes	PROVIDED
Title of Proposal	200 characters	Do not use symbols in titles.	☐
Project Summary/Abstract	30 lines MAX	Provide an abstract of the entire project.	☐
Project Narrative	2-3 sentences	State relevance of research to public health.	☐
***Research Strategy**	12 pages MAX (Sections include Significance, Innovation and Approach)	See new requirements to include in the significance and approach section regarding rigor or experimental design: Rigor and Reproducibility	☐
***Specific Aims**	1 page MAX	State precisely the goals of the proposed research and summarize the expected outcome(s) including the impact that the results of the proposed research will exert on the research field(s) involved. List succinctly the specific objectives of the research proposed.	☐
Data management & sharing plan	No page limit	https://sharing.nih.gov/data-management-and-sharing-policy/planning-and-budgeting-for-data-management-and-sharing/writing-a-data-management-and-sharing-plan#after See COM template.	☐
Facilities & Resources	No page limit	Provide a detailed description of the institutional facilities and resources, and how it will contribute to the success of the project. Include the institutional environment statement. See COM template.	☐
Equipment	No page limit	List major items of equipment already available for this project and, if appropriate, identify location and pertinent capabilities. See COM template.	☐
Biosketches	5 pages MAX	Required for key personnel. https://grants.nih.gov/grants/forms/biosketch.htm	☐
***Budget**	N/A	NIH requires applications requesting $500,000 or more in direct costs in any year must seek prior approval to submit at least 6 weeks before applying.	☐
***Detailed Justification**	No page limit	Full detailed budget justification. See COM template	☐
References/Bibliography	No page limit	No hyperlinks allowed. / Look for link	☐
Human Subjects Sections	If applicable	1. Inclusion of Individuals Across the Lifespan 2. Inclusion of Women and Minorities 3. Recruitment and Retention Plan 4. Study Timeline 5. Data Safety Monitoring Plan 6. Protection of Human Subjects Supplemental instructions	☐
Vertebrate Animals	If applicable - No page limit	Vertebrate Animals Section Training Module For the project proposed, reviewers will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following criteria:	☐
Cover Letter	If applicable - No page limit		☐
Select Agent Research	If applicable - No page limit		☐
Multiple PI leadership plan (if more than one PI)	If applicable - No page limit	Required for all applications designating multiple PDs/Pis.	☐
Subaward Docs	If applicable	For subawards: biosketch, budget, budget justification, scope of work, subrecipient commitment form, performance site location https://www.fau.edu/research-admin/docs/policies/sponsored-programs/fau-subrecipient-commitment-form-nov2023.pdf	☐
Support Letters	If applicable - No page limit		☐
Resource Sharing Plan	if applicable - No page limit	Only needed if developing a new software tool or new software tool or generating a unique model organism (usually genetic model) and plan to share that with the scientific community. See Data Sharing Plan, Sharing Model Organisms, and Genomic Data Sharing below.	☐

*Data Sharing Plan	If applicable - 1-paragraph	Description of how final research data will be shared	☐
*Sharing Model Organisms	If applicable - No page limit	Description of specific plan for sharing/distributing unique model organisms and related resources	☐
*Genomic Data Sharing	If applicable - No page limit	If applicable, plan to deposit into NIH-designated GWAS data repository	☐
Authentication of Key Biological and/or Chemical Resources	If applicable - Name file *Authentication of Key Resources Plan*	https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-068.html	☐
Introduction	If applicable - 1 page MAX	Use only for resubmission or revision applications to address reviewer comments.	☐

Other Resources to Review:

Format Attachments: https://grants.nih.gov/grants-process/write-application/how-to-apply-application-guide/format-attachments
Page Limits: https://grants.nih.gov/grants-process/write-application/how-to-apply-application-guide/page-limits
How to Apply: https://grants.nih.gov/grants-process/write-application/how-to-apply-application-guide
Using ASSIST: https://grants.nih.gov/grants-process/plan-to-apply/plan-within-your-organization/submission-options/using-assist-to-prepare-your-application
Research Office Policy https://www.fau.edu/medicine/research/grants/submission/
NIH Personnel Classifications https://www.niaid.nih.gov/grants-contracts/team-roles-agreements
Clinical Trial Information https://grants.nih.gov/policy-and-compliance/policy-topics/clinical-trials/definition
https://grants.nih.gov/policy/clinical-trials/CT-decision-tree.pdf
https://www.nih.gov/sites/default/files/about-nih/public-trust/clinical-trials-infographic.pdf

Notes

***OSP Deadline / 5 business days prior** If OSP does not receive proposal for review 5 business days in advance, proposal will receive a limited review

***Novelution Required Documents for routing**

***Budget:** Final budget must be provided for routing
***Detailed Justification:** Final detailed justification must be provided for routing
***Specific Aims:** A Specific Aims draft must be provided for routing
***Research Strategy:** A Research Strategy draft must be provided for routing

HUMAN SUBJECTS ADDITIONAL INFORMATION

Questions	Answers
Section 1 - Basic Information	
1.1 Study Title	
1.2 Is the study exempt from federal regulations?	Yes
1.4 Clinical Trial Questionnaire	
1.4.a Does the study involve participants	Yes
1.4.b. Are the participants prospectively assigned to an intervention?	Yes
1.4.c. Is the study designed to evaluate the effect of the intervention on the participants?	Yes
1.4.d. Is the effect that will be evaluated a health related biomedical or behavioral outcome?	Yes
1.5 Provide the ClinicalTrials.gov Identifier (e.g. NCT87654321) for this trial, if applicable	
Section 2 - Study Population Characteristics	
2.1. Conditions or Focus of Study	
2.2. Eligibility criteria	
Inclusion criteria	
Exclusion criteria	
2.3. Age Limits	Min/ Max Ages
2.6. Recruitment status (ie, not yet recruiting)	
2.8 Enrollment of First Participant?	date anticipated

Inclusion Enrollment Report

1. Inclusion Enrollment Report Title	
2. Using Existing Dataset or Resources	
3. Enrollment Location Type	Domestic
4. Enrollment Country(ies)	

Ethnic Categories					
	Not Hispanic or Latino		Hispanic or Latino		Total
Racial Categories	Female	Male	Female	Male	
American Indian/Alaska Native	1		4		5
Asian	12				12
Native Hawaiian or Other Pacific Islander					0
Black or African American					0
White					0
More than One Race					0
Total	13	0	4	0	17

Section	Information
Title of Proposal	A “new” application must have a different title from any other PHS project submitted for the same application due date with the same PD/PI. A “resubmission” or “renewal” application should normally have the same title as the previous grant or application. If the specific aims of the project have significantly changed, choose a new title. A “revision” application must have the same title as the currently funded grant. NIH and other PHS agencies limit title character length to 200 characters, including the spaces between words and punctuation.
Project Summary/Abstract	The Project Summary is meant to serve as a succinct and accurate description of the proposed work when separated from the application. 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 concisely the research design and methods for achieving the stated goals. This section should be informative to other persons working in the same or related fields and insofar as possible understandable to a scientifically or technically literate reader. Avoid describing past accomplishments and the use of the first person. Finally, please make every effort to be succinct. This section must be no longer than 30 lines of text, and follow the required font and margin specifications. An abstract which exceeds this allowable length may be flagged as an error by the agency upon submission. This would require a corrective action before the application will be accepted. Do not include proprietary, confidential information or trade secrets in the description section.
Project Narrative	For NIH and other PHS agencies applications, using no more than two or three sentences, describe the relevance of this research to public health. For example, NIH applicants can describe how, in the short or long term, the research would contribute to fundamental knowledge about the nature and behavior of living systems and/or the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.
Facilities & Resources	This information is used to assess the capability of the organizational resources available to perform the effort proposed. Identify the facilities to be used (Laboratory, Animal, Computer, Office, Clinical and Other). If appropriate, indicate their capacities, pertinent capabilities, relative proximity and extent of availability to the project. Describe only those resources that are directly applicable to the proposed work. Provide any information describing the Other Resources available to the project (e.g., machine shop, electronic shop) and the extent to which they would be available to the project. 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 subject populations or will employ useful collaborative arrangements. For **Early Stage Investigators (ESIs)**, describe institutional investment in the success of the investigator, e.g., resources for classes, travel, 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; and financial support such as protected time for research with salary support. If there are multiple performance sites, describe the resources available at each site.

Section	Information
Equipment	List major items of equipment already available for this project and, if appropriate identify location and pertinent capabilities.
Biosketches	Include biographical sketches of all senior/key personnel and Other Significant Contributors.
Budget	NIH requires applications requesting $500,000 or more in direct costs in any year must seek prior approval to submit at least 6 weeks before applying.
***Detailed Justification**	List all personnel, including names, percent of effort and roles on the project. NIH and other PHS agencies use the concept of person months as a metric for determining percent of effort. No individual salary information should be provided. Since the modules should be a reasonable estimate of costs allowable, allocable, and appropriate for the proposed project, applicants must use the current legislatively imposed salary limitation when estimating the number of modules.
Human Subjects Sections	If activities involving human subjects are planned at any time during the proposed project at any performance site, the Protection of Human Subjects, Inclusion of Women and Minorities, Inclusion of Children, and Inclusion Enrollment Report are required. Data Safety Monitoring Plan required if a NIH defined Clinical Trial is proposed.
Vertebrate Animals	If Vertebrate Animals are involved in the project, address each of the criteria below. This section should be a concise, complete description of the animals and proposed procedures. While additional details may be included in the Research Strategy, the responses to the criteria below must be cohesive and include sufficient detail to allow evaluation by peer reviewers and NIH staff. If all or part of the proposed research involving vertebrate animals will take place at alternate sites (such as project/performance or collaborating site(s)), identify those sites and describe the activities at those locations. Although no specific page limitation applies to this section of the application, be succinct. Failure to address the following criteria will result in the application being designated as incomplete and it will not be considered. The criteria are as follows: 1. Description of Procedures. Provide a concise description of the proposed procedures to be used that involve vertebrate animals in the work outlined in the Research Strategy section. Identify the species, strains, ages, sex and total number 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 to minimize discomfort, distress, pain and injury.
Select Agent Research	Select agents are hazardous biological agents and toxins that have been identified by HHS or 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. CDC and the Animal APHIS Select Agent Programs jointly maintain a list of these agents. See http://www.selectagents.gov/.

Section	Information
Multiple PI leadership plan (if more than one PI)	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, process 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. Do not submit a leadership plan if you are not submitting a Multiple PD/PI application.
Subaward Docs	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.
Cover Letter	Applicants are encouraged to include a cover letter with the competing application. The letter should contain any of the following information that applies to the application: 1. Application title. 2. Funding Opportunity (PA or RFA) title of the NIH initiative. 3. For late applications (see Late Application policy in http://grants.nih.gov/grants/funding/submissionpolicies.htm) include specific information about the timing and nature of the cause of the delay. 4. When submitting a Changed/Corrected Application after the due date, a cover letter is required explaining the reason for late submission of the Changed/Corrected Application. If you already submitted a cover letter with a previous submission and are now submitting a late Changed/Corrected Application, you must include all previous cover letter text in the revised cover letter attachment. The system does not retain any previously submitted cover letters; therefore, you must repeat all information previously submitted in the cover letter as well as any additional information. 5. Explanation of any subaward budget components that are not active for all periods of the proposed grant Section G.240 - Senior/Key Person Profile (Expanded) Form. 6. Statement that you have attached any required agency approval documentation for the type of application submitted. This may include approval for applications $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. 7. When intending to submit a video as part of the application, the cover letter must include information about the intent to submit it; if this is not done, a video will not be accepted. See NOT-OD-12-141 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 (NOT-OD-14-11 and NOT-OD-15-027.)

Section	Information
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 one page is suggested. -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. Reviewers will assess the information provided in this Section. Any reviewer questions associated with key biological and/or chemical resource authentication will need to be addressed prior to award.
Introduction	An Introduction must be included that summarizes the substantial additions, deletions, and changes to the application. The Introduction must also include a response to the issues and criticism raised in the Summary Statement. The Introduction is separate from the Cover Letter. The page limit for the Introduction may not exceed one page unless indicated otherwise.
Specific Aims	State concisely the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will exert on the research field(s) involved. List succinctly the specific 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.
References/Bibliography	Provide a bibliography of any references cited in the Project Narrative. Each reference must include the names of all authors (in the same sequence in which they appear in the publication), the article and journal title, book title, volume number, page numbers, and year of publication. Include only bibliographic citations. 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 â€“ In Process." A list of these journals is posted at: http://publicaccess.nih.gov/submit_process_journals.htm.

Section	Information
Research Strategy	Organize the Research Strategy in the specified order and using the instructions provided below, or as stated in the Funding Opportunity Announcement. Start each section with the appropriate section heading – Significance, Innovation, Approach. Cite published experimental details in the Research Strategy section and provide the full reference in the Bibliography and References Cited section. **1. Significance:** **a.** Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses. **b.** 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. **c.** Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields. **d.** Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved. **2. Innovation:** **a.** Explain how the application challenges and seeks to shift current research or clinical practice paradigms. **b.** 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. **c.** Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions. **3. Approach:** **a.** 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 Item 15 (Resource Sharing Plan), include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate. **b.** Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims. **c.** 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. **d.** 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. **e.** If your study(s) involves human subjects, you are expected to explain how relevant biological variables are important to the proposed experimental design and analyses. The sections on the Inclusion of Women and Minorities and Inclusion of Children can be used to expand your discussion on inclusion and justify the proposed proportions of individuals (such as males and females) in the sample. **f.** Please refer to NOT-OD-15-102 for further consideration of NIH expectations about sex as a biological variable. **g.** Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised. A full discussion on the use of select agents should appear in the Protection of Human Subjects attachment. **h.** If research on Human Embryonic Stem Cells (hESCs) is proposed but an approved cell line from the NIH hESC Registry cannot be identified, provide a strong justification for why an appropriate cell line cannot be chosen from the Registry at this time.

Research Strategy	If an applicant has multiple Specific Aims, then the applicant may address Significance, Innovation and Approach for each Specific Aim individually, or may address Significance, Innovation and Approach for all of the Specific Aims collectively. As applicable, also include the following information as part of the Research Strategy, keeping within the three sections listed above: Significance, Innovation, and Approach. **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 help to establish the likelihood of success of the proposed project. Early Stage Investigators should include preliminary data. **Progress Report for Renewal and Revision Applications**. For renewal/revision applications, provide a Progress Report. Provide the beginning and ending dates for the period covered since the last competitive review. Summarize the specific aims of the previous project period and the importance of the findings, and emphasize the progress made toward their achievement. Explain any significant changes to the specific aims and any new directions including changes to the specific aims and any new directions including changes resulting from significant budget reductions. For any studies meeting the NIH definition for clinical research, discuss previous participant enrollment (e.g., recruitment, retention, inclusion of women, minorities, children etc.) as part of the progress report, particularly if relevant to studies proposed in the renewal or revision application. You should not submit a Cumulative Inclusion Enrollment Report form unless the enrollment is part of the renewal or revision application. A list of publications, patents, and other printed materials should be included in the Progress Report Publication List attachment; do not include that information here.
Data Management & Sharing Plan	The goal of this policy is to maximize the availability of data from NIH-supported research to advance NIH's mission to enhance health, lengthen life, and reduce illness and disability. The DMS policy will provide a consistent, minimum expectation of data management and sharing for all research supported by the agency. Additionally, the policy applies to all research, funded or conducted in whole or in part by the NIH, that generates scientific data." For more information, please visit: https://sharing.nih.gov/data-management-and-sharing-policy/planning-and-budgeting-for-data-management-and-sharing/writing-a-data-management-and-sharing-plan#after
Resource Sharing Plan	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.

	1. Data Sharing Plan: Investigators seeking $500,000 or more in direct costs (exclusive of consortium F&A) in any year 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. Specific funding opportunity announcements may require that all applications include this information regardless of the dollar level. Applicants are encouraged to read the specific opportunity 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. See Data-Sharing Policy or https://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html.
	2. 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. See Sharing Model Organisms in Part III, 1.5.2, and NIH Guide NOT-OD-04-042. **3. Genomic Data Sharing:** Applicants seeking funding for research that generates large-scale human or non-human genomic data are expected to provide a plan for sharing of these data in the Resource Sharing Plan section of the funding application. 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 Genomic Data Sharing policy (GDS), provides examples of genomic research projects that are subject to the Policy. For further information see the NIH GDS Policy, NIH Guide NOT-OD-14-124, and the GDS website at http://gds.nih.gov/.

Section	Information
Research Strategy	Organize the Research Strategy in the specified order and using the instructions provided below, or as stated in the Funding Opportunity Announcement. Start each section with the appropriate section heading – Significance, Innovation, Approach. Cite published experimental details in the Research Strategy section and provide the full reference in the Bibliography and References Cited section. **1. Significance:** **a.** Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses. **b.** 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. **c.** Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields. **d.** Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved. **2. Innovation:** **a.** Explain how the application challenges and seeks to shift current research or clinical practice paradigms. **b.** 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. **c.** Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions. **3. Approach:** **a.** 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 Item 15 (Resource Sharing Plan), include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate. **b.** Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims. **c.** 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. **d.** 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. **e.** If your study(s) involves human subjects, you are expected to explain how relevant biological variables are important to the proposed experimental design and analyses. The sections on the Inclusion of Women and Minorities and Inclusion of Children can be used to expand your discussion on inclusion and justify the proposed proportions of individuals (such as males and females) in the sample. **f.** Please refer to NOT-OD-15-102 for further consideration of NIH expectations about sex as a biological variable. **g.** Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised. A full discussion on the use of select agents should appear in the Protection of Human Subjects attachment. **h.** If research on Human Embryonic Stem Cells (hESCs) is proposed but an approved cell line from the NIH hESC Registry cannot be identified, provide a strong justification for why an appropriate cell line cannot be chosen from the Registry at this time.

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	1. Data Sharing Plan: Investigators seeking $500,000 or more in direct costs (exclusive of consortium F&A) in any year 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. Specific funding opportunity announcements may require that all applications include this information regardless of the dollar level. Applicants are encouraged to read the specific opportunity 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. See Data-Sharing Policy or https://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html.
	2. 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. See Sharing Model Organisms in Part III, 1.5.2, and NIH Guide NOT-OD-04-042. **3. Genomic Data Sharing:** Applicants seeking funding for research that generates large-scale human or non-human genomic data are expected to provide a plan for sharing of these data in the Resource Sharing Plan section of the funding application. 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 Genomic Data Sharing policy (GDS), provides examples of genomic research projects that are subject to the Policy. For further information see the NIH GDS Policy, NIH Guide NOT-OD-14-124, and the GDS website at http://gds.nih.gov/.