Updated 03/2020

Instructions for Grant Applications using PHS 398

These instructions pertain to applications for research project grants that have not transitioned to electronic submission using the SF424 (R&R).

Form Approved Through 02/28/2023

OMB No. 0925-0001

Table of Contents

PART I. INSTRUCTIONS FOR PREPARING AND SUBMITTING AN APPLICATION

Instructions for Preparing and Submitting a Paper Application

1. Foreword

The PHS 398 instructions contain information for preparing grant applications to the National Institutes of Health (NIH) and other Public Health Service (PHS) agencies. These instructions pertain to applications for research project grants that have not transitioned to electronic submission using the SF424 (R&R).

Applicants to PHS agencies other than NIH should contact the agency using the PHS Agency Contacts Table in 1.4 below because some awarding components have application requirements that differ from those for NIH.

NIH continues to transition grant activity codes from the PHS 398 to the SF424 (R&R) and electronic submission through Grants.gov. The PHS 398 is required for all grant activity codes that have not transitioned to the SF424 (R&R). Once an activity code has transitioned to electronic submission, all applications to that code must be an electronic application submission via forms that are provided a part of the electronic application packages, either through the NIH ASSIST system, an institutional system-to-system solution, or the Grants.gov Workspace.

Information on Transition Strategy and Timeline can be found at the Timeline of NIH Transitions to Electronic Submission of Competing Grant Applications. Bookmark the PHS 398 Grant Application website for easy electronic access to this document.

Policy Changes

This 03/2020 revision only updates the OMB expiration date to 02/28/2023.

These instructions incorporate numerous clarifications, updates and policy announcements that have appeared in the NIH Guide for Grants and Contracts since the 03/2016 revision of the PHS 398 application. Since the Guide also publishes multiple funding opportunity announcements (FOA), the Office of Extramural Research posts Policy Notices, clarifications, and other updates on this webpage: NIH Policy Notices. Applicants are expected to be aware of any relevant Notices that appear in the Guide.

Substantive changes to instructions and form pages fall into the following categories and are highlighted as follows:

Biographical Sketch

- Updated biosketch instructions so that scholastic performance requires only scientific/professional graduate courses to be listed

Research Plan

- PHS Inclusion Enrollment Report: Discontinued use (data collection moved to new PHS Human Subjects and Clinical Trials Information form)

PHS Human Subjects and Clinical Trials Information form

- There is a new form for consolidated human subjects, inclusion enrollment report, and clinical trial information.
- Includes attachment to comply with NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research.
- Includes the updated appendix policy that eliminates clinical trial-related materials. See the NIH Guide Notice on Allowable Appendix Materials for more information.

Important Reminders for All Applicants

Prepare a *succinct* Research Plan and follow the Table of Page Limits unless the FOA specifies otherwise. Sections 4-11 of the Research Plan have no maximum allowable pages, but should also be succinct.

Several elements of an application are not required at the time the application is submitted. This information is requested later in the review cycle (i.e., just-in-time) to ensure that it is current. See NIH Grants Policy Statement, Section 2.5.1: Just-in-Time Procedures.

1.1 (Reserved)

1.2 NIH Extramural Research and Research Training Programs

The NIH Office of Extramural Research is the focal point for policies and guidelines for extramural research grants administration.

The Division of Communications and Outreach (DCO) is the central source for general information about NIH extramural research and research training programs, funding activity codes, the peer review system, and application procedures. Grants Information (GrantsInfo) is a communication service within the DCO. Information about the NIH extramural research and research training programs, funding opportunities, and the grant application process, can be obtained by e-mailing your request to: GrantsInfo@nih.gov, or calling 301-945-7573.

1.3 Research Grant Programs and Program Guidelines

For a complete listing of program guidelines, visit the Types of Grant Programs page.

1.4 Interactions with PHS Staff

Applicants are **strongly encouraged** to communicate with PHS staff throughout the entire application, review and award process. Web site addresses and staff phone numbers of relevant NIH awarding components and other PHS agencies are listed in the table below.

All inquiries regarding the assignment, review, or recommendation on funding of applications are to be made only to PHS officials.

PHS Agency Contacts

PHS AGENCY	AWARDING COMPONENT	TELEPHONE NUMBER
NIH	National Institutes of Health (NIH)	301-496-4000
NIH	*Eunice Kennedy Shriver* National Institute of Child Health and Human Development	301-496-0104
NIH	Fogarty International Center	301-496-1653
NIH	National Cancer Institute	301-496-3428
NIH	National Center for Complementary and Integrative Health	301-496-4792
NIH	National Center for Advancing Translational Sciences	301-496-6023
NIH	National Eye Institute	301-451-2020
NIH	National Heart, Lung, and Blood Institute	301-435-0260

PHS AGENCY	AWARDING COMPONENT	TELEPHONE NUMBER
NIH	National Human Genome Research Institute	301-496-7531
NIH	National Institute on Aging	301-496-9322
NIH	National Institute on Alcohol Abuse and Alcoholism	301-443-4375
NIH	National Institute of Allergy and Infectious Diseases	301-496-7291
NIH	National Institute of Arthritis and Musculoskeletal and Skin Diseases	301-594-2463
NIH	National Institute of Biomedical Imaging and Bioengineering	301-451-4792
NIH	National Institute on Deafness and Other Communication Disorders	301-496-1804
NIH	National Institute of Dental and Craniofacial Research	301-594-4800
NIH	National Institute of Diabetes and Digestive and Kidney Diseases	301-594-8834
NIH	National Institute on Drug Abuse	301-443-2755
NIH	National Institute of Environmental Health Sciences	919-541-7723
NIH	National Institute of General Medical Sciences	301-594-4499
NIH	National Institute of Mental Health	301-443-3367
NIH	National Institute on Minority Health and Health Disparities	301-402-1366
NIH	National Institute of Neurological Disorders and Stroke	301-496-9248
NIH	National Institute of Nursing Research	301-594-6906
NIH	National Library of Medicine	301-496-4621
NIH	Center For Scientific Review	301-435-0715
AGENCY FOR HEALTHCARE RESEARCH AND QUALITY (AHRQ)	Agency for Healthcare Research and Quality	301-427-1447
CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)	Coordinating Center for Health Information and Services	404-498-1186
CDC	Office of Infectious Disease	404-639-3770
CDC	National Center for Environmental Health	770-488-4668
CDC	National Center for Injury Prevention and Control	770-488-8390
CDC	National Center for Chronic Disease Prevention and Health Promotion	404-639-4621
CDC	National Institute for Occupational Safety and Health	404-498-2530
CDC	Procurement and Grants Office	770-488-2700
FOOD AND DRUG ADMINISTRATION	Food and Drug Administration	301-827-7185
INDIAN HEALTH SERVICE	Indian Health Service	301-443-0578
AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY	Agency for Toxic Substances and Disease Registry	404-842-6630
OFFICE OF PUBLIC HEALTH AND SCIENCE	Office of Population Affairs	240-453-2800
OFFICE OF PUBLIC HEALTH AND SCIENCE	Office of Family Planning	240-453-2888

BEFORE SUBMISSION

Applicants are strongly encouraged to contact NIH staff with their questions before submitting an application.

- Contact GrantsInfo at 301-945-7573 or email GrantsInfo@nih.gov, and/or the Division of Receipt and Referral in the Center for Scientific Review (CSR) at 301-435-0715:
    - To identify Institutes/Centers (ICs) at NIH or other non-NIH agencies, and/or a Scientific Review Group (SRG), that might be appropriate for the application. Note that requests for assignment to an IC and/or a SRG may be made in a cover letter (See section 3.1 Cover Letter) at the time of application submission.
    - To learn about grant programs.
    - To receive advice on preparing and submitting an application (e.g., format, structure).
- Contact program staff in the relevant awarding component:
    - To determine whether a proposed application topic would fit into the NIH IC or other non-NIH agency's programmatic area.
    - To learn about programmatic areas of interest to the IC or other non-NIH agencies.
    - To find out about requesting an assignment to an IC.
    - To discuss responding to a Request for Applications.
- Contact Scientific Review Officers (SRO) in the Center for Scientific Review to discuss requesting assignment to a CSR SRG.

AFTER SUBMISSION

If the initial assignment to an IC or SRG seems inappropriate, the Program Director/Principal Investigator (PD/PI) may request reassignment. Such requests should be made in writing to:

Division of Receipt and Referral

Center for Scientific Review

National Institutes of Health

6701 Rockledge Drive, Suite 2030, MSC 7720

Bethesda, MD 20892-7720

Fax requests (301-480-1987) are also acceptable.

Although these requests will be carefully considered, the final determination will be made by the PHS agency.

Applicants must never contact reviewers regarding their applications because discussion of the scientific content of an application or an attempt to influence review outcome will create serious breaches of confidentiality in the review process. Reviewers are required to notify the Scientific Review Officer if they are contacted by an applicant. Communication by the applicant to a reviewer may delay the review or result in the return of the application without review.

Communications from the Division of Receipt and Referral (DRR) are accessible to applicants and applicant organizations in the eRA Commons in the “Correspondence” section of the Commons detailed status screen for the application. Applicants will be notified by email to check their Commons account. DRR will notify an applicant when: 1) additional information is required before her/his application can be assigned to a scientific review group (SRG) and NIH Institute or Center (IC) for

funding consideration; 2) an applicant's request for an IC assignment cannot be honored; or 3) it has been determined that the application does not comply with NIH policy. For additional information, see eRA's Status Information page.

AFTER ASSIGNMENT

Contact the SRO to discuss the review assignment, to request permission to send additional/corrective materials, and/or to discuss any review concerns (e.g., expertise needed on the SRG, conflicts, reviewers that may have bias).

AFTER PEER REVIEW

Feedback to applicants is very important. Once the PD/PI reviews the Summary Statement in the eRA Commons (paper copies of the Peer Review Outcome Letter and Summary Statement will not be mailed to the PI. Electronic copies may be accessed through the eRA Commons), the appropriate awarding component program official (noted in the Summary Statement) may be contacted:

- To discuss the review outcome of the application and obtain guidance.
- To get feedback and answers to any questions about the Summary Statement.
- To find out the meaning of a numerical designation pertaining to human subjects or vertebrate animals on the Summary Statement.
- To find out the funding status of an application.

The Peer Review Outcome Letter and Summary Statement will not be mailed to the PD/PI and may only be accessed through the eRA Commons.

1.5 Grants Policy Statements

The *NIH Grants Policy Statement* serves as a term and condition of award and is a compilation of the salient features of policies and various policy issues regarding the administration of NIH awards.

The *HHS Grants Policy Statement* serves as a term and condition of award and is a compilation of the salient features of policies and various policy issues regarding the administration of grant awards from other PHS agencies, excluding NIH awards.

1.6 References

Applicants New to NIH: Getting Started

Getting Started at NIH website

Award Information and Data

Research Portfolio Online Reporting Tool (RePORT)

Contact Information for an NIH Staff Person

NIH Enterprise Directory (NED)

NIH locator: 301-496-4000

eRA Commons

eRA Commons website

Institutions and Program Directors/Principal Investigators (PD/PIs) are required to register with the eRA Commons. Registered PD/PIs can check assignment/contact information, review outcome, and other important information.

Call the Service Desk at 1-800-504-9552 (toll-free) or 301-402-7469. Business hours are M-F 7am-8pm Eastern Time.

eRA Service Desk online request form

Grant Writing Tips and Sample Applications

Grant Writing Tips Sheets

Grants Process Overview

Grants Information

Welcome to NIH Grants Information page
E-mail: GrantsInfo@nih.gov
Telephone: 301-945-7573

NIH Grants and Funding Help Page

Contacting NIH Staff at the NIH Institutes and Centers page

This site provides a self-help wizard to guide inquiries to the correct NIH website for additional information on specific topics.

NIH Office of Extramural Research Human Subjects Website

Research Involving Human Subjects website

This site provides HHS and NIH requirements and resources for the extramural community involved in human subjects research.

Biosafety, Biosecurity, and Emerging Biotechnology

Biosafety, Biosecurity, and Emerging Biotechnology website

NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines), dual use research of concern (DURC), and the NIH Stem Cell Registry
Telephone: 301-496-9838

Office for Human Research Protections (Department of Health and Human Services)

Office for Human Research Protections website

Information about human subject protections, Institutional Review Boards, and Federal Wide Assurances.
Telephone: 1-866-447-4777 or 301-496-7005

Office of Laboratory Animal Welfare (OLAW)

Office of Laboratory Animal Welfare website

Information about animal welfare policy requirements, Institutional Animal Care and Use Committees (IACUC), and Animal Welfare Assurances.
Telephone: 301-496-7163

Receipt/Referral of an Application

CSR's The Assignment Process page

Division of Receipt and Referral
Center for Scientific Review
Telephone: 301-435-0715
Fax: 301-480-1987

Specific Application: Before Review

Telephone or e-mail the Scientific Review Officer identified for the application in the eRA Commons.

Specific Application: Post Review

Telephone or e-mail the NIH Program Official named in the Summary Statement for the application.

1.7 Authorization

The PHS requests the information described in these instructions pursuant to its statutory authorities for awarding grants, contained in Sections 301 (a) and 487 of the PHS Act, as amended (42 USC 241a and 42 USC 288). Therefore, such information must be submitted if an application is to receive due consideration for an award. Lack of sufficient information may hinder the ability of the PHS to review an application and to monitor the grantee's performance.

1.7.1 Collection of Personal Demographic Data

Federal agencies have a continuing commitment to monitor the operation of its review and award processes to detect, and deal appropriately with, any instances of real or apparent inequities. In addition, section 403 of the 2007 NIH Reform Act requires NIH to report to Congress specifically on postdoctoral individuals supported on research grants, and section 489 of the PHS Act requires NIH to perform a continuing assessment of research personnel needs. Personal demographic data on PD/PIs and those with a postdoctoral role is vital to comply with these requirements.

NIH collects personal data through the eRA Commons Personal Profile. The data is provided one-time by the individual through a secure electronic system and is confidential. The NIH maintains application and grant records as part of a system of records as defined by the Privacy Act: NIH 09-25-0225 https://era.nih.gov/privacy-act-and-era.htm. When completing the data entry in the Commons Personal Profile, the individual is responsible for providing true, accurate, and complete data. All analyses conducted on date of birth, citizenship, gender, race, ethnicity, disability, and/or disadvantaged background data will report aggregate statistical findings only and will not identify individuals. Declining to provide information does not affect consideration of an application; however, for some programs (e.g., Ruth L. Kirschstein National Research Service Awards and Research Career Development Awards) citizenship data is required to determine eligibility.

The PHS also requests the last four digits of the Social Security Number (SSN) for accurate identification of individuals and for management of PHS grant programs. Please be aware that no individual will be denied any right, benefit, or privilege provided by law because of refusal to disclose this portion of the SSN. The PHS requests the last four digits of the SSN under Section 301(a) and 487 of the PHS act as amended (42 U.S.C. 241a and U.S.C. 288).

1.8 Paperwork Burden

The PHS estimates that it will take approximately 35 hours to complete this application for a regular research project grant. This estimate excludes time for development of the scientific plan. Other items such as human subjects are cleared and accounted for separately and therefore are not part of the time estimate. An agency may not conduct or sponsor the collection of information unless it displays a currently valid OMB control number. Nor is a person required to respond to requests for the collection of information without this 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 Office, 6705 Rockledge Drive MSC 7974, Bethesda, MD 20892-7974, ATT: PRA (0925-0001). Do not send applications to this address.

2. General Instructions

2.1 Introduction

Read all of the instructions thoroughly prior to application preparation.

These instructions pertain to applications for research project grants that have not transitioned to electronic submission using the SF424 (R&R).

For other specialized grants or cooperative agreements, request additional instructions from the appropriate NIH awarding component or other PHS agency. Phone numbers for contacting the appropriate staff are listed in the Agency Contact Table. For further assistance, contact:

GrantsInfo

National Institutes of Health (NIH)

E-mail: GrantsInfo@nih.gov

Phone: 301-435-0714

Read and follow the instructions carefully to avoid delays, misunderstandings and possible return of the application. Adherence to font and margin requirements is necessary for several reasons. No applicant should have an advantage over other applicants by providing more content using smaller, denser type. Small type sizes may also make it difficult for reviewers to read the application.

The NIH Center for Scientific Review (CSR), Division of Receipt and Referral, has the responsibility to make the final determination of legibility and the authority to return applications. This decision is final and not subject to appeal. Inquiries should be directed to the:

CSR, Division of Receipt and Referral
Phone: 301-435-0715; TTY 301-451-5936; Fax: 301-480-1987

2.2 Registration Processes

Please refer to Prepare to Apply-Register page for more information about registering the Organization/Organization Representative, as well as Investigators and other individual users.

2.2.1 (Reserved)

2.2.2 (Reserved)

2.3 (Reserved)

2.4 Funding Opportunities

Grants for health-related research and research training projects or activities make up the largest category of funding provided by the NIH Institutes/Centers (ICs) and other non-NIH agencies. Most applications for support are unsolicited and originate with individual investigators who develop proposed plans for research or research training within an area that is relevant to the NIH. Research project grants are awarded to organizations/institutions on behalf of PD/PIs to facilitate the pursuit of a scientific objective when the idea for the research is initiated by the investigator. If the funding agency anticipates substantial program involvement during the conduct of the research, a cooperative

agreement will be awarded, rather than a grant. The NIH typically awards grants and cooperative agreements for terms ranging from one to five years. Organizational/institutional sponsorship assures that the awardee organization will provide the facilities and the financial stability necessary to conduct the research, and be accountable for the funds. For more detailed information, visit the Types of Grant Programs page.

2.4.1 NIH Guide for Grants and Contracts

The *NIH Guide for Grants and Contracts*, a weekly electronic publication, contains announcements about funding opportunities, such as Requests for Applications (RFAs) and Program Announcements (PAs), including Parent Announcements, from NIH and other PHS agencies. The *NIH Guide* also contains vital information about policies and procedures. To subscribe to the *NIH Guide*, visit the NIH Guide LISTSERV page.

2.4.2 Funding Opportunity Announcements (FOAs)

See the Understanding Funding Opportunities page for more information.

2.5 (Reserved)

2.6 Format Specifications

Refer to the Format Attachments page for more information on formatting attachments.

2.7 "Resubmission" Applications

Learn more about resubmission policies and application requirements.

For more information on the types of applications, see the Types of Applications page.

2.8 "Revision" Application

Learn about submission requirements for competing revisions.

For more information on the types of applications, see the Types of Applications page.

Administrative Supplements

Learn about submission requirements for administrative supplements.

For more information on the types of applications, see the Types of Applications page.

2.9 Similar, Essentially Identical, or Identical Applications

Submissions of identical applications to one or more components of the PHS are not allowed.

Simultaneous submissions of identical applications to one or more components of the PHS are not allowed, and the NIH will **not** accept similar grant applications with essentially the same research focus from the same applicant organization for the same due date. This includes derivative or multiple applications that propose to develop a single product, process or service that, with non-substantive modifications, can be applied to a variety of purposes. Likewise, identical or essentially identical grant applications submitted by different applicant organizations will not be accepted for the same due date.

Applicant organizations should ascertain and assure that the materials they are submitting on behalf of the PD/PI are the original work of the PD/PI and have not been used elsewhere in the preparation and submission of a similar grant application. Applications to the NIH are grouped by scientific discipline for review by individual Scientific Review Groups. The reviewers can thus easily identify multiple grant applications for essentially the same project. In these cases, application processing may be delayed or the application(s) may not be reviewed.

Essentially identical applications will only be reviewed in the following circumstances: 1) an application for an Independent Scientist Award (K02) proposing essentially identical research in an application for a research project; 2) an application for a research project identical to a subproject of a program project or center grant application; 3) submissions of applications previously submitted to an RFA that were not paid or resubmissions of investigator-initiated applications originally submitted to an RFA (see the NIH Grants Policy Statement, Section 2.3.7.3: Resubmission of Unfunded RFA Applications); and 4) resubmissions of applications with a changed grant activity code.

2.10 (Reserved)

2.11 (Reserved)

2.12 (Reserved)

2.13 Post-Submission Application Materials

Post-submission application materials are those submitted after submission of the grant application but prior to the initial peer review. The policy is based on the principle that, for the majority of applications, the only post-submission materials that these agencies will accept are those resulting from an unforeseen event. See the NIH Grants Policy Statement, Section 2.3.7.7: Post-Submission Grant Application Materials for additional information.

Post-submission materials can only be submitted as a PDF attachment. The SRO is responsible for uploading acceptable materials into the official electronic grant file maintained in the eRA Commons. The PD/PI can check his/her application via the Commons to see these materials in the section titled "Additions for Review". This procedure provides the information to reviewers in a secure manner.

2.14 Application Due Dates

See the NIH Submission Policies page for more information.

2.15 Submission, Review and Award Cycles

See the Due Dates page for more information. For specialized grant applications, refer to the FOA and/or consult with the appropriate PHS agency prior to the preparation of an application.

For more information about application assignment, see the Submission and Assignment Process page.

2.16 Resources for Finding Help

2.16.1 (Reserved)

2.16.2 Finding Help for the eRA Commons Registration

If help is needed with the eRA Commons registration process for the applicant organization and PD/PIs, contact the eRA Service Desk:

- eRA Website
- eRA Commons Website
- eRA Commons Online Help
- eRA Service Desk
- eRA Commons Phone: 301-402-7469
  866-504-9552 (Toll Free)

The eRA Service Desk hours of operation are Monday-Friday from 7:00 a.m. to 8:00 p.m. Eastern Time (except Federal holidays).

Note: To help expedite your Help Desk request, we recommend that you have the following information readily available (additional details may be required depending upon the type of issue/request):

- Full Name of Affected User
- Full Name of Institution/Organization
- Grants.gov Tracking Number
- Submission Date
- Funding Opportunity Announcement (FOA)
- Principal Investigator's (PI) Username
- Signing Official's (SO) Username

2.16.3 Finding Help for Application Preparation

If after reviewing these application instructions, help is needed in preparing the application, contact GrantsInfo:

GrantsInfo Phone: 301-945-7573

GrantsInfo Email: GrantsInfo@nih.gov

3. Submission of the Grant Application

Submit a complete application. The application must be complete and accurate at the time of submission. Applications may not be reviewed if they are incomplete, illegible, fail to follow instructions, or present insufficient material to permit an adequate review.

There is no guarantee that the Scientific Review Officer will accept or the peer reviewers will consider additional material. See the NIH Grants Policy Statement, Section 2.3.7.7: Post-Submission Grant Application Materials and the NIH Guide Notice on the Updated Appendix Policy.

3.1 Cover Letter

Applicants are encouraged to include a cover letter with the competing application. The letter is only for internal agency use and will not be shared with peer reviewers. Place the letter at the beginning of the original application; do not copy it. Attach the cover letter, addressed to the Division of Receipt and Referral, in accordance with the FOA and/or these instructions.

The letter should contain any of the following information, as applicable:

- Application title.
- Title of FOA (PA or RFA).
- For late applications (see Late Application policy on NIH's) include specific information about the timing and nature of the delay.
- For changed/corrected applications submitted after the due date, a cover letter is required, and it must explain the reason for late submission of the changed/corrected applications. If you already submitted a cover letter with a previous submission and are now submitting a late 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.
- Statement that you have attached any required agency approval documentation for the type of application submitted. This may include approval for applications that request $500,000 or more, approval for Conference Grant or Cooperative Agreement (R13 or U13), etc. It is recommended that you include the official communication from an NIH official as part of your cover letter attachment.
- When intending to submit a video as part of the application, the cover letter must include information about the intent to submit it; if this is not done, the video will not be accepted. See NIH Grants Policy Statement, Section 2.3.7.7: Post-Submission Grant Application Materials for additional information.
- Include a statement in the cover letter if the proposed studies will generate large-scale human or non-human genomic data as detailed in the NIH Genomic Data Sharing Policy (see the NIH Grants Policy Statement, Section 2.3.7.10: NIH Genomic Data Sharing and Section 8.2.3.3: Genomic Data Sharing (GDS) Policy/Policy for Genome-Wide Association Studies (GWAS)).

3.2 Number of Copies

Submit the **original and two** identical, legible, single-sided photocopies of each application. The **original must be signed** by an Authorized Organization Representative.

3.3 Bindings and Packaging

Submit the following materials in *one* package:

- cover letter (original only);
- original application;
- two copies of the application, made after the original has been signed and **not** including the cover letter;
- Appendix materials – two identical CDs of all appendix material in PDF format.

Do not include more than one application (original plus two copies and appendices) in each mailing envelope.

Cover letter. Place the original cover letter at the beginning of the original application. It should not be duplicated.

The original application. The original application must be single-sided, with the required signature on the Face Page. Do **not** staple or otherwise bind the original application. Rubber bands or clips are acceptable. Assemble the pages in the order specified in the table of contents.

Two identical, single-sided copies of the original application. Make the copies **after** an Authorized Organization Representative has signed the Face Page so that the official's signature is present on the copies. Do **not** include the cover letter in the copies. Do not staple or otherwise bind the five copies of the original application. Rubber bands or clips are acceptable.

Two identical CDs containing all appendix material. When preparing CDs:

- Use PDF format.
- Label each disk with the PD/PI name and application title.
- If burning CD-ROM disks on a Mac, select the ISO 9660 format.
- Do not use compression techniques for the electronic files.
- Do not use password protection, encryption, digital signature and/or digital certification in the PDF files.

Appendix materials submitted in paper are not accepted and may lead to a delay in the review process.

3.4 Application Mailing Address

For applications to NIH, use the mailing label provided at the end of the forms.

Send the application to the following address, making sure to use the correct ZIP code:

Center for Scientific Review

National Institutes of Health

6701 Rockledge Drive, Suite 1040

MSC 7710

Bethesda, MD 20892-7710

(United States Postal Service (USPS) Express or Regular mail)

or

Bethesda, MD 20817 **(Express/Courier Non-USPS Service)**

C.O.D. applications will not be accepted.

All applications and other deliveries to the Center for Scientific Review must come either via courier delivery (e.g., Federal Express, DHL, UPS) or via the USPS. Applications delivered by individuals to the Center for Scientific Review will not be accepted. For additional information, see the NIH Grants Policy Statement, Section 2.3.9.1 Paper Applications.

There may be additional instructions for submission of responses to RFAs; check the FOA for details.

For applications to other (non-NIH) PHS agencies, refer to the FOA for submission instructions and mailing addresses.

4. Completing the PHS 398 Forms and Format Pages

Prepare the application using the PHS 398 MS Word or PDF form pages and format pages as provided at the PHS 398 Grant Application page.

- *Form pages* must be identical to those provided. You may substitute computer-generated facsimiles for government-provided forms; however, they must maintain the exact wording and format of the government forms, including all captions and spacing.
- *Format pages* are intended to assist you in the development of specific sections of the application. Alternatively, you may create a page similar to any format provided as long as all the requisite information is included.
- Shading/colors may not be used in any text portions, including the face page.
- Font sizes on some PHS 398 form pages vary due to field or space limitations. The PHS 398 Microsoft Word (MS Word) and Portable Document File (PDF) Form Pages as provided are acceptable to NIH. All other sections of the application (e.g., Biographical Sketch; Introduction, if necessary; and the Research Plan) must conform to the font requirements stated in Section 2.6 Format Specifications above.
- Some fields on the PDF Form Pages are pre-set to auto calculate. In these cases, a zero will appear until actual data are entered.

4.1 Face Page

The first part of the Face Page (Form Page 1) must be printed on a single page. The Face Page must not have any shading or colors. Form Page 1-continued is only for multi-PD/PI applications; if used, it should be printed as a separate page.

The information provided on the Face Page of the application and the fiscal information, including the calculation of F&A costs, must be verified by the official signing for the applicant organization.

1. Title of Project

Do not exceed 81 characters, including spaces and punctuation. Choose a descriptive title that is specifically appropriate. A new application must have a different title from any other PHS project with the same PD/PI. A Renewal or Resubmission 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.

2. Response to Specific Request for Applications or Program Announcement or Solicitation

Check “Yes” and insert the appropriate announcement number (e.g., PA-16-287) and title of the announcement if the application is submitted in response to an RFA or a PA issued through the NIH Guide for Grants and Contracts.

3. Program Director/Principal Investigator

3a. Name (Last, first, middle)

Name the one person responsible to the applicant organization for the scientific and technical direction of the project. **PHS staff conduct official business only with the named PD/PI and institutional officials.** A Revision application **must** have the same PD/PI as the currently funded grant.

When multiple PD/PIs are proposed, use the Face Page-Continued page to provide 3a – 3h for all PD/PIs. NIH requires one PD/PI be designated as the "contact PD/PI" for all communications between the PD/PIs and the agency. The contact PD/PI must meet all eligibility requirements for PD/PI status in the same way as other PD/PIs, but has no special roles or responsibilities within the project team beyond those mentioned above. The contact PD/PI may be changed during the project period. The contact PD/PI should be listed in block 3 of Form Page 1 (the Face Page), with all additional PD/PIs listed on Form Page 1-Continued. When inserting the name of the PD/PI in the header of each application page, use the name of the "Contact PD/PI, et. al." The contact PD/PI must be from the applicant organization if PD/PIs are from more than one institution.

All individuals designated as PD/PI must be registered in the eRA Commons and must be assigned the PD/PI role in that system (other roles such as SO or IAR will not give the PD/PI the appropriate access to the application records). Each PD/PI must include his/her respective eRA Commons ID in the eRA Commons User Name field.

3b. Degree(s)

Indicate up to three academic and professional degrees or other credentials, such as licenses (e.g., R.N.).

3c. Position Title

Provide the academic or professional title of the PD/PI. If more than one title, indicate the one most relevant to the proposed project (e.g., Professor of Biochemistry, Chief of Surgical Service, or Group Leader).

3d. Mailing Address

Provide complete information (including room number, building, and street address) necessary for postal delivery. All written communications with the PD/PI will use this address. For electronic mail, enter the appropriate e-mail address (not a website URL).

3e. Department, Service, Laboratory, or Equivalent

Indicate organizational affiliation, such as Department of Medicine, Materials Research Laboratory, or Social Sciences Institute.

3f. Major Subdivision

Indicate school, college, or other major subdivision, such as medical, dental, engineering, graduate, nursing, or public health. If there is no such subdivision, enter "None."

3g. Telephone and Fax

Provide a daytime telephone number and, if available, a fax number.

3h. eRA Commons User Name

The Commons User Name is the ID assigned to and used by the individual to access the eRA Commons. **All** PD/PIs are required to be registered in the eRA Commons and **must** provide their Commons User Name. The PD/PI must enter the date of his/her terminal research degree, or end date of medical residency, to receive consideration as an Early Stage Investigator. All data must contain the most recent information in order for the application to be processed accurately.

4. Human Subjects Research

No (Human Subjects Involved)

Check "No" if activities involving human subjects are not planned at any time during the proposed project period. The remaining parts of "Section 4: Human Subjects Research" are then not applicable.

Yes (Human Subjects Involved)

Check "Yes" if activities involving human subjects are planned at any time during the proposed project period, either at the applicant organization or at any other Project/Performance Site or collaborating institution. Check "Yes" if the research is exempt from HHS regulatory requirements for the protection of human subjects (see the Frequently Asked Questions from Applicants section on Exemptions for more information).

If you plan to conduct research involving human subjects, but do not have definite plans at the time of application, you will need to include 6 of the Research Plan. Certification of IRB review and approval must be provided and accepted by the awarding component before the research may occur.

An IRB approval date is not required at the time of submission when IRB review is pending. This may be requested later in the pre-award cycle as a Just-In-Time requirement. See the NIH Grants Policy Statement, Section 2.5.1: Just-in-Time Procedures for more information. See the definition of a human subject.

To help determine whether research that involves the use of human data or biological specimens is human subjects research, refer to the Research Involving Human Subjects website.

Additional information is available at:

- OHRP Decision Charts
- OHRP Guidance on Repositories
- OHRP Memo on Engagement

4a. Research Exempt

Check "Yes" if the activities proposed are exempt from the regulations at 45 CFR Part 46. Insert the exemption number(s) corresponding to one or more of the exemption categories listed at the Research Involving Human Subjects website.

OHRP guidance states that appropriate use of Exemptions described in 45 CFR 46 should be determined by an authority independent from the investigators (see OHRP's FAQs on Exempt Research Determination). Institutions often designate their IRB to make this determination. Because NIH does not require IRB approval at the time of application, the exemptions designated in 4a often represent the opinion of the PD/PI, and the justification provided for the exemption by the PD/PI is evaluated during peer review.

Proposed research may include more than one research project; thus the application may include individual projects that meet the requirements for non-exempt or exempt human subjects research, or are not defined as human subjects research. Human subjects research should be designated as exempt if **all** of the proposed research meets the criteria for one or more of the six exemptions.

Check "No" if any of the planned activities involving human subjects are not exempt, and complete the remaining parts of 4.

4b. Federal-Wide Assurance No.

Enter the approved Federal Wide Assurance (FWA) number that the applicant has on file with the Office for Human Research Protections. Enter the 8-digit number. Do not, enter FWA before.

Enter "None" in 4b if the applicant organization does not have an approved FWA on file with OHRP. In this case, the signature on the Face Page is a declaration that the applicant organization will comply with 45 CFR Part 46 and proceed to obtain a FWA (see the OHRP Federalwide Assurance (FWA) for the Protection of Human Subjects page.

Do not enter the human subjects assurance number of any Project/Performance Site or collaborating institution in the space provided.

4c. Clinical Trial

Check “Yes” or “No” to indicate whether the project includes a clinical trial. Refer to the OER glossary’s definition of “clinical trial.”

All NIH-funded clinical trials are expected to register and submit results information to Clinicaltrials.gov, as per the "NIH Policy on Dissemination of NIH-Funded Clinical Trial Information" for competing applications and contract proposals submitted on or after 1/18/2017. See the Requirements for Registering & Reporting NIH-funded Clinical Trials in ClinicalTrials.gov for more information.

4d. NIH-Defined Phase III Clinical Trial

Check “Yes” or “No” to indicate whether the project is an NIH-Defined Phase III Clinical Trial. Refer to the definition of "NIH-Defined Phase III Clinical Trial."

5. Vertebrate Animals

Check “No” if activities involving vertebrate animals are not planned at any time during the proposed project period, and leave 5a blank. Note that the generation of custom antibodies constitutes an activity involving vertebrate animals.

Check “Yes” if activities involving vertebrate animals are planned at any time during the proposed project period. If animal involvement is anticipated within the period of award but plans are indefinite, check "Yes" and in the Research Plan, Section 5.5: Vertebrate Animals, provide an explanation and indicate when it is anticipated that animals will be used. If an award is made prior to the involvement of animals, the grantee must provide all of the information required by 5.5 (Research Plan, Section 5.5: Vertebrate Animals), and verification of IACUC approval to the awarding component. IACUC approval must have been granted within three years to be valid.

NIH does not require verification of review and approval of the proposed research by the IACUC before peer review of the application. However, this information is required under Just-in-Time policy (see NIH Grants Policy Statement, Section 2.5.1: Just-in-Time Procedures).

5a. Animal Welfare Assurance

Enter the OLAW approved Animal Welfare Assurance number of the applicant organization in 5a. To determine whether the organization holds an Animal Welfare Assurance, see the lists of Domestic and Foreign Assured institutions.

Enter “None” in 5a if the applicant organization does not have an OLAW-approved Animal Welfare Assurance. **Do not enter the Animal Welfare Assurance number of any Project/Performance Site or collaborating institution.** When an applicant organization does not have an Animal Welfare Assurance, the Authorized Organization Representative’s signature constitutes declaration that the applicant organization will submit an Animal Welfare Assurance when requested by OLAW.

6. Dates of Proposed Period of Support

Request no more than 5 years of support, unless specifically authorized in the FOA. Note that some programs specify fewer years.

New application. Consult the schedule on the Due Dates page for an appropriate beginning date. Refer to the FOA for beginning dates for PHS agencies other than NIH.

Renewal application. Choose a beginning date immediately following the termination date of the current period of support.

Revision application. Submit a Revision application only for a period within the current period of the active grant. At the time of submission, the Revision request must be within the time period of the original (parent) award period, and any extension must be done **before** submission. Make the ending date of the Revision's first budget period coincide with the ending date of the budget period that is to be supplemented, regardless of the Revision's beginning date. If requesting supplemental funds for the future years of a currently funded grant, make the future years' budget periods coincide with those of the currently funded grant.

Budget Request

All amounts requested in 7 and 8 and on the budget pages must be in U.S. dollars.

7. Costs Requested for Initial Budget Period

7a. Direct Costs ($)

From Form Page 4, enter the "Subtotal Direct Costs for Initial Budget Period."

7b. Total Costs ($)

Enter the sum of: 1) the "Total Direct Costs for Initial Budget Period" from Form Page 4 and 2) the Facilities and Administrative costs for the initial budget period, as calculated on the Checklist Form Page.

Note the "Total Direct Costs" used to calculate 7b includes any consortium F&A costs.

8. Costs Requested for Proposed Period of Support

8a. Direct Costs ($)

From Form Page 5, enter the sum of "Subtotal Direct Costs" for all years.

8b. Total Costs ($)

Enter the sum of: 1) "Total Direct Costs for Entire Proposed Project Period" from Form Page 5; and, 2) the total Facilities and Administrative costs for all years calculated on the Checklist Form Page.

Note the "Total Direct Costs" used to calculate 8b includes any consortium F&A costs. Please ensure number(s) complies with application requirements.

9. Applicant Organization

Name the one organization that will be legally and financially responsible for the conduct of activities supported by the award. Provide a complete address of that organization.

10. Type of Organization

Check the appropriate box. See definitions of Applicant Organization Types in the OER glossary.

11. Entity Identification Number, DUNS Number, Cong. District

Entity Identification Number. Enter the 12-digit Entity Identification Number (EIN) assigned to the applicant organization by the Department of Health and Human Services Payment Management System for payment and accounting purposes. This number is an expansion of the 9-digit EIN assigned by the IRS. If the institution has not yet been assigned a number, enter either (1) the organization's Internal Revenue Service employer identification number (nine digits) or (2) the words "Applied for" to indicate that the organization does not have an EIN but has applied to the local office of the IRS for one. **Do not enter the PD/PI's social security number**; it is not appropriate for this.

Data Universal Numbering System (DUNS) number. Enter the DUNS number. Applicant organizations **must have** a Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number as the Universal Identifier when applying for Federal grants or cooperative agreements. The DUNS number is a nine-digit number assigned by Dun and Bradstreet Information Services. An AOR should be consulted to determine the appropriate number. If the organization does not have a DUNS number, an AOR should complete the US D&B D-U-N-S Number Request Form or contact Dun and Bradstreet by telephone directly at 1-866-705-5711 (toll-free) to obtain one. A DUNS number will be provided immediately by telephone at no charge. Note this is an organizational number. Individual PD/PIs do not need to register for a DUNS number.

Congressional District. Enter the number of the Congressional District of the applicant organization.

If you do not know the Congressional District: Go to the United States House of Representatives website and search for the Congressional District by entering the ZIP+4. If you do not know the ZIP+4, look it up on the USPS Look Up Zip Code website.

12. Administrative Official to be Notified if Award is Made

Name the applicant organization administrative official to be notified if an award is made. Provide a complete address for postal delivery and the telephone, fax, and e-mail address for the administrative official.

13. Official Signing for Applicant Organization

Name an individual authorized to act for the applicant organization and to assume the obligations imposed by the Federal laws, requirements, and conditions for a grant or grant application, including the applicable Federal regulations. Provide a complete address for postal delivery and the telephone, fax, and e-mail address for the signing official.

14. Applicant Organization Certification and Acceptance

An original signature, in ink, is required. Only an institutional official with formal designated or delegated authority to sign on behalf of the organization may sign the form. The signature must be dated. *In signing the application Face Page, the Authorized Organization Representative of the applicant organization certifies that the applicant organization will comply with all applicable policies, assurances and/or certifications referenced in the application.*

The applicant organization is responsible for verifying its eligibility and the accuracy, validity, and conformity with the most current institutional guidelines of all the administrative, fiscal, and scientific information in the application, including the Facilities and Administrative rate. Deliberate withholding, falsification, or misrepresentation of information could result in administrative actions, such as withdrawal of an application, suspension and/or termination of an award, debarment of individuals, as well as possible criminal penalties. The signer further certifies that the applicant organization will be accountable both for the appropriate use of any funds awarded and for the performance of the grant-supported project or activities resulting from this application. The grantee institution may be liable for the reimbursement of funds associated with any inappropriate or fraudulent conduct of the project activity.

Assurances and Certifications

The list of assurances, certifications, and other policies that apply to applications submitted to NIH and other PHS agencies is found in the NIH Grants Policy Statement, Section 4: Public Policy Requirements, Objectives and Other Appropriation Mandates.

4.2 Summary, Relevance, Project/Performance Sites, Senior/Key Personnel, Other Significant Contributors, and Human Embryonic Stem Cells

FORM PAGE 2 and 2-continued

Do NOT insert additional pages between Form Page 1 and Form Page 2.

Project Summary and Relevance

The first and major section of the Description is a **Project Summary**. It 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.

The second section of the Description is **Relevance**. Using no more than two or three sentences, describe the relevance of this research to public health. In this section, be succinct and use plain language that can be understood by a general, lay audience.

DO NOT EXCEED THE SPACE PROVIDED.

Use text only (no figures or other information not in standard text). Do not include proprietary, confidential information or trade secrets in the description section. If the application is funded, the project description will be entered into an NIH database and will become public information.

Project/Performance Site(s)

Indicate where the work described in the Research Plan will be conducted. If there are more than two Project/Performance Sites, use the Project/Performance Site Format Page to list all the sites, including Department of Veterans Affairs (VA) facilities and foreign sites. Provide an explanation on the Resources Format Page of the application, and state whether a consortium/contractual arrangement is involved with one or more collaborating organizations for the conduct of a portion of the work described in the Research Plan. One of the sites indicated must be the applicant organization or be identified as off-site in accordance with the conditions of the applicant organization's negotiated Facilities and Administrative (F&A) agreement. This information must agree with the F&A information provided in the rest of the application.

If a Project/Performance Site is engaged in research involving human subjects, the applicant organization is responsible for ensuring that the Project/Performance Site operates under an appropriate Federal Wide Assurance for the protection of human subjects and complies with 45 CFR Part 46 and other NIH human subject related policies described in the PHS 398 and the NIH Grants Policy Statement, Section 4.1.15.1: Federalwide Assurance Requirements.

For research involving live vertebrate animals, the applicant organization must ensure that all Project/Performance Sites hold an OLAW-approved Animal Welfare Assurance. If the applicant organization has neither an animal care and use program, facilities to house animals and conduct research on site, nor an IACUC, and the animal work will be conducted at an institution with an Animal Welfare Assurance, the applicant must obtain an Inter-institutional Assurance from OLAW prior to an award.

Senior/Key Personnel

In addition to the PD/PI, Senior/key Personnel are defined as individuals who contribute to the scientific development or execution of the project in a substantive, measurable way, whether or not salaries are requested.

Typically, these individuals have doctoral or other professional degrees, although individuals at the masters or baccalaureate level should be included if their involvement meets the definition of Senior/key Personnel. **Consultants and those with a postdoctoral role should also be included if they meet the same definition.**

Senior/key Personnel must devote measurable effort (described in person months) to the project, whether or not salaries are requested. "Effort of zero person months" or "as needed" are not acceptable levels of involvement for those designated as Senior/key Personnel.

Start with the PD/PI(s). List the PD/PI's last name first. When multiple PIs are proposed, list the contact PI first, then all additional PIs in alphabetical order. Then list all other Senior/key Personnel in alphabetical order, last name first. For each individual provide name, eRA Commons User Name (if known), organization name (their institutional affiliation), and role on the project. Under role on the project, indicate how the individual will function on the proposed project. *Use additional consecutively numbered pages as necessary.*

Other Significant Contributors

This category identifies individuals who have committed to contribute to the scientific development or execution of the project, but are not committing any specified measurable effort (i.e., person months) to the project. These individuals are typically presented at "effort of zero person months" or "as needed." Individuals with measurable effort may **not** be listed as Other Significant Contributors (OSCs). Consultants should be included if they meet this definition.

A biosketch, including Research Support information, will be required for Senior/key Personnel and OSCs, as this highlights their relevant accomplishments. Reviewers use these pages to address the "investigator(s)" review criterion (see Research Project Evaluation Criteria in Section 6. The Peer Review Process).

However, if an award is to be made, Other Support information will not be required or accepted for OSCs since considerations of overlap do not apply to these individuals.

Should the level of involvement for an individual listed as an OSC increase to measurable effort, he/she must be redesignated as Senior/key Personnel. This change must be made before any compensation is charged to the project.

Human Embryonic Stem Cells

If the proposed project involves human embryonic stem cells, in this section list the registration number of the specific cell line(s) from the NIH Human Embryonic Stem Cell Registry. Use continuation pages as needed. If a specific line cannot be referenced at the time of application submission, include a statement that one from the registry will be used.

4.3 Research Grant Table of Contents

FORM PAGE 3

Provide the page number for each category listed on the Table of Contents. Throughout your application, place page numbers at the bottom of each page, and consecutively number pages. **Do not include unnumbered pages, and do not use suffixes, such as 5a, 5b.**

4.4 Budget Instructions

FORM PAGE 4

DETAILED BUDGET FOR INITIAL BUDGET PERIOD

Each element listed on Form Page 4 must be clearly justified on Form Page 5. List only the direct costs requested in this application. Do not include any items that are treated by the applicant organization as Facilities and Administrative (F&A) costs according to a Federal rate negotiation agreement, except for those F&A costs included in consortium/contractual costs. Applications from foreign organizations must request budgets in U.S. dollars. Foreign organizations may not include any charge-back of customs and import fees, such as consular fees, customs surtax, value-added taxes (VAT) and other related charges.

Note: If you are requesting a budget of $500,000 direct costs or more for any year, you must obtain prior approval from Institute/Center staff. This limit is exclusive of any consortium F&A costs. If the subtotal Direct Costs on Form Page 5 equals or exceeds $500,000 in any year, prior approval is required. (See the NIH Grants Policy Statement, Section 2.3.7.2: Acceptance for Review of Unsolicited Applications Requesting $500,000 or More in Direct Costs**.)**

The following items pertain to the completion of Form Page 4 (Detailed Budget for Initial Budget Period – Direct Costs Only).

Personnel

Name. Starting with the PD/PI(s), list the names of all applicant organization employees who are involved on the project during the initial budget period, regardless of whether a salary is requested. Include all collaborating investigators, individuals in training, and support staff.

Role on Project. Identify the role of each individual listed on the project. Describe their specific functions under Justification on Form Page 5. Provide budget narrative for ALL personnel by position, role, and level of effort using person months (calendar, academic and/or summer). This includes any "to-be-appointed" positions.

Cal/Acad/Summer Months Devoted to Project. Enter the number of months devoted to the project. Three columns are provided depending on the type of appointment being reflected: academic, calendar, and/or summer months. Individuals may have consecutive appointments within a calendar year, for example for an academic period and a summer period. In this case, each appointment should be identified separately using the corresponding column.

If effort does not change throughout the year, use only the calendar months column. If effort varies between academic and summer months, leave the calendar months column blank and use only the academic and summer months columns. In cases where no contractual appointment exists with the applicant organization and salary is requested, enter the number of months for the requested period.

Institutional Base Salary. An applicant organization may choose to leave this column blank. However, PHS staff will require this information prior to award. See the definition of "Institutional Base Salary."

Salary Requested. Regardless of the number of months being devoted to the project, indicate only the amount of salary being requested for this budget period for each individual listed.

Some PHS grant programs are currently subject to a legislatively imposed salary limitation. Any adjustment for salary limits will be made at the time of award. For guidance on current salary limits see the Salary Cap Summary on the NIH grants website or contact the organization's office of sponsored programs.

NIH grants also limit the compensation for graduate students. Compensation includes salary or wages, fringe benefits and tuition remission. While actual institutional-based compensation should be

requested and justified, this may be adjusted at the time of the award. For more guidance on this policy, see: NIH Grants Policy Statement, Section 2.3.7.9: Graduate Student Compensation.

Fringe Benefits. Fringe benefits may be requested in accordance with institutional guidelines for each position, provided the costs are treated consistently by the applicant organization as a direct cost to all sponsors.

Totals. Calculate the totals for each position and enter the subtotals in each column where indicated.

The applicant organization and its consortium/contractor(s) may omit salaries and fringe benefits for individuals from copies of the application that are available to non-Federal reviewers. In such cases, replace the numbers with asterisks. You must show the subtotals. Provide one copy, for use only by PHS staff, with the asterisks replaced by the salaries and fringe benefits.

Special Instructions for Joint University and Department of Veterans Affairs (VA) Appointments

Individuals with joint university and VA appointments may request the university's share of their salary in proportion to the effort devoted to the research project. The individual's salary with the university determines the base for computing that request. Signature by the institutional official on the application certifies that: (1) the individual is applying as part of a joint appointment specified by a formal Memorandum of Understanding between the university and the VA; and (2) there is no possibility of dual compensation for the same work, or of an actual or apparent conflict of interest regarding such work. Additional information may be requested by the awarding components.

Consultant Costs

Whether or not costs are involved, provide the names and organizational affiliations of all consultants (see definition of "Consultant"), other than those involved in consortium/contractual arrangements. Include consultant physicians in connection with patient care and persons who are confirmed to serve on external monitoring or advisory committees. Describe the services to be performed on Form Page 5 under "Justification." Include the number of days of anticipated consultation, the expected rate of compensation, travel, per diem, and other related costs.

Equipment

List each item of equipment (see definition of "Equipment") with amount requested separately and justify each purchase on Form Page 5.

Supplies

Itemize supplies in separate categories, such as glassware, chemicals, radioisotopes, etc. Categories in amounts less than $1,000 do not have to be itemized. If animals are to be purchased, state the species and the number to be used.

Travel

Itemize travel requests and justify on Form Page 5. Provide the purpose and destination of each trip and the number of individuals for whom funds are requested.

Inpatient and Outpatient Care Costs

If inpatient and/or outpatient costs are requested for research with human subjects, provide the names of any hospitals and/or clinics and the amounts requested for each on Form Page 5.

State whether each hospital or clinic has a currently effective HHS-negotiated research patient care rate agreement and, if not, what basis is used for calculating costs. If an applicant does not have a HHS-negotiated rate, the PHS awarding component can approve a provisional rate. Indicate, in detail,

the basis for estimating costs in this category, including the number of patient days, estimated cost per day, and cost per test or treatment. If both inpatient and outpatient costs are requested, provide information for each separately. If multiple sites are to be used, provide detailed information by site.

Include information regarding projected patient accrual for the project/budget periods and relate this information to the budget request for patient care costs. If patient accrual is anticipated to be lower at the start or during the course of the project, plan budget(s) accordingly.

Provide specific information regarding anticipated sources of Other Support for patient care costs, e.g., third party recovery or pharmaceutical companies. Include any potential or expected utilization of General Clinical Research Centers/Clinical Translation Science Awards.

Alterations and Renovations

Itemize by category and justify on Form Page 5 the costs of essential alterations and renovations including repairs, painting, removal or installation of partitions, shielding, or air conditioning. Where applicable, provide the square footage and costs. Note, costs for any Alterations and Renovations (A&R) were previously unallowable from foreign institutions, international organizations and domestic applications with foreign subawards. However an HHS policy change now allows for minor A&R (≤$500,000) on these applications. When requesting minor A&R costs under this policy, provide detailed information on the planned A&R in the budget justification.

Other Expenses

Itemize any other expenses by category and unit cost. These might include animal maintenance (unit care costs and number of care days), patient travel, patient participation incentives, donor fees, publication costs, computer charges, rentals and leases, equipment maintenance, service contracts, and tuition remission when budgeted separately from salary/fringe benefits.

You may also request direct costs related to the use of single Institutional Review Board (sIRB) for multi-site human subjects research.

For more information on charging direct and indirect costs for single IRB activities, see the Scenarios to Illustrate the Use of Direct and Indirect Costs for Single IRB Review under the NIH Policy on the Use of a Single IRB for Multi-Site Research. **Note:** If you intend to request an exception to the sIRB policy based on compelling justification, do not account for this exception in your proposed budget. The proposed budget must reflect all necessary sIRB costs without an exception (i.e. applicants should not assume that an exception will be granted when considering what sIRB costs to include in the budget). See the FAQs on the NIH Policy on the Use of a Single IRB for Multi-Site Research Costs for more information.

Justify costs on Form Page 5.

Consortium/Contractual Costs – Direct Costs

Each participating consortium/contractual organization must submit a separate detailed budget for both the initial budget period (Form Page 4) and the entire proposed project period (Form Page 5).

Consortium arrangements may involve personnel costs, supplies, and other allowable costs, including Facilities and Administrative (F&A) costs. Contractual costs for support services, such as the laboratory testing of biological materials, clinical services, or data processing, are occasionally sufficiently high to warrant a similar categorical breakdown of costs.

For each budget from a participating consortium/contractual organization, leave the "Consortium/Contractual Direct Costs" category blank and use the "Subtotal Direct Costs" category to total the consortium direct costs. When F&A costs are requested by a consortium organization, enter those costs in the "Consortium/Contractual F&A Costs" category for each supplementary budget. Provide the F&A cost base and rate information in the budget justification section. The "Total Direct

Costs for Initial Budget Period" category can be used for the consortium/contractual Total Costs (Direct Costs plus F&A).

For the applicant organization budget, list the sum of all consortium/contractual costs (direct and F&A). Insert additional budget page(s) after Form Page 5, numbering them sequentially. (Do not use 5a, 5b, 5c, etc.)

Budget Totals for Applicant Organization

For Face Page "Costs Request for Initial Budget Period - Direct Costs", use the "Subtotal Direct Costs for Initial Budget Period" on Form Page 4.

For Face Page "Costs Request for Initial Budget Period - Total Costs", add together the "Total Direct Costs for Initial Budget Period" from Form Page 4 and the F&A costs calculated for the initial budget period on the Checklist Form Page.

For Face Page "Costs Requested for Proposed Period of Support – Direct Costs", total the "Subtotal Direct Costs" for all years on Form Page 5 (see 4.5 below).

For Face Page "Costs Requested for Proposed Period of Support – Total Costs", add together the "Total Direct Costs for Entire Proposed Project Period" on Form Page 5 and the Total F&A costs for all years calculated on the Checklist Form Page.

Revision Application

For a Revision application, show only those items for which additional funds are requested. If the initial budget period of the Revision application is less than 12 months, prorate the personnel costs and other appropriate items of the detailed budget.

4.5 Budget for Entire Proposed Project Period Direct Costs Only

FORM PAGE 5

In the first column ("Initial Budget Period") enter the budget category totals of the initial budget period costs from Form Page 4.

Enter the totals under each budget category for all additional years of support requested. Identify with an asterisk (*), and justify any significant increases or decreases from the initial year budget. Also, justify budgets with more than a standard escalation from the initial to the future year(s) of support.

Justification

If the applicant organization is a foreign institution, or if the project includes a foreign component, provide a justification on Form Page 5. Describe special opportunities for furthering research programs through the use of unusual talents, resources, populations, or environmental characteristics that augment existing U.S. resources. Indicate whether similar research is being done in the United States. See the definition of "foreign component."

4.6 Biographical Sketch

Additional NIH and Other PHS Agencies Instructions for a Biographical Sketch

- Include biographical sketches of all **senior/key personnel and Other Significant Contributors**.
- Use the sample format on the Biographical Sketch Format Page to prepare this section for all grant applications.

- Figures, tables (other than those included in the provided format pages), or graphics are not allowed in the biosketch. Do not embed or attach files (e.g. video, graphics, sound, data).
- The biosketch may not exceed five pages per person. This five-page limit includes the table at the top of the first page.

The following instructions pertain to the completion of the biosketch.

Name:

Fill in the name of the senior/key person or other significant contributor in the "Name" field of the Biosketch Format Page.

eRA Commons User Name:

If the individual is registered in the eRA Commons, fill in the eRA Commons User Name in the "eRA Commons User Name" field of the Biosketch Format Page.

The "eRA Commons User Name" field is required for the PD/PI (including career development and fellowship applicants), primary sponsors of fellowship applicants, all mentors of candidates for mentored career development awards, and candidates for diversity and reentry research supplements.

The "eRA Commons User Name" field is optional for other project personnel.

The eRA Commons User Name should match the information provided in the Credential field of the R&R Senior/Key Person Profile (Expanded) Form in your grant application.

Position Title:

Fill in the position title of the senior/key person or other significant contributor in the "Position Title" field of the Biosketch Format Page.

Education/Training

Complete the education block. Begin with the baccalaureate or other initial professional education, such as nursing. Include postdoctoral, residency, and clinical fellowship training, as applicable, listing each separately.

For each entry provide:

- the name and location of the institution
- the degree received (if applicable)
- the month and year of end date (or expected end date). For fellowship applicants only, also include the month and year of start date.
- the field of study (for residency entries, the field of study should reflect the area of residency training)

Following the education block, complete Sections A-D of the biographical sketch.

A. Personal Statement

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

You may cite up to four publications or research products that highlight your experience and qualifications for this project. Research products can include, but are not limited to, audio or video products; conference proceedings such as meeting abstracts, posters, or other presentations;

patents; data and research materials; databases; educational aids or curricula; instruments or equipment; models; protocols; and software or netware.

You are allowed to cite interim research products. **Note:** interim research products have specific citation requirements. See related Frequently Asked Questions for more information.

Note the following additional instructions for ALL applicants/candidates:

- If you wish to explain factors that affected your past productivity, such as family care responsibilities, illness, disability, or military service, you may address them in this "A. Personal Statement" section.
- Indicate whether you have published or created research products under another name.
- You may mention specific contributions to science that are not included in Section C. Do not present or expand on materials that should be described in other sections of this Biosketch or application.
- Figures, tables, or graphics are not allowed.

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

- For institutional research training, institutional career development, or research education grant applications, faculty who are not senior/key persons are encouraged, but not required, to complete the "A. Personal Statement" section.
- Applicants for dissertation research awards should, in addition to addressing the points noted above, also include a description of their career goals, their intended career trajectory, and their interest in the specific areas of research designated in the FOA.
- Candidates for research supplements to promote diversity in health-related research should, in addition to addressing the points noted above, also include a description of their general scientific achievements and/or interests, specific research objectives, and career goals. Indicate any current source(s) of educational funding.

B. Positions and Honors

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

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

- Students, postdoctorates, and junior faculty should include scholarships, traineeships, fellowships, and development awards, as applicable.
- Clinicians should include information on any clinical licensures and specialty board certifications that they have achieved.

C. Contributions to Science

Who should complete the "Contributions to Science" section:

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

Format:

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

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

Content:

For each contribution, indicate the following:

- the historical background that frames the scientific problem;
- the central finding(s);
- the influence of the finding(s) on the progress of science or the application of those finding(s) to health or technology; and
- your specific role in the described work.

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

You are allowed to cite interim research products. **Note:** interim research products have specific citation requirements. See related Frequently Asked Questions for more information.

You may provide a URL to a full list of your published work. This URL must be to a Federal Government website (a .gov suffix). NIH recommends using My Bibliography. Providing a URL to a list of published work is not required.

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

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

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

- High school students are *not* required to complete Section D. Additional Information: Research Support and/or Scholastic Performance.
- Career development award applicants should complete the "Research Support" section but skip the “Scholastic Performance” section.
- Generally, the following types of applicants can skip the “Research Support” section and must complete **only** the “Scholastic Performance” section. However, when these applicants also have Research Support, they may complete both sections.
  - applicants for predoctoral and postdoctoral fellowships
  - applicants to dissertation research grants
  - candidates for research supplements to promote diversity in health-related research from the undergraduate through postdoctoral levels

Research Support

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

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

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

- **Research Support:** As part of the Biosketch section of the application, “Research Support” highlights your accomplishments, and those of your colleagues, as scientists. This information will be used by the reviewers in the assessment of each your qualifications for a specific role in the proposed project, as well as to evaluate the overall qualifications of the research team.
- Other Support**:** NIH staff may request complete and up-to-date “other support” information from you as part of Just-in-Time information collection.

Scholastic Performance

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

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

Information on Other Support beyond that required in the biographical sketch should NOT be submitted with the application.

4.6.1 Other Support Information

Refer to the Other Support page.

4.7 Resources

RESOURCES FORMAT PAGE

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, clinical, animal, computer, office, 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, 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 ESIs 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.
- Describe any special facilities used for working with biohazards or other potentially dangerous substances. Note: Information about Select Agents must be described in the Research Plan, 5.5.6 (Select Agent Research).

4.8 All Personnel Report

ALL PERSONNEL REPORT FORMAT PAGE - Renewal Applications Only

Use **only** when requested by the awarding component.

Always list the PD/PI(s). In addition, **list all other personnel** (salaried and unsalaried) **for the current budget period** at the applicant organization or elsewhere, who participated in the project during the current budget period for at least one person month or more, regardless of the source of compensation. A person month equals approximately 160 hours or 8.3% of annualized effort. Include the Commons ID (when applicable) names of individuals, all degrees, the last four digits of the Social Security number, role on project, date of birth (MM/YY), and number of person months devoted to the project (indicate academic, calendar, and/or summer).

When requesting the last four digits of the Social Security numbers from personnel, explain that provision of the Social Security number is voluntary, and the information will be used only for program management purposes. For competing applications, the Commons ID is required all PD/PIs. For progress reports, the Commons ID is required for all PD/PIs, all individuals with a postdoctoral role, and all individuals supported by a Reentry or Diversity Supplement. The Commons ID will be required in the future for all individuals with a graduate student or undergraduate role. The Commons ID is strongly encouraged, but not required for all other personnel.

Use the following categories for describing Role on Project:

- PD/PI
- Co-Investigator
- Faculty
- Postdoctoral (scholar, fellow, or other postdoctoral position)
- Technician
- Staff Scientist (doctoral level)
- Statistician
- Graduate Student (research assistant)
- Non-student Research Assistant
- Undergraduate Student
- High School Student
- Consultant
- Other (please specify)

If personnel are supported by a Reentry or Diversity Supplement please indicate such after the Role on Project, using the following abbreviations:

- RS - Reentry Supplement
- DS - Diversity Supplement

Individuals designated as Other Significant Contributors, e.g. those that may contribute to the scientific development or execution of the project, but are not committing any specified measurable effort to the project, should **not** be included in this report unless their involvement has changed so that they are now participating in the project during the current budget period for at least one person month or more.

5. Preparing the Research Plan, the Checklist, and the Appendix

5.1 (Reserved)

5.2 (Reserved)

5.3 (Reserved)

5.4 Research Plan Format and Notice of Proprietary Information

5.4.1 Research Plan Format

No Specific Form Page - Use CONTINUATION PAGE

The Continuation Page should be used for all Research Plan content EXCEPT the PHS Human Subjects and Clinical Trials Information content. You must use the separate fillable PDF for the Human Subjects and Clinical Trials Information content.

Note: The PHS Human Subjects and Clinical Trial Information fillable form can be opened in Internet Explorer. However, you may download it from any browser.

The Research Plan consists of the items listed in Section 5.5 below, as applicable. It should be self-contained and include sufficient information to evaluate the project, independent of any other document (e.g., previous application). Be specific and informative, and avoid redundancies. For grant writing tips, see NIH's Write Your Application page. Carefully follow all instructions.

Page Limits

All applicants must follow the page limits described in the Table of Page Limits, unless the FOA specifies otherwise. All tables, graphs, figures, diagrams, and charts must be included within the Research Strategy page limit. If PAs or RFAs contain specific page limits, those instructions always supersede these PHS 398 instructions.

Format Attachments

See the Format Attachments page for more information on how to format text within attachments, including hyperlinks and URLs.

5.4.2 Notice of Proprietary Information

Applicants are discouraged from submitting information considered proprietary unless it is deemed essential for proper evaluation of the application. However, when the application contains information that constitutes trade secrets, or information that is commercial or financial, or information that is

confidential or privileged, identify the pages in the application that contain this information by marking those paragraphs or lines with an asterisk (*) at the beginning of the paragraph. Indicate at the beginning of the Research Plan which pages contain asterisks and a note stating: *"The following sections marked with an asterisk contain proprietary/privileged information that [name of applicant] requests not be released to persons outside the Government, except for purposes of review and evaluation."*

When information in the application constitutes trade secrets or information that is commercial or financial, or information that is confidential or privileged, it is furnished to the Government in confidence with the understanding that the information shall be used or disclosed only for evaluation of this application. However, if a grant is awarded as a result of or in connection with the submission of this application, the Government shall have the right to use or disclose the information to the extent authorized by law. This restriction does not limit the Government's right to use the information if it is obtained without restriction from another source.

Although the grantee institution and the PD/PI will be consulted about any such release, the PHS will make the final determination. Any indication by the applicant that the application contains proprietary or privileged information does not automatically shield the information from release in response to a Freedom of Information Act (FOIA) request should the application result in an award (see 45 CFR Part 5). If an applicant fails to identify proprietary information at the time of submission as instructed in the application guide, a significant substantive justification will be required to withhold the information if requested under FOIA.

5.5 Content of Research Plan

The Research Plan consists of the items listed below, as applicable. Begin each section of the Research Plan with a section header (e.g., Introduction, Specific Aims, Research Strategy, etc.).

The Research Strategy, Section 5.5.3, is composed of three distinct sections – Significance, Innovation, and Approach. Note the Approach section also includes Preliminary Studies for new applications and a Progress Report for renewal and revision applications.

Applicants must follow the table of page limits unless specified otherwise in the FOA. If the activity code is not listed in the table of page limits, follow the page limits given in the FOA. All page limits include all tables and figures.

1. Introduction to Application (Resubmission or Revision Applications only)
2. Specific Aims
3. Research Strategy (Significance, Innovation, and Approach)
4. Bibliography and References Cited/Progress Report Publication List
5. Vertebrate Animals
6. Select Agent Research
7. Multiple PD/PI Leadership Plan
8. Consortium/Contractual Arrangements
9. Letters of Support (e.g., Consultants)
10. Resource Sharing Plan(s)
11. Authentication of Key Biological and/or Chemical Resources
12. PHS Human Subjects and Clinical Trials Information

5.5.1 Introduction (Resubmission or Revision Applications only)

Resubmission applications: See specific instructions on the content of the introduction on the NIH's Resubmission Applications page.

Competing Revisions: See specific instructions on the content of the introduction on the NIH's Competing Revisions page.

5.5.2 Specific Aims

The Specific Aims attachment is required unless otherwise specified in the FOA.

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).

5.5.3 Research Strategy

Organize the Research Strategy in the specified order and using the instructions provided below or as stated in the FOA. 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.

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

- Use the Research Strategy section to discuss the overall strategy, methodology, and analyses of your proposed research, but do not duplicate information collected in the PHS Human Subjects and Clinical Trials Information form.
- The PHS Human Subjects and Clinical Trials Information form will capture detailed study information, including eligibility criteria; inclusion of women, minorities, and children; protection and monitoring plans; and statistical design and power.
- You are encouraged to refer to information in the PHS Human Subjects and Clinical Trials Information form as appropriate in your discussion of the Research Strategy (e.g., see Question 2.4 Inclusion of Women, Minorities, and Children on this form).

Note for Applicants with Multiple Specific Aims: You may address the Significance, Innovation, and Approach either for each Specific Aim individually or for all of the Specific Aims collectively.

1. Significance

- Explain the importance of the problem or critical barrier to progress that the proposed project addresses.
- Describe the scientific premise for the proposed project, including consideration of the strengths and weaknesses of published research or preliminary data crucial to the support of your application.
- Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.

2. Innovation

- Explain how the application challenges and seeks to shift current research or clinical practice paradigms.

- Describe any novel theoretical concepts, approaches or methodologies, instrumentation or intervention(s) to be developed or used, and any advantage over existing methodologies, instrumentation, or intervention(s).
- Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions.

3. Approach

- Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Describe the experimental design and methods proposed and how they will achieve robust and unbiased results. Unless addressed separately in the Resource Sharing Plan, include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate.
- For trials that randomize groups or deliver interventions to groups, describe how your methods for analysis and sample size are appropriate for your plans for participant assignment and intervention delivery. These methods can include a group- or cluster-randomized trial or an individually randomized group-treatment trial. Additional information is available at the Research Methods Resources 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 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.
- 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.

As applicable, also include the following information as part of the Research Strategy, keeping within the three sections (Significance, Innovation, and Approach) listed above.

Preliminary Studies for New Applications.

For new applications, include information on preliminary studies. Discuss the PD/PI's preliminary studies, data, and or experience pertinent to this application. Except for Exploratory/Developmental Grants (R21/R33), Small Research Grants (R03), and Academic Research Enhancement Award (AREA) Grants (R15), preliminary data can be an essential part of a research grant application and can help to establish the likelihood of success of the proposed project. Early stage investigators should include preliminary data.

Progress Report for Renewal and Revision Applications.

Note that the Progress Report falls within the Research Strategy and is therefore included in the page limits for the Research Strategy.

For renewal/revision applications, provide a Progress Report. Provide the beginning and ending dates for the period covered since the last competitive review. In the Progress Report, you should:

- 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 resulting from significant budget reductions.
- Discuss previous participant enrollment (e.g., recruitment, retention, inclusion of women, minorities, children, etc.) for any studies meeting the NIH definition for clinical research. Use the Progress Report section to discuss, but not duplicate, information collected elsewhere in the application.

Do not include a list of publications, patents, or other printed materials in the Progress Report. That information will be included in the "Progress Report Publication List" attachment.

5.5.4 Bibliography and References Cited/Progress Report Publication List

(a) Bibliography and References Cited - Provide a bibliography of any references cited in the Research Plan and in the Human Subjects and Clinical Trials Information form (5.1.12).

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

Citations that are not covered by the Public Access Policy, but are publicly available in a free, online format may include URLs or PubMed ID (PMID) numbers along with the full reference. The references should be limited to relevant and current literature.

You are allowed to cite interim research products. **Note:** interim research products have specific citation requirements. See related Frequently Asked Questions for more information.

(b) Progress Report Publication List - For Renewal applications list the titles and complete references to all appropriate publications, manuscripts accepted for publication, patents, and other printed materials that have resulted from the project since it was last reviewed competitively.

List the titles and complete references to all appropriate publications, manuscripts accepted for publication, patents, and other printed materials that have resulted from the project since it was last reviewed competitively.

You are allowed to cite interim research products. **Note:** interim research products have specific citation requirements. See related Frequently Asked Questions on citing interim research products and claiming them as products of your NIH award.

Provide the NIH Manuscript Submission reference number (e.g., NIHMS97531) or the PubMed Central (PMC) reference number (e.g., PMCID234567) for each of the following:

- Articles that fall under the Public Access Policy,
- Articles that were authored or co-authored by the applicant and arose from NIH support,
- Articles that were authored or co-authored by the applicant and arose from AHRQ funding provided after February 19, 2016 (see the Guide Notice on Policy for Public Access to AHRQ-Funded Scientific Publications).

If the PMCID is not yet available because the Journal submits articles directly to PMC on behalf of their authors, indicate “PMC Journal – In Process.” NIH maintains a list of such journals.

Citations that are not covered by the Public Access Policy, but are publicly available in a free, online format may include URLs or PubMed ID (PMID) numbers along with the full reference.

5.5.5 Vertebrate Animals

If live vertebrate animals are involved in the project, address each of the following criteria:

1. **Description of Procedures:** Provide a concise description of the proposed procedures to be used that involve vertebrate animals in the work outlined in the "Research Strategy" attachment. The description must include sufficient detail to allow evaluation of the procedures. Identify the species, strains, ages, sex, and total numbers of animals by species, to be used in the proposed work. If dogs or cats are proposed, provide the source of the animals.
2. **Justifications:** Provide justification that the species are appropriate for the proposed research. Explain why the research goals cannot be accomplished using an alternative model (e.g. computational, human, invertebrate, in vitro).
3. **Minimization of Pain and Distress:** Describe the interventions including analgesia, anesthesia, sedation, palliative care and humane endpoints that will be used to minimize discomfort, distress, pain, and injury.

Each of the criteria must be addressed. Failure to adequately address the criteria may negatively affect the application's impact score. In addition to the 3 criteria above, you should also:

- Identify all project performance (or collaborating) sites and describe the proposed research activities with vertebrate animals that will be conducted at those sites.
- Explain when and how animals are expected to be used if plans for the use of animals have not been finalized.

See the following pages for more information:

- NIH's Office of Laboratory Animal Welfare website
- NIH's Vertebrate Animals Section Worksheet
- See the NIH Grants Policy Statement, Section 4.1.1: Animal Welfare Requirements (an applicable Animal Welfare Assurance will be required if the grantee institution does not have one)

5.5.6 Select Agent Research

For more information:

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 the Federal Select Agent Program website.

See also the NIH Grants Policy Statement, Section 4.1.24.1.1: Select Agents.

Content:

Excluded select agents: If the activities proposed in the application involve only the use of a strain(s) of select agents which has been excluded from the list of select agents and toxins as per 42 CFR 73.3, the select agent requirements do not apply. Use this "Select Agent Research" attachment to identify the strain(s) of the select agent that will be used and note that it has been excluded from this list. The CDC maintains a list of exclusions, which is available on the Select Agents and Toxins Exclusions 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 Project/Performance Site(s) is a foreign institution, provide the name(s) of the country or countries where Select Agent research will be performed.
    - *An "entity" is defined in 42 CFR 73.1 as "any government agency (Federal, State, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity."
3. Provide a description of all facilities where the Select Agent(s) will be used.
    - Describe the procedures that will be used to monitor possession, use and transfer of the 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.

5.5.7 Multiple Project Director/Principal Investigator (PD/PI) Leadership Plan

A rationale for choosing a multiple PD/PI approach should be described. The governance and organizational structure of the leadership team and the research project should be described, including communication plans, processes for making decisions on scientific direction, and procedures for resolving conflicts. The roles and administrative, technical, and scientific responsibilities for the project or program should be delineated for the PD/PIs and other collaborators.

If budget allocation is planned, the distribution of resources to specific components of the project or the individual PD/PIs should be delineated in the Multiple PD/PI Leadership Plan. In the event of an award, the requested allocations may be reflected in a footnote on the Notice of Grant Award.

For more Information:

For background information on the multiple PD/PI initiative, see NIH's Multiple Principal Investigators page.

5.5.8 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.

Note: The signature of the authorized organization representative in Face Page, 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 for more information.

5.5.9 Letters of Support

Attach a file with all letters of support, including any letters necessary to demonstrate the support of consortium participants and collaborators such as Senior/Key Personnel and Other Significant Contributors included in the grant application.

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

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

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

Do not include consultant biographical sketches in the "Letters of Support" attachment, as consultant biosketches should be in the "Biographical Sketch" section.

5.5.10 Resource Sharing Plan(s)

Data Sharing Plan: Investigators seeking $500,000 or more in direct costs (exclusive of consortium F&A) in any budget period are expected to include a brief 1-paragraph description of how final research data will be shared, or explain why data-sharing is not possible (for example human subject concerns, the Small Business Innovation Development Act provisions, etc.). Specific FOAs may require that all applications include this information regardless of the dollar level. Applicants are encouraged to read the FOA carefully and discuss their data-sharing plan with their program contact at the time they negotiate an agreement with the Institute/Center (IC) staff to accept assignment of their application. **For more information**, see the NIH Data Sharing Policy or the NIH Grants Policy Statement, Section 2.3.7.10: NIH Genomic Data Sharing and Section 8.2.3.3: Genomic Data Sharing (GDS) Policy/ Policy for Genome-Wide Association Studies (GWAS).

Sharing Model Organisms: Regardless of the amount requested, all applications where the development of model organisms is anticipated are expected to include a description of a specific plan for sharing and distributing unique model organisms or state why such sharing is restricted or not possible. **For more information**, see the NIH Grants Policy Statement, Section 8.2.3.2: Sharing Model Organisms.

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. Examples of large-scale genomic data include genome-wide association studies (GWAS), single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, epigenomic, and gene expression data. Supplemental Information to the NIH GDS provides examples of genomic research projects that are subject to the Policy**. For more information** see the NIH GDS Policy, the NIH Grants Policy Statement, Section 8.2.3.3: Genomic Data Sharing (GDS) Policy/ Policy for Genome-Wide Association Studies (GWAS), and the GDS website.

Note on GDS: For proposed studies generating human genomic data under the scope of the GDS Policy, an institutional certification may be submitted at the time of application submission, but it is not required at that time. The institutional certification, however, will be requested as Just-in-Time (JIT) information prior to award. The institutional certification, or in some cases, a provisional institutional certification, must be submitted and accepted before the award can be issued.

For more information:

NIH considers the sharing of unique research resources developed through NIH-sponsored research an important means to enhance the value and further the advancement of the research. When resources have been developed with NIH funds, and the associated research findings published or provided to NIH, it is important that they be made readily available for research purposes to qualified individuals within the scientific community. See the NIH Grants Policy Statement, Section 8.2.3: Sharing Research Resources.

5.5.11 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. 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 be generated with NIH funds and: 1) may differ from laboratory to laboratory or over time; 2) may have qualities and/or qualifications that could influence the research data; and 3) are integral to the proposed research. These include, but are not limited to, cell lines, specialty chemicals, antibodies, and other biologics.
- Standard laboratory reagents that are not expected to vary do not need to be included in the plan. Examples are buffers and other common biologicals or chemicals.
- See NIH's page on Rigor and Reproducibility for more information.

5.5.12 PHS Human Subjects and Clinical Trials Information

FILLABLE PHS HUMAN SUBJECTS AND CLINICAL TRIALS INFORMATION PDF

Note: The PHS Human Subjects and Clinical Trials Information fillable form can be opened in Internet Explorer. However, you may download it from any browser.

This form is separate from the Research Plan, but part of the overall application. You must use the separate fillable PDF for the PHS Human Subjects and Clinical Trials Information form. Full instructions on completing this form can be found in the PHS Human Subjects and Clinical Trial Information form-specific instructions of the Application Guide for electronic applications.

Although certain question in the form apply to every applicant, others apply only to certain applicants. For example, you will only be able to extract (and fill out) a study record if your answer is “Yes” to the “Are Human Subjects Involved?” question at the beginning of the form. Moreover, although the form-specific instructions in the Application Guide apply, certain form behavior differences will occur in your paper application. Differences include:

- None of your answers will be pre-populated from any previous forms.
- There are no validations on the paper version of the form, so form behavior will differ from the electronic version. However, you must still complete all required sections.

5.6 Checklist

CHECKLIST FORM PAGE

Type of Application

Check all that apply.

Inventions and Patents (Renewal Applications Only)

If no inventions were conceived or reduced to practice during the course of work under this project, check “No.” The remaining parts of the item are then not applicable.

If any inventions were conceived or reduced to practice during the previous period of support, check “Yes.” Also indicate whether this information has been reported previously to the PHS or to the applicant organization official responsible for patent matters.

Note: NIH recipient organizations must promptly report inventions to the Extramural Inventions and Technology Resources Branch of the Office of Policy for Extramural Research Administration, OER, NIH, Bethesda, MD 20892-2750, (301) 435-1986. Invention reporting compliance according to regulations at 37 CFR 401.14 is described at the iEdison.gov page. The grantee is encouraged to submit reports electronically using Interagency Edison. See the NIH Grants Policy Statement, Section 8.4.1.6: Invention Reporting.

1. Program Income

If no program income is anticipated during the period(s) for which grant support is requested, so state.

If program income is anticipated, use the format provided. If the application is funded, the Notice of Award will provide specific instructions regarding the use of such income.

2. Assurances/Certifications

Each application to the PHS requires that the policies, assurances, and certifications provided in the NIH Grants Policy Statement, Section 4: Public Policy Requirements, Objectives and Other Appropriation Mandates, be verified by the signature of the official signing for the applicant organization on the Face Page of the application.

3. Facilities and Administrative Costs (F&A)/Indirect Costs

Indicate the applicant organization’s most recent F&A cost rate established with the appropriate HHS Regional Office, or, in the case of for-profit organizations, the rate established with the Division of Financial Advisory Services (DFAS), NIH. If the applicant organization does not have a current negotiated rate, it should develop a provisional rate for application purposes, and immediately upon notification that an award will be made, it should submit the provisional F&A cost rate proposal to the appropriation negotiation office. This proposal is to be based on the organization’s most recently completed fiscal year in accordance with the principles set forth in the pertinent HHS guidance for establishing indirect cost rates, and submitted to the appropriate HHS Regional Office or the DFAS, NIH. If the applicant organization has a current negotiated rate with another Federal agency, the negotiated rate must be adjusted to treat any independent research and development (IR&D) costs in accordance with HHS policy. F&A costs will NOT be paid on construction grants, grants to Federal organizations, grants to individuals, and conference grants. Follow any additional instructions provided for Institutional Training, including Ruth L. Kirschstein National Research Service Awards, and specialized grant applications.

Foreign institutions and international organizations (non-U.S. entities) may request funds for limited F&A costs (8 percent of modified total direct costs less equipment) to support the costs of compliance with HHS and NIH requirements including, but not limited to, protection of human subjects, animal welfare, invention reporting, financial conflict of interest and research misconduct.

5.7 Appendix

Format:

Appendices must be submitted on CDs. You must submit **two identical CDs containing all appendix material.** Appendix materials submitted in paper are not accepted and may lead to a delay in the review process. See 3.3 Bindings and Packaging for more information on formatting your CDs.

Content:

A maximum of 10 PDF attachments is allowed in the Appendix. If more than 10 allowable appendix attachments are needed, combine the remaining information into attachment #10.

Only limited items are allowed in the Appendix. Use file names for attachments that are descriptive of the content.

A summary sheet listing all of the items included in the Appendix is encouraged but not required. When including a summary sheet, it should be included in the first appendix attachment.

The only allowable appendix materials are:

- Blank data collection forms, blank survey forms, and blank questionnaire forms - or screenshots thereof
- Simple lists of interview questions

  Note: In your blank forms and lists, do not include items such as: data, data compilations, lists of variables or acronyms, data analyses, publications, manuals, instructions, descriptions or drawings/figures/diagrams of data collection methods or machines/devices.

- Blank informed consent/assent forms
- Other items *only if* they are specified in the FOA as allowable appendix materials

No other items are allowed in the Appendix. Simply relocating disallowed materials to other parts of the application will result in a noncompliant application.

Some FOAs may have different instructions for the Appendix. Always follow the instructions in your FOA if they conflict with these instructions.

Note: Applications will be withdrawn and not reviewed if they do not follow the appendix requirements in these instructions or in your FOA.

Information that expands upon or complements information provided in any section of the application – even if it is not required for the review – is not allowed in the Appendix unless it is listed in the allowed appendix materials above or in your FOA. For example, do not include material transfer agreements (MTA) in the appendix unless otherwise specified in the FOA.

For more information:

- The NIH Guide Notice on Reminder: NIH Applications Must Be Complete and Compliant With NIH Policy and Application Instructions At Time of Submission.
- Failure of reviewers to address non-required appendix materials in their reviews is not an acceptable basis for an appeal of initial peer review. For more information, see the NIH Grants Policy Statement, Section 2.4.2: Appeals of Initial Scientific Review.
- Appendix Policy Frequently Asked Questions

6. Peer Review Process

See NIH's Peer Review page for more information.