U.S. Department of Health and Human Services
Public Health Service
Grant Application (PHS 398)

Instructions for PHS 398
Rev. 06/2012

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PART I

Instructions for Preparing and Submitting an 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 agencies.

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. This PHS 398 is required for all grant activity codes that have not transitioned to the SF424 (R&R), including Resubmission, Renewal, Revision, changes of grantee institution, and cooperative agreement applications. Once an activity code has transitioned to electronic submission the applicant must apply through Grants.gov using the SF424 (R&R) and electronic PHS 398 components that are provided as part of the electronic application forms.

For more information on NIH's transition plans, including a timeline for the transition of various activity codes, see the website for Electronic Submission of Grant Applications: http://grants.nih.gov/grants/ElectronicReceipt/.

Bookmark this website (http://grants.nih.gov/grants/funding/phs398/phs398.html) for easy electronic access to this document.

Policy Changes

These instructions incorporate numerous clarifications, updates and policy announcements that have appeared in the NIH Guide for Grants and Contracts since the 11/2007 revision of the PHS 398 application. Since the Guide also publishes multiple funding opportunity announcements, 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:

Enhancing Peer Review Initiative (http://enhancing-peer-review.nih.gov/index.html)

- The Research Plan is restructured and aligned with peer review criteria.
- Shorter page limits are adopted for Rs (except R25), with other activity codes scaled accordingly.
- The Biographical Sketch now requires a Personal Statement, and encourages applicants to limit the number of publications to 15.
- Instructions for describing Resources are modified to address the scientific environment and the institutional investment in Early Stage Investigators.

Commitment to New and Early Stage Investigators (http://grants.nih.gov/grants/new_investigators/index.htm)

- The 398 Face Page checkbox for “new investigator” is eliminated. The status of new and early stage investigators will be determined electronically from information entered into the eRA Commons Personal Profile.
- Personal Data Form page is eliminated. Information will be collected in the eRA Commons Personal Profile.
- New and early stage investigator policies are described in Part III, 1.15.

Implementation of NIH Reform Act of 2006 (P.L. 109-482)

- One-time eRA Commons Registration requirement is implemented for all individuals with a postdoctoral role and one month or more of measurable effort. The definition of postdoctoral scholar is added.
- Table 12A, required for institutional research training applications, is modified to collect data on percentage of students who successfully attain a doctoral degree and average time to receive a doctoral degree.
- A new Assurance for Institutions Receiving Awards for Training of Graduate Students for Doctoral Degrees is required, as applicable (Part III, 2.16).

Transition of CDAs and Institutional Research Training Applications to Electronic Submission

- The Career Development Awards (CDA or "K" programs, with the exception of K12s) transitioned to electronic submission in February, 2009. CDA application instructions are now included as Part 1, Section 7 of the SF424 (R&R) Application Guide for NIH and Other PHS Agencies.
- The Institutional Research Training Application Including Ruth L. Kirschstein - NRSA Applications transitioned to electronic submission for the January 25, 2010 application receipt date. Instructions for such applications are now included at Part 1.Section 8 of the SF424 (R&R) Application Guide for NIH and Other PHS Agencies.

Important Reminders for all Applicants

Font and margin specifications must be followed; if not, application processing may be delayed or the application may not be reviewed. NIH requires the use of one of four approved fonts and a font size of 11 points or larger. The approved font options include two serif fonts (Palatino and Georgia) and two sans serif fonts (Arial and Helvetica). A symbol font may be used to insert Greek letters or special characters; the font size requirement still applies. A smaller font size may be used for figures, graphs, diagrams, charts, tables, figure legends, and footnotes, but this type must follow the font typeface requirement and be readily legible.

Prepare a *succinct* Research Plan and follow the Table of Page Limits unless the FOA specifies otherwise. Sections 4-15 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 Just-In-Time Policy in Part III. 1.7.

1.1 Application Guide Format

This edition of the PHS 398 is organized into three parts, and is available in two different formats: MS Word and PDF. Within each Part are links to pertinent sections of the application, other documents, or NIH web pages. To use these links in the MS Word version effectively, you must enable the "web" tool bar in order to have a "back button" to return to a page after using a link. The three parts of the 398 are described below:

Part I: Instructions for Preparing and Submitting an Application

Part I includes instructions on submitting a grant application, completing the PHS 398 forms and format pages, preparing the cover letter, Research Plan, and checklist, and information on the peer review process.

Part II: Supplemental Instructions for Preparing the Protection of Human Subjects Section of the Research Plan

Part II includes instructions for research that proposes to involve human subjects, including scenarios and detailed instructions to complete Items 6-9 of the Research Plan (Human Subjects Research).

Part III: Policies, Assurances, Definitions and Other Information

Part III includes information on policies, assurances, definitions, and other information relating to submitting applications to the PHS. Applicants should refer to this document as well as the PHS 398 instructional materials, Grants Information (GrantsInfo), and the relevant Grants Policy Statement for additional sources of information. The NIH Grants Policy Statement applies to all NIH awardees; other PHS agencies use the HHS Grants Policy Statement.

Form pages are available *separately* on the NIH website (http://grants.nih.gov/grants/funding/phs398/phs398.html#forms).

THESE INSTRUCTIONS AND APPLICATION FORMS (Revised xx/2009) SUPERSEDE ALL PREVIOUS EDITIONS. Carefully read the instructions. Submission of an application that fails to meet the PHS requirements will be grounds for the PHS to delay the review or to return the application without peer review. A properly prepared application will facilitate the administrative processing and peer review that must occur before an award can be made.

While the instructions are generally applicable, grant programs of PHS agencies other than NIH may have additional specific instructions. Applicants should contact an official listed in the table of PHS agencies to obtain the most current information and instructions.

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 (http://grants.nih.gov/grants/oer.htm).

The Division of Extramural Outreach and Information Resources (DEOIR) 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) may be contacted by e-mailing GrantsInfo@nih.gov, or calling (301) 435-0714.

1.3 Research Grant Programs and Program Guidelines

A partial list of research grant programs that use the paper PHS 398 Grant Application is provided below, however, not all awarding components use all programs. For a complete listing of program guidelines, visit the OER Grants website http://grants.nih.gov/grants/funding/funding_program.htm. As grant programs transition to electronic submission through Grants.gov using the SF 424 (R&R) they will no longer use this paper PHS 398 application. See http://grants.nih.gov/grants/ElectronicReceipt/files/timeline_NIH_transitions.pdf for the latest information on the transition to electronic submission.

Research Program Projects and Centers:

- Program Project Grant (P01)
- Exploratory Grants (P20)
- Center Core Grants (P30)
- Biotechnology Resource Grants (P41)

- Research Center Grant (P50)
- Comprehensive Center (P60)

Other Grant Programs

- Research Centers in Minority Institutions (G12)
- Resource-Related Research Projects (R24, U24)

1.4 Interactions with PHS Staff

The PHS agencies encourage applicants to communicate with staff throughout the entire application, review and award process. Web site addresses and phone numbers of relevant NIH awarding components and other PHS agencies are listed in the table below. The non-NIH agencies listed below use this application form, but some have application requirements that differ from NIH. For specific instructions for AHRQ, CDC, FDA and IHS, refer to the links provided below and the terms and conditions of the Notice of Award.

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 (LINK TO WEB SITE)	AWARDING COMPONENT (LINK TO WEB SITE)	TELEPHONE NUMBER
NATIONAL INSTITUTES OF HEALTH (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 Alternative Medicine	301-496-4792
NIH	National Center for Research Resources	301-496-6023
NIH	National Eye Institute	301-451-2020
NIH	National Heart, Lung, and Blood Institute	301-435-0260
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

PHS AGENCY (LINK TO WEB SITE)	AWARDING COMPONENT (LINK TO WEB SITE)	TELEPHONE NUMBER
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	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	Coordinating Center for Infectious Disease	404-639-3770
CDC	Coordinating Center for Environmental Health & Injury Prevention	770-488-4668
CDC	Coordinating Center for Health Promotion	770-488-8390
CDC	Office of Public Health Research	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	301-594-4004
OFFICE OF PUBLIC HEALTH AND SCIENCE	Office of Family Planning	301-594-4008

BEFORE SUBMISSION

Applicants may contact NIH staff with a variety of questions before submitting an application.

- Contact GrantsInfo at (301) 435-0714 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 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.

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, 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

http://grants.nih.gov/grants/useful_links.htm

Award Information and Data

http://report.nih.gov
Research Portfolio Online Reporting Tool (RePORT)

Contact Information for an NIH Staff Person

http://ned.nih.gov
NIH locator: 301-496-4000

eRA Commons

https://commons.era.nih.gov/commons/index.jsp

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.

Email the Commons Help Desk at commons@od.nih.gov.

Call the Commons Help Desk at 1-800-504-9552 (toll-free) or 301-402-7469; 301-451-5939 (TTY). Business hours are M-F 7am-8pm Eastern Time.

Grant Writing Tips and Sample Applications

http://grants.nih.gov/grants/grant_tips.htm

Grants Information

http://grants.nih.gov/grants/giwelcome.htm
E-mail: GrantsInfo@nih.gov
Telephone: 301-435-0714; 301-451-5936 (TTY)

NIH Office of Extramural Research Human Subjects Website

http://grants.nih.gov/grants/policy/hs/index.htm

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

Office of Biotechnology Activities (OBA)

http://oba.od.nih.gov/oba/index.html

NIH Guidelines for Research Involving Recombinant DNA Molecules and Institutional Biosafety Committee Registration
Telephone: 301-496-9838

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

http://www.hhs.gov/ohrp

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)

http://grants.nih.gov/grants/olaw/olaw.htm

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

http://www.csr.nih.gov/EVENTS/AssignmentProcess.htm

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 Person Profile. The data is provided one-time by the individual through a secure, electronic system, is confidential, and is maintained under the Privacy Act record system 09-25-0036, "Grants: IMPAC (Grant/Contract Information)." 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 Sections 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 form. 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 or any materials related to training or career award 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

2.2.1 (Reserved)

2.2.2 DUNS Registration for the Applicant Organization & Subaward/Consortium Organizations

A Data Universal Numbering System (DUNS) number is required for all applications (paper and electronic) and must be obtained by the organization prior to submission. For organizations that already have multiple DUNS numbers, one DUNS number should be selected by an Authorized Organization Representative (AOR) and used consistently for all application submissions. The Authorized Organization Representative should be consulted to determine the appropriate number to use for applications.

The DUNS number is considered the Federally-recognized unique identifier and is used for reporting purposes, particularly those associated with the *Federal Financial Assistance Transparency Act (FFATA) of 2006* (P.L. 109-282).

FFATA also includes a requirement for reporting on subaward information. Therefore an accurate DUNS number for each first-tier subaward/consortium organization must also be provided as part of the Project/Performance Site information.

Additional information on DUNS registration is found at:
http://fedgov.dnb.com/webform/displayHomePage.do

A DUNS number is required for Central Contractor Registration (see 2.2.3. below).

2.2.3 Central Contractor Registration (CCR) for the Applicant Organization

Prior to submission of all applications (paper and electronic), applicant organizations are required to be registered in the Central Contractor Registration (CCR). Organizations must maintain the currency of the information in the registry and renew the registration annually. A DUNS number is required for CCR registration.

CCR is a government-wide registry for organizations doing business with the U.S. Government. The registry collects, validates, stores, and disseminates data in support of agency acquisition missions, including Federal agency contract and assistance awards. The CCR registry will be used by Federal agencies to validate the DUNS number provided as part of the application process. Validation of the DUNS number will be critical for agencies to comply with the requirements of the *Federal Financial Assistance Transparency Act (FFATA) of 2006* (P.L. 109-282).

Organizational information entered into the CCR must match that in the eRA Commons. Since CCR Registration can take several days to complete, the process should be started well in advance of a submission date to avoid potential delays. An Authorized Organization Representative should be consulted to determine if the organization has properly completed and maintained CCR registration. Additional information on CCR registration is found at: http://www.ccr.gov/.

2.2.4 eRA Commons Registration

The applicant organization, all PD/PI(s), and all individuals with a postdoctoral role (see definition of postdoctoral scholar in Part III.3 and one month or more of measurable effort, must complete a **one-time** registration in the eRA Commons. Access to the Commons is vital for all steps in the process after application submission. An organization and PD/PIs must be registered in the Commons for purposes of retrieval of grant information, institute/center assignments, review outcomes, and Summary Statements. Institutional/organizational officials are responsible for registering PD/PIs and individuals with a postdoctoral role in the eRA Commons. PD/PIs and individuals with a postdoctoral role should work with their AOR (also known as the Signing Official, or SO, in the eRA Commons) to determine their institutional/organizational process for registration.

IMPORTANT: The eRA Commons registration process should be started at least **two (2) weeks** prior to submission. A valid PD/PI Commons user name ID must be entered in item 3.h of the Face Page. Commons user name IDs for those with a postdoctoral role are not required at the time of application submission, but are required as part of the Non-Competing Continuation Progress Report (PHS 2590).

2.2.4.1 Commons Registration for the Organization

Organizations may verify their current registration status by accessing the "List of Grantee Organizations Registered in NIH eRA Commons" (http://era.nih.gov/commons/quick_queries/index.cfm#commons).

To register an Organization in the eRA Commons:

1. Open the eRA Commons homepage (https://commons.era.nih.gov/commons/).
2. Click Grantee Organization Registration (found in "About the Commons" links on the right side of the screen).
3. Follow the step-by-step instructions. Remember to fax in the registration signature page to eRA.
4. Click Submit. The organization is registered when the NIH confirms the information and sends an email notification of registered Signing Official (SO) account (userid/password).

Organizational data elements, such as Institutional Profile Number (IPF), Entity Identification Number (e.g., 5555555555A5) and DUNS Number must be accurately identified. **Note the DUNS number must be included in the Institutional Profile, and must match the number on the application.**

Since eRA has not required a DUNS number during eRA Commons registration, many accounts do not contain valid information in this field. Prior to submission, the Authorized Organization Representative/SO should verify that the organization's eRA Commons profile contains the valid DUNS number that will be used for the submission process. The SO has the ability to edit this field in the organization profile in Commons.

To confirm that the organization has a DUNS number or to find out if the DUNS number you have matches the one in the Commons, access the List of Grantee Organizations Registered in NIH eRA Commons (http://era.nih.gov/commons/quick_queries/index.cfm#commons). This listing of grantee organizations registered in Commons and their DUNS numbers can be accessed without logging into Commons.

2.2.4.2 Commons Registration for the Project Director/Principal Investigator (PD/PI) and Individuals with a Postdoctoral Role

The individual(s) designated as the PD/PI(s) on the application must be registered in the Commons. The PD/PI must hold a PI account **and** be affiliated with the applicant organization. **This registration must be done by an organizational official (or delegate) who is already registered in the Commons.** To register PD/PIs in the Commons, refer to the NIH eRA Commons System Users Guide

(http://era.nih.gov/Docs/COM_UGV2630.pdf). For applications reflecting multiple PD/PIs, all PD/PIs must be assigned the PD/PI role, even those at organizations other than the applicant organization. The contact PD/PI for a multiple PD/PI application must be affiliated with the applicant organization.

Once the PD/PI has received email confirming his/her registration within the Commons, the PD/PI must verify that all Personal Information located within the Personal Profile tab in the eRA Commons System is accurate. Please have the PD/PI review and update, as needed, data elements such as first name, middle initial, last name, prefix and/or suffix to PD/PI name (including all embedded punctuation), email, phone, fax, street address, city, state, country, zip and degrees earned. 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.

Both PD/PI and SO need separate accounts in Commons since both must verify the application. If you are the SO for your organization as well as a PI of the grant, you will need two separate accounts with different user names – one with SO authority and one with PI authority. When an organization is registered, an SO account is created. Log on to the account with the SO authority role and create another account with PI authority.

Individuals with a postdoctoral role and one month or more of effort must also be registered in the eRA Commons and should verify that all Personal Information located within the Personal Profile tab in the eRA Commons System is accurate. The Commons user name ID for those with a postdoctoral role is not required at the time of application submission, but will be required as part of the Non-Competing Continuation Progress Report (PHS 2590).

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 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 a list and brief description of grant activity codes, see Part III, 4.1.

2.4.1 NIH Guide for Grants and Contracts

The *NIH Guide for Grants and Contracts*, a weekly electronic publication (http://grants.nih.gov/grants/guide), 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 http://grants.nih.gov/grants/guide/listserv.htm.

2.4.2 Funding Opportunity Announcements (FOAs)

To hasten the development of a program or to stimulate submission of applications in an area of high priority or special concern, an awarding component will encourage applications through the issuance of a PA to describe new, continuing, or expanded program interests, or issuance of an RFA inviting applications in a well-defined scientific area to accomplish a scientific purpose.

Definitions are as follows:

Parent Announcements: Electronic grant applications must be submitted in response to a Funding Opportunity Announcement (FOA). For applicants who wish to submit what were formerly termed "investigator-initiated" or "unsolicited" applications, NIH and other PHS agencies have developed Parent Announcements. Responding to such an omnibus or umbrella Parent FOA ensures that the correct application package is used and enables NIH to receive the application from Grants.gov. Additional information about, as well as links to published Parent Announcements, can be found at: http://grants.nih.gov/grants/guide/parent_announcements.htm.

Program Announcement (PA): A formal statement about a new or ongoing extramural activity or program. It may serve as a reminder of continuing interest in a research area, describe modification in an activity or program, and/or invite applications for grant support. Most applications in response to PAs may be submitted to a standing submission date and are reviewed with all other applications received at that time.

Request for Applications (RFA): A formal statement that solicits grant or cooperative agreement applications in a well-defined scientific area to accomplish specific program objectives. An RFA indicates the estimated amount of funds set aside for the competition, the estimated number of awards to be made, and the application submission date(s). Applications submitted in response to an RFA are usually reviewed by a Scientific Review Group (SRG) specially convened by the awarding component that issued the RFA.

PAs (including Parent Announcements) and RFAs are published in the *NIH Guide for Grants and Contracts* (http://grants.nih.gov/grants/guide), the *Federal Register* (http://www.gpoaccess.gov/nara/index.html), and on Grants.gov under Find Grant Opportunities (http://www.grants.gov/applicants/find_grant_opportunities.jsp). Read the announcement carefully for special instructions. The instructions in the announcement may differ from these general instructions, and the instructions in the announcement **always** supersede these general instructions. Each announcement published in the *NIH Guide for Grants and Contracts*, the *Federal Register*, Grants.gov Find, or other public document contains contact information under *Inquiries* in addition to information specific to the announcement.

While individual announcements will continue to carry an announcement number reference to "PA" or "RFA", all announcements are "Funding Opportunity Announcements (FOAs)." This general term will be used to reference any type of funding announcement. NIH will continue to use the PA and RFA references in the actual announcement number to distinguish between the various types of announcements.

All applications submitted to the NIH must be submitted in response to a FOA published in the NIH Guide for Grants and Contracts.

2.5 (Reserved)

2.6 Format Specifications

Follow font and format specifications. Otherwise, application processing may be delayed or the application may not be reviewed.

Font

- Use an *Arial, Helvetica, Palatino Linotype or Georgia typeface, a black font color, and a font size of 11 points or larger*. A symbol font may be used to insert Greek letters or special characters; the font size requirement still applies.
- Type density, including characters and spaces, must be no more than 15 characters per inch.
- Type may be no more than six lines per inch.
- Use black ink that can be clearly copied.
- Print must be clear and legible.

Paper Size and Page Margins

- Use standard size *(8 ½" x 11")* sheets of paper.
- Use at least one-half inch margins (top, bottom, left, and right) for all pages, including continuation pages. No information should appear in the margins, including the PD/PI's name and page numbers.

Page Formatting

- Because a number of reviewers will be reviewing applications as electronic documents and not paper versions, applicants are strongly encouraged to use only a standard, single-column format for the text. Avoid using a two-column format since it can cause difficulties when reviewing the document electronically.
- The application must be single-sided and single-spaced.
- Consecutively number pages throughout the application. Do not use suffixes (e.g., 5a, 5b).
- Do not include additional pages between the face page and page 2.
- Do not include unnumbered pages.

Figures, Graphs, Diagrams, Charts, Tables, Figure Legends, and Footnotes

- A smaller type size is acceptable, but it must be in black ink, readily legible, and follow the font typeface requirement.

Grantsmanship

- Use English and avoid jargon.
- If terms are not universally known, spell out the term the first time it is used and note the appropriate abbreviation in parentheses. The abbreviation may be used thereafter.

Photographs and Images

- Do not include photographs or other materials that are not printed directly on an application page in the body of the application. Pictures or other materials that are glued or taped onto application pages are incompatible with the current duplication/scanning process.
- You may include black-and-white or color images in the six (6) submitted copies provided such images are printed directly on the application page and are critical to the content of the application.

Copies

- Send the original application (signed by an Authorized Organization Representative) and five identical, legible, single-sided photocopies.
- Do not use photo reduction.

- The application must contain only material that reproduces well when photocopied in black and white. Glossy photographs or other materials that cannot be photocopied must be submitted in the appendix (see Section 5.7). *Note:* Photographs may be included in the appendix; however, a photo copy of each must also be included within the page limits of the Research Strategy.

Page Limits

All applications for NIH funding must be self-contained within specified page limits.

Observe the page number limits provided in the table below, unless the FOA specifies otherwise. Page limits for activity codes not listed below should follow the page limits specified in the FOA.

SECTION OF APPLICATION Also refer to the relevant section of the application instructions and the FOA.	PAGE LIMITS *
Introduction to Revision or Resubmission Applications	1 page
Introduction to Revision or Resubmission Applications For each project and core of multi-component applications	1 page
Specific Aims	1 page
Research Strategy (Item 5.5.3 of Research Plan) For Activity Codes R03, R13/U13, R21, R36, R41, R43, Fellowships (F), SC2, SC3	6 pages
Research Strategy (Item 5.5.3 of Research Plan) For Activity Codes R01, single project U01, R10, R15, R18, U18, R21/R33, R24, R33, R34, U34, R42, R44, DP3, G08, G11, UH2, UH3, SC1, X01	12 pages
Research Strategy (Item 5.5.3 of Research Plan) For all other Activity Codes, including Cs, Ps, Ss, Ts, Us, etc.	follow FOA instructions *
Biosketch (per person) For all Activity Codes except DP1 and DP2	4 pages
Biosketch (per person) For DP1 and DP2	2 pages
Appendix **	No page limits, but content limitations. See relevant section of instructions and FOA

*** FOA instructions always supersede these instructions.**

** Applicants are prohibited from using the appendix to circumvent page limits in any section of the application for which a page limit applies. For additional information regarding Appendix material and page limits, refer to NIH Guide Notice NOT-OD-10-077.

2.7 Resubmission Applications

For all original new (i.e. never submitted) and competing renewal applications submitted for the January 25, 2009 due date and beyond, NIH will accept only a single amendment (A1) to the original application (called a resubmission application). A lengthy hiatus after the initial submission may be marked by significant advances in the scientific field and the comments of the reviewers may no

longer be relevant. Therefore, a resubmission application must be submitted within 37 months after the date of receipt ("receipt date") of the initial New, Renewal, or revision application (see NOT-OD-10-140). After 37 months, you may submit a New application. Any second resubmission will be administratively withdrawn and not accepted for review.

For original new and competing applications submitted prior to January 25, 2009, applicants are permitted two resubmissions (A1 and A2). For these “grandfathered” applications, any second resubmission (A2) must be submitted no later than the appropriate due date for Cycle III; NIH will not accept any A2 resubmissions after that date. See NIH Policy on Submission of a Revised/Resubmission (amended) Application in Part III, 1.3.

NIH has established new policies for application resubmissions of certain categories. See Resubmission of Unpaid RFA Applications and Resubmission of Applications with a Changed Grant Activity Code in Part III, 1.2.

There are four requirements for a Resubmission application:

- The Summary Statement must be available in the eRA Commons (http://commons.era.nih.gov/commons/).
- The PD/PI(s) must make significant changes to the application.
- An Introduction must be included that summarizes the substantial additions, deletions and changes to the application. The Introduction must also include a response to the issues and criticism raised in the Summary Statement. Use the Introduction to Application of the Research Plan (see 5.5.1) to provide this information. The Introduction may not exceed one page, unless the FOA specifies otherwise.
- The substantial scientific changes must be marked in the text of the application by bracketing, indenting, or changing typography. Do not underline or shade the changes. Deleted sections should be described but not marked as deletions. If the changes are so extensive that essentially all of the text would be marked, explain this in the Introduction. The Research Strategy/Progress Report section (see 5.5.3.c) should incorporate work completed since the prior version of the application was submitted.

See NOT-OD-07-083 for special conditions and due dates for new investigator resubmission applications submitted for consecutive review cycles. Note this applies only to new investigator R01s submitted for standard receipt dates and reviewed in recurring SRGs in CSR, and selected other study sections only (e.g., NOT-MH-08-002).

Acceptance of a resubmission application will not automatically withdraw the prior version. eRA keeps all versions (e.g., 01, A1) of a grant application active and provides an internal Multiple Active Applications (MAA) flag for each application in an active cluster. The cluster allows applicants to identify quickly all versions of one application. If any version in a cluster is awarded, all other applications within the cluster will be automatically withdrawn without any additional action by applicants or staff.

Investigators who have submitted multiple versions of an application and have not been successful often ask NIH what constitutes a “new application.” It is recognized that investigators are trained in a particular field of science and are not likely to make drastic changes in their research interests. However, a new application following multiple reviews is expected to be substantially different in content and scope with more significant differences than are normally encountered in a Resubmission application. Simply rewording the title and Specific Aims or incorporating minor changes in response to comments in the previous Summary Statement does not constitute a substantial change in scope or content. Changes to the Research Plan should produce a significant change in direction and approach for the research project. Thus, a new application would include substantial changes in all sections of the Research Plan, particularly the Specific Aims and the Research Strategy sections.

In the referral process, NIH staff look at all aspects of the application, not just the title and Project Summary. Requesting review by a different review committee does not affect the implementation of this policy. When necessary, previous applications are analyzed for similarities to the present one. Thus, identical applications or those with only minor changes will not be accepted for review. If identified after assignment or review, identical applications will be withdrawn.

2.8 Revision Application

A Revision application (formerly called a competing supplement) may be submitted to request support for a significant expansion of a project's scope or research protocol. Revision applications are not appropriate when the sole purpose is to restore awards to the full SRG-recommended level if they were administratively reduced by the funding agency. **A Revision application must not be submitted until after the original application has been awarded and must not extend beyond the term of the current award period.**

Introduction: Provide a one-page introduction at the beginning of the Research Plan (see 5.5.1) that describes the nature of the revision and how it will influence the Specific Aims and Research Strategy of the current grant. The body of the application should contain sufficient information from the original grant application to allow evaluation of the proposed revision in relation to the goals of the original application. Note that all revision applications must be submitted by the same PD/PI (or contact PD/PI for multi-PI grants) as listed on the current award and applicants must use the same budget format as the current award. Any budgetary changes for the remainder of the project period of the current grant should be discussed under the budget justification.

If the Revision application relates to a specific line of investigation presented in the original application that was not recommended for approval by the SRG, then the applicant must respond to the criticisms in the prior Summary Statement, and substantial changes must be clearly evident and summarized in the Introduction.

Administrative Supplements

An administrative supplement provides additional funding to meet increased costs that are within the scope of an approved application, but that were unforeseen when the new or competing Renewal application was submitted. If considering administrative supplemental funding, consult in advance with the designated Grants Management Officer and Program Official. It is important to submit a request before the grant expires. To be considered for an administrative supplement, submit a request in writing to the Institute/Center, not to the Division of Receipt and Referral, Center for Scientific Review. The request must be signed by the authorized Business Official and describe the need for additional funding and the categorical costs. In the letter, point out what will NOT be accomplished if such a request is denied. Administrative supplements may **not** be submitted using the 398 Application.

2.9 Similar, Essentially Identical, or Identical Applications

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. 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. 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; and 2) an application for a research project identical to a subproject of a program project or center grant application.

2.10 (Reserved)

2.11 (Reserved)

2.12 (Reserved)

2.13 Post-Submission of Application Materials

Grant application materials will only be accepted after submission of the application but before the initial peer review if they result from unforeseen administrative issues. Exceptions to this policy are indicated below. See NOT-OD-10-091 for additional information.

The materials should be sent as a PDF attachment to an e-mail. E-mail communication is preferred. If e-mail is not feasible, please send in a hard copy.

The original application is kept intact; any application material sent post-submission is sent separately to reviewers. Updated or supplemental grant application materials used in the peer review process will be retained as part of the official grant file and remain part of the permanent record for that application.

Acceptable post-submission materials include:

- Revised budget page(s) (e.g., change in budget request due to new funding or institutional acquisition)
- Biographical sketches (e.g., change in senior/key personnel due to the loss of an investigator)
- Letters of support or collaboration resulting from a change in senior/key personnel due to the loss of an investigator
- Adjustments resulting from natural disasters (e.g., loss of an animal colony)
- Adjustments resulting from change of institution (e.g., PI moved to another university)
- News of an article accepted for publication

Unacceptable post-submission materials [for all applications but those under Exceptions below] include:

- Updated Specific Aims or Research Strategy pages
- Late-breaking research findings
- Supplemental pages - information not contained in the existing application
- New letters of support or collaboration that do not result from a change in senior/key personnel due to the loss of an investigator

Exceptions to this policy include:

- Applications submitted in response to Requests for Applications (RFAs) that have only one due date. Post-submission materials for these applications will be accepted as outlined in NOT-OD-10-070
- Applications for training grants (see NOT-OD-10-104)
- Certain NIH Funding Opportunity Announcements (FOAs) may allow certain other types of post-submission materials to facilitate the goals of the program. Such stipulations must be explained in the FOA in the NIH Guide for Grants and Contracts

Page limits for post-submission materials under the new policy:

- All post-submission materials must conform to NIH policy on font size, margins, and paper size as referenced in Part I.2.6 of the applicable application instructions
- NIH additional form pages such as budget, biographical sketches, and other required forms must follow NIH standards for required NIH form pages.
- If post-submission material is not required on a form page, each explanation or letter is limited to one page (see Acceptable post-submission materials above)
- If the application has subprojects or cores, each subproject or core is allowed explanations or letters (see Acceptable post-submission materials above), but each explanation or letter is limited to one page

The additional materials must be submitted to the NIH SRO with the concurrence of the applicant organization's designated AOR/SO. Although the content of post-submission materials may originate from the PD/PI, Contact PD/PI for multiple PD/PI applications, or organizational officials, the AOR must send the materials directly to the SRO, or must send his/her concurrence to the PD/PI who will forward the materials and concurrence to the SRO. A communication from the PD/PI only or with a "cc" to the AOR will not be accepted.

The deadline for receipt of additional materials is one month (30 calendar days) prior to the peer review meeting. FOAs may provide stricter or more lenient guidance.

After the initial peer review phase is completed, the NIH Chief Grants Management Officer is the NIH official responsible for accepting additional materials. Most of the material submitted after the initial peer review can be submitted as part of the Just-in-Time process (see Part III, 1.7).

2.14 Application Submission Dates

Paper application submission dates fall under two different categories: 1) Standard Postmark/Submission Dates (also known as "send by" dates) and 2) Special Receipt Dates (also known as "arrive by" dates) which are specified in RFAs and PAs.

Applications submitted for the standard submission dates listed at http://grants.nih.gov/grants/dates.htm are considered on time if they are sent on or before the appropriate date listed and a proof of mailing is provided. The critical determination is when the application is sent, not when it arrives at NIH. Proof of timely mailing consists of one of the following: a legibly dated U.S. Postal Service postmark, or a dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks are not acceptable.

Weekend/Federal holiday submission dates. If a submission date falls on a weekend, it will be extended to the following Monday; any time the date falls on a Federal holiday the submission date will be extended to the following business day. The application will be on time if it is sent on or before the following business day.

Funding Opportunity Announcements (RFAs and PARs). Applications in response to announcements with special receipt dates must be received at NIH by the specified date. However, an application received after the deadline may be acceptable if it carries a legible proof-of-

mailing date assigned by the carrier not later than 1 week prior to the deadline date. Note that this differs from the procedures for submitting applications for the standard due dates, which are considered submission or "send by" dates.

Modified Application Submission and Review Policy. A continuous submission process is available to appointed members of chartered standing NIH Study Sections, Boards of Scientific Counselors, Advisory Boards or Councils, Program Advisory Committees, and peer reviewers who have served as regular or temporary members of peer review committees six times in 18 months. This alternative submission and review process is limited to R01, R21, and R34 application that would normally be received on standard submission dates. See the Peer Review Policies & Practices, Continuous Submission web page for additional information on the continuous submission process and eligibility requirements.

Late applications. Permission is **not** granted in advance for submission of a late application. Late applications are accepted only in extenuating circumstances. If an application is submitted late, a cover letter explaining the reasons for the delay **must** be included with the signed, completed application. Late applications are evaluated on an individual basis considering the reasons provided. Contacting the Division of Receipt and Referral in advance will not influence the acceptance of a late application. For additional information on late applications, see NIH Guide Notices OD-08-027 and OD-08-111.

2.15 Submission, Review and Award Cycles

The PHS submission, review, and award schedule is provided at this website: http://grants.nih.gov/grants/dates.htm. Note that many activity codes have transitioned to electronic submission and the SF424 (R&R) application and instructions. The PHS 398 should only be used for those activity codes where the Application Form is identified as PHS 398. Applicants should refer to the OER Electronic Submission of Grant Applications website, http://grants.nih.gov/grants/ElectronicReceipt/ for details on the transition to electronic submission.

For specialized grant applications, consult with the appropriate PHS agency prior to the preparation of an application.

Application Assignment Information

Competing grant applications submitted to the PHS agencies will be processed through the Division of Receipt and Referral, CSR, unless otherwise stated. Administrative information about the application is entered into a computer system. The application will be assigned to an appropriate Scientific Review Group and awarding component(s). Assignment is based on the scientific content of the application using established referral guidelines. Business rule validations are conducted by NIH staff.

Assignment to Review Group. The Center for Scientific Review (CSR) will assign appropriately completed applications to the Scientific Review Groups (commonly referred to as "SRGs" or "study sections") that will perform the scientific/technical merit review. The CSR lists the recurring review panels (http://cms.csr.nih.gov/PeerReviewMeetings/CSRIRGDescription/), and you may suggest a specific group in the PHS 398 Cover Letter component. See Part I, Section 3.1 for a suggested format for requesting a specific SRG in the Cover Letter.

Assignment to Relevant Potential Awarding Component(s) (ICs). In addition, CSR will assign each application to the agency awarding component that is the potential funding component. When the scientific areas and the research proposed in a grant application are sufficiently relevant to the program responsibilities of two or more awarding components, CSR may assign your application to all such components. The component that has the most relevant program responsibility is designated as the primary assignee. The other components that have an interest in your application are designated as secondary assignees. If your application is eligible for funding and the primary assignee does not intend to make an award, the secondary assignees will be given the opportunity to do so. Although

these suggestions will be taken into consideration, the final determination will be made by the agencies participating in this solicitation.

After the submission date, usually within 2 weeks, the following information regarding the grant application will be available in the NIH eRA Commons for viewing by the PD/PI(s) and an authorized organization official:

- application assignment number;
- name, address, and telephone number of the Scientific Review Officer of the Scientific Review Group to which the application has been assigned for peer review; and
- assigned Institute/Center information.

If assignment information is not available in the eRA Commons within two weeks of the submission date, contact the Division of Receipt and Referral, Center for Scientific Review (CSR), National Institutes of Health, Bethesda, MD 20892-7720, (301) 435-0715. If there is a change in assignment, you will receive a notification and the change will be reflected in the eRA Commons.

Applicants must **not** communicate directly with any review group member about an application either before or after the review. Failure to strictly observe this policy will create serious breaches of confidentiality in the peer review process. From the time of assignment to the time the review of the application is complete, applicant investigators must direct all questions to the Scientific Review Officer. This individual is in charge of the review group and is identified in the eRA Commons.

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 Commons Helpdesk:

eRA Commons Helpdesk: http://ithelpdesk.nih.gov/eRA/

eRA Commons Helpdesk Email: commons@od.nih.gov

eRA Commons Phone: 301-402-7469
866-504-9552 (Toll Free)
301-451-5939 (TTY)

The eRA Commons Helpdesk hours of operation are Monday-Friday from 7:00 a.m. to 8:00 p.m. Eastern Time.

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: 301-435-0714
301-451-5936 (TTY)

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 Part I, 2.13 Submission of Supplementary or Corrective Information, and NOT-OD-07-018).

3.1 Cover Letter

Applicants are encouraged to include a cover letter with the 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.

- Application title.
- Funding Opportunity Announcement (PA, RFA or Parent Announcement title, if applicable).
- Request of an assignment (referral) to a particular IC or Scientific Review Group (SRG). While requests are given careful consideration, the PHS makes the final determination for assignments. (See suggested format below.)
- List of individuals (e.g., competitors) who should not review the application and why.
- Disciplines involved, if multidisciplinary.
- Statement that any required NIH approval documentation for the type of application submitted is enclosed. This may include approval for applications requesting $500,000 or more, approval for Conference Grant, Cooperative Agreement, etc.
- For late applications (see Late Application Policy), include an explanation of the delay as part of the cover letter.

Suggested Cover Letter Format

The Division of Receipt and Referral (DRR), Center for Scientific Review (CSR) is responsible for assigning applications to ICs and to Scientific Review Groups (SRGs). DRR will be utilizing knowledge management approaches as an adjunct to the work of referral experts as part of an overall plan to shorten the time from submission to review. Analysis has shown that requests made by investigators are a valuable source of information in this process. In order to facilitate the use of these requests in conjunction with knowledge management analysis of the content of the application, applicants are requested to use the following format when assignment requests are contained in a cover letter.

- List one request per line.
- Place Institute/Center (IC) and SRG review requests (if both are made) on separate lines.
- Place positive and negative requests (if both are made) on separate lines.
- Include name of IC or SRG, followed by a dash and the acronym. Do not use parentheses.
- Provide explanations for each request in a separate paragraph.

Examples:

Please assign this application to the following:

Institutes/Centers

National Cancer Institute - NCI

National Institute for Dental and Craniofacial Research – NIDCR

Scientific Review Groups

Molecular Oncogenesis Study Section – MONC

Cancer Etiology Study Section – CE

Please do not assign this application to the following:

Scientific Review Groups

Cancer Genetics Study Section – CG

The reasons for this request are [provide a narrative explanation for the request(s)].

3.2 Number of Copies

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

Do not include more than one application (original plus 5 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.

Five 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.

Five 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 http://grants.nih.gov/grants/ guide/notice-files/NOT-OD-03-040.html.

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 http://grants.nih.gov/grants/funding/phs398/phs398.html.

- *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 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.

Item 1. Title of Project

Do not exceed 81 characters, including the spaces between words 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.

Item 2. Response to Specific Request for Applications (RFA) or Program Announcement (PA)

Check "Yes" and insert the appropriate announcement number (e.g., PA-06-512) 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.

Item 3. Program Director(s)/Principal Investigator(s) (PD/PI)

Item 3a. Name of Program Director/Principal Investigator (PD/PI)

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 items 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.

Item 3b. Degree(s)

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

Item 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).

Item 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).

Item 3e. Department, Service, Laboratory, or Equivalent

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

Item 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."

Item 3g. Telephone and Fax Numbers

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

Item 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.

Item 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 Item 4 are then not applicable.

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 DHHS regulatory requirements for the protection of human subjects (see Exemption Categories).

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 item 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.

NIH does not require certification of review and IRB approval of proposed research prior to NIH peer review of an application (see http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-031.html and Part II, Human Subjects Research supplemental instructions). However, any modification of the Research Plan section of the application required by the IRB or to address human subjects concerns raised during review, must be submitted for approval before award. See also the Just-In-Time Policy and IRB Approval.

The DHHS regulations "Protection of Human Subjects" (45 CFR Part 46, administered by OHRP) define a human subject as "a living individual about whom an investigator conducting research obtains: data through *intervention* or *interaction* with the individual or *identifiable private information*." See Part III.3 for the definitions of italicized terms used in the definition of human subject.

To help determine whether research that involves the use of human data or biological specimens is human subjects research, refer to http://grants.nih.gov/grants/policy/hs/.

Additional information is available at:

- OHRP Decision Charts: http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html
- OHRP Guidance on Repositories: http://www.hhs.gov/ohrp/policy/reposit.html; http://www.hhs.gov/ohrp/policy/engage08.html
- OHRP Memo on Engagement: http://www.hhs.gov/ohrp/policy/engage08.html

Item 4a. Exemptions from Department of Health and Human Services (DHHS) Human Subjects Regulations

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 six exemption categories listed in Part III under Human Subjects Research Definitions and Terms.

OHRP guidance states that appropriate use of Exemptions described in 45 CFR 46 should be determined by an authority independent from the investigators (http://answers.hhs.gov/ohrp/categories/1564). 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 item 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 Item 4.

Item 4b. Human Subjects Assurance Number

If the applicant organization has a current approved Federal Wide Assurance (FWA) on file with the OHRP (http://www.hhs.gov/ohrp/), enter the number in the space provided.

Enter "None" in Item 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 http://www.hss.gov/ohrp).

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

Item 4c. Clinical Trial

Check "Yes" or "No" to indicate whether the project includes a clinical trial. Refer to the definition of "clinical trial" in Part III.3, under Human Subjects Research Definitions and Terms.

Note that Public Law 110-85, enacted 09/27/2007, mandates registration and results reporting of applicable clinical trials in ClinicalTrials.gov (see Part II, 4.1.6 and Part III, 2.1.6).

Item 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" in Part III.3, under Human Subjects Research Definitions and Terms.

Item 5. Vertebrate Animals

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

Check “Yes” if activities involving vertebrate animals are anticipated or planned at any time during the proposed project period, either at the applicant organization or at any other Project/Performance Site or collaborating institution. If animal involvement is anticipated within the period of award but plans are indefinite and it is not possible to describe the use of animals, check "Yes" and in the Research Plan, item 12, provide an explanation and indicate when it is anticipated that animals will be used. Before activities with animals begin, the applicant must provide all of the information required by 5.5, Research Plan, item 12, Vertebrate Animals, with verification of current IACUC approval, to the awarding component for prior approval. IACUC approval must have occurred within the past three years to be considered current.

NIH does not require verification of review and approval of the proposed research by the Institutional Animal Care and Use Committee (IACUC) before peer review of the application. However, this information is required under Just-In-Time Policy.

Item 5a. Animal Welfare Assurance

If the applicant organization has a current approved Animal Welfare Assurance on file with the Office of Laboratory Animal Welfare (OLAW), enter the Assurance number of the applicant organization in Item 5a. To determine whether the organization holds an Animal Welfare Assurance, contact the IACUC or see http://grants.nih.gov/grants/olaw/olaw.htm#assur.

Enter “None” in Item 5a if the applicant organization does not have an Animal Welfare Assurance on file with OLAW. **Do not enter the Animal Welfare Assurance number of any Project/Performance Site or collaborating institution.** The signature on the Face Page constitutes declaration that the applicant organization will comply with PHS Policy on Humane Care and Use of Laboratory Animals by submitting an Animal Welfare Assurance when requested by OLAW and providing verification of IACUC approval when requested by the PHS awarding component.

Item 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 at http://grants.nih.gov/grants/dates.htm 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 Items 7 and 8 and on the budget pages must be in U.S. dollars.

Item 7. Costs Requested for Initial Budget Period

Item 7a. Direct Costs

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

Item 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 Item 7b includes any consortium F&A costs.

Item 8. Costs Requested for Proposed Period of Support

Item 8a. Direct Costs

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

Item 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 Item 8b includes any consortium F&A costs. Please ensure number(s) complies with application requirements.

Item 9. Applicant Organization

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

Item 10. Type of Organization

Check the appropriate box. See definitions of Applicant Organization Types definitions in Part III, 3.

Item 11. Entity Identification Number, DUNS Number, Congressional 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 item.

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. To locate the appropriate district see http://congress.org/congressorg/dbq/officials/?lvl=L.

Item 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.

Item 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.

Item 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 Assurances and Certifications listed below are explained in Part III: Policies, Assurances, Definitions, and Other Information. Applicants and grantees must comply with a number of additional public policy requirements. Refer to the *NIH Grants Policy Statement* (http://grants.nih.gov/grants/policy/policy.htm) for additional information.

The policies, assurances and certifications listed below may or may not be applicable to the project, program, or type of applicant organization. If unable to certify compliance, provide an explanation and place it after the Checklist Form Page (5.6).

Human Subjects Research

Research on Transplantation of Human Fetal Tissue

Research Using Human Embryonic Stem Cells

Women and Minority Inclusion Policy

Inclusion of Children Policy

ClinicalTrials.gov Requirements

Vertebrate Animals

Debarment and Suspension

Drug-Free Workplace

Lobbying

Non-Delinquency on Federal Debt

Research Misconduct

Civil Rights

Handicapped Individuals

Sex Discrimination

Age Discrimination

Recombinant DNA, including Human Gene Transfer Research

Financial Conflict of Interest

Smoke-Free Workplace

Prohibited Research

Select Agent Research

Program Director/Principal Investigator(s) Assurance

Impact of Grant Activities on the Environment and Historic Properties

Institutions Receiving Awards for Training of Graduate Students for Doctoral Degrees

4.2 Description, 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.

4.2.1 Description: Project Summary and Relevance

The first and major component 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 component 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.

4.2.2 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 GPS.

For research involving live vertebrate animals, the applicant organization must ensure that all Project/Performance Sites hold OLAW-approved Assurances. If the applicant organization does not have an animal program or facilities and the animal work will be conducted at an institution with an Assurance, the applicant must obtain an Assurance from OLAW prior to an award.

4.2.3 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.*

4.2.4 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.

4.2.5 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 stem cell registry found at: http://stemcells.nih.gov/research/registry/eligibilityCriteria.asp. 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. Place page numbers at the bottom of each page, and consecutively number pages throughout the application. **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 item 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 Policy on the Acceptance for Review of Unsolicited Applications That Request $500,000 or More in Direct Costs**.)** The following items pertain individually 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.

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 Definitions in Part III.3.

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 Web site 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: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-017.html.

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, 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 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.

Patient 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 DHHS-negotiated research patient care rate agreement and, if not, what basis is used for calculating costs. If an applicant does not have a DHHS-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. **Justify costs on Form Page 5.**

Consortium/Contractual 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 Item 7a, use the “Subtotal Direct Costs for Initial Budget Period” on Form Page 4.

For Face Page Item 7b, 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 Item 8a, total the “Subtotal Direct Costs” for all years on Form Page 5 (see 4.5 below).

For Face Page Item 8b, 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 Period of Support

FORM PAGE 5

In the first column 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 for Foreign Application or Component

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. For a definition of foreign component, see Definitions in Part III.3.

4.6 Biographical Sketch

BIOGRAPHICAL SKETCH FORMAT PAGE

Follow the instructions on the Biographical Sketch Format Page. This section must contain the biographical sketches of all individuals listed as **Senior/key Personnel and Other Significant Contributors**, following the order as listed on Form Page 2.

All individuals who have the PD/PI role **must** be registered in the eRA Commons, and **must** include the assigned Commons User Name. This information is required, and is equivalent to the “Credential,

e.g., agency login" in the federal-wide SF 424 (R&R) Senior/Key Person Profile. For information on the eRA Commons, see https://commons.era.nih.gov/commons/index.jsp.

Use the sample format on the Biographical Sketch Format Page to prepare this section for **all** grant applications. The Biographical Sketch may not exceed 4 pages. This 4-page limit includes the table at the top of the first page. (See sample of a completed Biographical Sketch: http://grants.nih.gov/grants/funding/phs398/phs398.html#biosample.)

Complete the educational block at the top of the format page beginning with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training, separately referencing residency training when applicable. For each entry provide the name and location of the institution, the degree received (if applicable) the month and year the degree was received; and the field of study. For residency entries, the field of study section should reflect the area of residency.

Following the educational block, complete sections A, B, C and D:

A. Personal Statement. Briefly describe why your experience and qualifications make you particularly well-suited for your role (e.g., PD/PI, mentor, participating faculty) in the project that is the subject of the application. Within this section you may, if you choose, briefly describe factors such as family care responsibilities, illness, disability, and active duty military service that may have affected your scientific advancement or productivity.

B. Positions and Honors. List in chronological order previous positions, concluding with the present position. List any honors. Include present membership on any Federal Government public advisory committee.

C. Selected Peer-reviewed Publications. NIH encourages applicants to limit the list of selected peer-reviewed publications or manuscripts in press to no more than 15. Do not include manuscripts submitted or in preparation. The individual may choose to include selected publications based on recency, importance to the field, and/or relevance to the proposed research. 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." A list of these Journals is posted at: http://publicaccess.nih.gov/submit_process_journals.htm. Citations that are not covered by the Public Access Policy, but are publicly available in a free, online format may include URLs or PubMed ID (PMID) numbers along with the full reference (note that copies of publicly available publications are not acceptable as appendix material.)

D. Research Support. List both selected ongoing and completed research projects for the past three years (Federal or non-Federally-supported). *Begin with the projects that are most relevant to the research proposed in the application.* Briefly indicate the overall goals of the projects and responsibilities of the key person identified on the Biographical Sketch. Do not include number of person months or direct costs.

Do not confuse "Research Support" with "Other Support." Though they sound similar, these parts of the application are distinctly different. 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 individual's qualifications for a specific role in the proposed project, as well as to evaluate the overall qualifications of the research team. In contrast, "Other Support" information is required for all applications that are selected to receive grant awards and includes detailed financial information (see Part I, 4.6.1). NIH staff will request complete and up-to-date "Other Support" information *after* peer review. This information will be used to check that the proposed research is not already funded through other sources.

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

4.6.1 Other Support Information

OTHER SUPPORT FORMAT PAGE

Do not submit unless requested by the NIH Institute/Center (IC).

There is no form page for Other Support. Follow the sample format on the Other Support Format Page. The sample is intended to provide guidance regarding the type and extent of information requested.

The following instructions should be followed in completing the information:

- Information on active and pending Other Support is required for Senior/key Personnel, excluding consultants. For individuals with no active or pending support, indicate “None.” Neither the application under consideration nor the current PHS award for this project should be listed as Other Support. Do not include Other Support for individuals listed as "Other Significant Contributors" unless their involvement has changed so that they now meet the definition of "Senior/key Personnel."
- If the support is provided under a consortium/subcontract arrangement or is part of a multiproject award, indicate the project number, PD/PI, and source for the overall project, and provide all other information for the subproject only.

Instructions for Selected Items

Project Number: If applicable, include a code or identifier for the project.

Source: Identify the agency, institute, foundation, or other organization that is providing the support. Include institutional, federal, public and private sources of support.

Major Goals: Provide a brief statement of the overall objectives of the project, subproject, or subcontract.

Dates of Approved/Proposed Project: Indicate the inclusive dates of the project as approved/proposed. For example, in the case of NIH support, provide the dates of the approved/proposed competitive segment.

Annual Direct Costs: In the case of an active project, provide the current year’s direct cost budget. For a pending project, provide the proposed direct cost budget for the initial budget period.

Percent Effort/Person Months: For an active project, provide the level of actual effort in person months (even if unsalaried) for the current budget period. Person months should be classified as academic, calendar and/or summer. For a pending project, indicate the level of effort in person months as proposed for the initial budget period. In cases where an individual’s appointment is divided into academic and summer segments, indicate the proportion of each devoted to the project.

Overlap: After listing all support, summarize for each individual any potential overlap with the active or pending projects and this application in terms of the science, budget, or an individual’s committed effort.

Special Instructions for Individuals with Multiple Research Appointments (e.g., dual university/Department of Veterans Affairs appointments)

When an individual holds multiple appointments involving support for research activities, information from each appointment must be included separately in the Other Support documentation. The support

from each funding source should be clearly and separately delineated so that the separate appointments can be considered independently when determining any potential overlap.

List each appointment separately and include enough information on the type of appointment; (e.g., full time academic or 6/8 VA) so that an assessment of an individual's commitment can be made. Within each appointment, include appropriate sources of research support providing the standard detailed information cited above.

Note that when an individual has multiple appointments it is possible that the combined effort can result in excess of 12 calendar months (not from any one institution, but a combination of multiple appointments). In all cases, an individual's combined total professional effort must meet a test of reasonableness.

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, 5.5.11 (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. The Commons ID is required for all PD/PIs and all individuals with a postdoctoral role; it is optional 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 Research Plan consists of items 1-15 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 http://grants.nih.gov/grants/grant_tips.htm. Carefully follow all instructions.

Page Limits

All applicants must follow the page limits described in 2.6, 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.

Applicants are prohibited from using the appendix to circumvent page limits in any section of the application for which for which a page limit applies. For additional information regarding Appendix material and page limits, refer to NIH Guide Notice NOT-OD-10-077.

Use of URLs

Unless otherwise specified in a solicitation, Internet website addresses (URLs) may not be used to provide information necessary to the review because reviewers are not obligated to view the Internet sites. Moreover, reviewers are cautioned that they should not directly access an Internet site (except to review publications cited in the Biographical Sketch or Progress Report Publication List) as it could compromise their anonymity.

Other Materials

Do not include photographs or other materials that are not printed directly on the application page in the body of the application. Pictures or other materials glued or taped into the application pages are incompatible with the duplication/scanning process.

PDF images of material such as electron micrographs or gels may be included in the Appendix; however, a photocopy of each must also be included within the page limits of the Research Strategy (see Section 5.7).

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. 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.

5.5 Content of Research Plan

The Research Plan consists of the following items (5.5.1 – 5.5.15), 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 in Part I, 2.6, unless specified otherwise in the FOA. If the activity code is not listed in the table of page limits, follow the page limits required 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. Inclusion Enrollment Report (Resubmission or Revision Applications only)
5. Bibliography and References Cited/Progress Report Publication List
6. Protection of Human Subjects
7. Inclusion of Women and Minorities
8. Targeted/Planned Enrollment Table
9. Inclusion of Children
10. Vertebrate Animals
11. Select Agent Research
12. Multiple PD/PI Leadership Plan
13. Consortium/Contractual Arrangements
14. Letters of Support (e.g., Consultants)
15. Resource Sharing Plan(s)

5.5.1 Introduction (Resubmission or Revision Applications only)

See specific instructions in 2.7 Resubmission Applications and 2.8 Revision Applications on the content of the Introduction. First time (new) applications should not include an Introduction unless specified in the FOA.

The Introduction is a required attachment for Resubmissions and Revisions. The Introduction is limited to one page unless specified otherwise in the FOA.

5.5.2 Specific Aims

State concisely the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will exert on the research field(s) involved.

List succinctly the specific objectives of the research proposed, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology.

The Specific Aims attachment is required unless otherwise specified in the FOA. Specific Aims are limited to one page.

5.5.3 Research Strategy

Organize the Research Strategy in the specified order and using the instructions provided below. 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 (item 5.5.5).

Follow the page limits for the Research Strategy in the Table of Page Limits, unless specified otherwise in the FOA.

(a) Significance

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

(b) 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.

(c) Approach

- Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Unless addressed separately in Item 5.5.15, include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate.

- 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.
- Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised. A full discussion on the use of Select Agents should appear in 5.5.11 below.
- 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.

If an applicant has multiple Specific Aims, then the applicant may address Significance, Innovation and Approach for each Specific Aim individually, or may address Significance, Innovation and Approach for all of the Specific Aims collectively.

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

- ***Preliminary Studies for New Applications.*** For new applications, include information on Preliminary Studies. Discuss the PD/PI's preliminary studies, data, and/or experience pertinent to this application. Except for Exploratory/Development Grants (R21/R33), Small Research Grants (R03), Academic Research Enhancement Award (AREA) Grants (R15), and Phase I Small Business Research Grants (R41/R43), preliminary data can be an essential part of a research grant application and help to establish the likelihood of success of the proposed project. Early Stage Investigators should include preliminary data. (However, for R01 applications, reviewers will be instructed to place less emphasis on the preliminary data in applications from Early Stage Investigators than on the preliminary data in applications from more established investigators.)
- ***Progress Report for Renewal and Revision Applications.*** For renewal/revision applications, provide a Progress Report. Provide the beginning and ending dates for the period covered since the last competitive review. Summarize the specific aims of the previous project period and the importance of the findings, and emphasize the progress made toward their achievement. Explain any significant changes to the specific aims and any new directions including changes resulting from significant budget reductions. A list of publications, manuscripts accepted for publication, patents, and other printed materials should be included in 5.5.5 (Progress Report Publication List); do not include that information here.

5.5.4 Inclusion Enrollment Report (Renewal or Revision Applications only)

If the Renewal or Revision application involves clinical research, then you must report on the enrollment of research subjects and their distribution by ethnicity/race and sex/gender using the Inclusion Enrollment Report for each protocol.

5.5.5 Bibliography and References Cited/Progress Report Publication List

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. When citing articles in (a) or (b) below 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." A list of these Journals is posted at: http://publicaccess.nih.gov/submit_process_journals.htm. Citations that are not covered by the Public Access Policy, but are publicly available in a free, online format may include URLs or PubMed ID (PMID) numbers along with the full reference (note that copies of these publications are not accepted as appendix material, see Section 5.7).

(a) Bibliography and References Cited - Provide a bibliography of any references cited in the Research Plan. Each reference must include names of all authors (in the same sequence in which they appear in the publication), the article and journal title, book title, volume number, page numbers, and year of publication. Include only bibliographic citations. Follow scholarly practices in providing citations for source materials relied upon in preparing any section of the application.

The references should be limited to relevant and current literature. While there is not a page limitation, it is important to be concise and to select only those literature references pertinent to the proposed research.

(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.

5.5.6 Protection of Human Subjects

Refer to Part II of the PHS 398: Supplemental Instructions for Preparing the Protection of Human Subjects Section of the Research Plan if the proposed research will involve human subjects.

If the proposed research will not involve human subjects but involves human specimens and/or data from subjects, applicants must provide a justification in this section for the claim that no human subjects are involved.

Do not use the protection of human subjects section to circumvent the page limits of the Research Strategy.

5.5.7 Inclusion of Women and Minorities

To determine if Inclusion of Women and Minorities applies to the application, see Part II Supplemental Instructions for Preparing the Protection of Human Subjects Section of the Research Plan, Sections 4.2 and 5.6.

5.5.8 Targeted/Planned Enrollment Table

If this application involves the Inclusion of Women and Minorities, complete the Targeted/Planned Enrollment Table for each protocol; see Part II Supplemental Instructions for Preparing the Protection of Human Subjects Section of the Research Plan, Section 4.3.

5.5.9 Inclusion of Children

To determine if Inclusion of Children applies to the application, see Part II Supplemental Instructions for Preparing the Protection of Human Subjects Section of the Research Plan, Sections 4.4 and 5.7.

5.5.10 Vertebrate Animals

If vertebrate animals are involved in the project, address each of the five points below. This section should be a concise, complete description of the animals and proposed procedures. While additional details may be included in the Research Strategy, the responses to the five required points

below must be cohesive and include sufficient detail to allow evaluation by peer reviewers and NIH staff.

If all or part of the proposed research involving vertebrate animals will take place at alternate sites (such as project/performance or collaborating site(s)), identify those sites and describe the activities at those locations.

Although no specific page limitation applies to this section of the application, be succinct. Failure to address the following five points will result in the application being designated as incomplete and will be grounds for the PHS to defer the application from the peer review round. Alternatively, the application's impact/priority score may be negatively affected.

If the involvement of animals is indefinite, 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 submit to the NIH awarding office detailed information as required in 1-5 above and verification of IACUC approval. If the grantee does not have an Animal Welfare Assurance then an appropriate Assurance will be required (see Part III, 2.2).

The five points are as follows:

1. Provide a detailed description of the proposed use of the animals for the work outlined in the Research Strategy section. Identify the species, strains, ages, sex, and numbers of animals to be used in the proposed work.
2. Justify the use of animals, the choice of species, and the numbers to be used. If animals are in short supply, costly, or to be used in large numbers, provide an additional rationale for their selection and numbers.
3. Provide information on the veterinary care of the animals involved.
4. Describe the procedures for ensuring that discomfort, distress, pain, and injury will be limited to that which is unavoidable in the conduct of scientifically sound research. Describe the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices, where appropriate, to minimize discomfort, distress, pain, and injury.
5. Describe any method of euthanasia to be used and the reason(s) for its selection. State whether this method is consistent with the recommendations of the American Veterinary Medical Association (AVMA) Guidelines on Euthanasia. If not, include a scientific justification for not following the recommendations.

Do not use the vertebrate animal section to circumvent the page limits of the Research Strategy.

5.5.11 Select Agent Research

Select Agents are hazardous biological agents and toxins that have been identified by DHHS 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 maintains a list of these agents; see http://www.cdc.gov/od/sap/docs/salist.pdf.

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 section 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 at http://www.cdc.gov/od/sap/sap/exclusion.htm.

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 DHHS for an exclusion from the list, use this section to indicate the status of the request or the intent to apply for an exclusion and provide a brief justification for the exclusion.

If any of the activities proposed in the application involve the use of Select Agents at any time during the proposed project period, either at the applicant organization or at any other Project/Performance Site, 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.

If you are responding to a specific Funding Opportunity Announcement (e.g., PA or RFA), address any requirements specified by the FOA.

Reviewers will assess the information provided in this section, and any questions associated with Select Agent research will need to be addressed prior to award.

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

For applications designating multiple PD/PIs, a leadership plan must be included. A rationale for choosing a multiple PD/PI approach should be described. The governance and organizational structure of the leadership team and the research project should be described, including communication plans, process for making decisions on scientific direction, and procedures for resolving conflicts. The roles and administrative, technical, and scientific responsibilities for the project or program should be delineated for the PD/PIs, including responsibilities for human or live vertebrate animal subject studies as appropriate. Do not submit a leadership plan if you are not submitting a Multiple PD/PI application.

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

5.5.13 Consortium/Contractual Arrangements

Explain the programmatic, fiscal, and administrative arrangements to be made between the applicant organization and the consortium organization(s). For applications including multiple PD/PIs, this information may be included as part of the Leadership Plan above. If consortium/contractual activities represent a significant portion of the overall project, explain why the applicant organization, rather than the ultimate performer of the activities, should be the grantee.

The signature of the Authorized Organization Representative on the Face Page 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.

5.5.14 Letters of Support (e.g., Consultants)

Provide all appropriate letters of support, including any letters necessary to demonstrate the support of consortium participants and collaborators such as Senior/Key Personnel and Other Significant Contributors included in the grant application. Letters are not required for personnel (such as research assistants) not contributing in a substantive, measurable way to the scientific development or execution of the project. Letters should stipulate expectations for co-authorship, and whether cell lines, samples or other resources promised in the letter are freely available to other investigators in the scientific community or will be provided to the particular investigators only. For consultants, letters should include rate/charge for consulting services and level of effort/number of hours per year anticipated. In addition, letters ensuring access to core facilities and resources should stipulate whether access will be provided as a fee-for-service. Do not place these letters in the Appendix. Consultant biographical sketches should be in the Biographical Sketch section.

5.5.15 Resource Sharing Plan(s)

NIH considers the sharing of unique research resources developed through NIH-sponsored research an important means to enhance the value and further the advancement of the research. When resources have been developed with NIH funds and the associated research findings published or provided to NIH, it is important that they be made readily available for research purposes to qualified individuals within the scientific community. See Part III, 1.5 Sharing Research Resources.

(a) Data Sharing Plan: Investigators seeking $500,000 or more in direct costs (exclusive of consortium F&A) in any year are expected to include a brief 1-paragraph description of how final research data will be shared, or explain why data-sharing is not possible. Specific Funding Opportunity Accouncements may require that all applications include this information regardless of the dollar level. Applicants are encouraged to read the specific opportunity carefully and discuss data-sharing plans with their program contact at the time they negotiate an agreement with the Institute/Center (IC) staff to accept assignment of their application. See Data-Sharing Policy or http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html.

(b) Sharing Model Organisms: Regardless of the amount requested, all applications where the development of model organisms is anticipated are expected to include a description of a specific plan for sharing and distributing unique model organisms or state why such sharing is restricted or not possible. See Sharing Model Organisms Policy, and NIH Guide NOT-OD-04-042.

(c) Genome-Wide Association Studies (GWAS): Regardless of the amount requested, applicants seeking funding for a genome-wide association study are expected to provide a plan for submission of GWAS data to the NIH-designated GWAS data repository, or an appropriate explanation why submission to the repository is not possible. GWAS is defined as any study of genetic variation across the entire genome that is designed to identify genetic associations with observable traits (such as blood pressure or weight) or the presence or absence of a disease or condition. For further information see Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies, NIH Guide NOT-OD-07-088, and http://gwas.nih.gov/.

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 http://www.iedison.gov. The grantee is encouraged to submit reports electronically using Interagency Edison (http://www.iedison.gov). See also "Inventions and Patents" in Part III, 1.6.

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 Part III and listed in Part 1, 4.1 under Item 14, be verified by the signature of the official signing for the applicant organization on the Face Page of the application.

3. Facilities and Administrative (F&A) Costs

Indicate the applicant organization's most recent F&A cost rate established with the appropriate DHHS 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 DHHS guidance for establishing indirect cost rates, and submitted to the appropriate DHHS 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 DHHS 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 DHHS and NIH requirements including, but not limited to, protection of human subjects, animal welfare, invention reporting, financial conflict of interest and research misconduct.

4. Disclosure Permission Statement

In the case this application does not result in an award, check "yes" to provide permission for the Government to disclose the title of the proposed project, and the name, address, telephone number and email address of the official signing for the applicant organization, to organizations that may be interested in contacting you for further information (e.g., possible collaborations, investment). Check "no" if you do not provide this permission. Your response will not affect any peer review or funding decisions.

5.7 Appendix

Graphs, diagrams, tables, and charts should be included in the body of the Research Strategy unless a PDF file is necessary to show detail. Not all activity codes allow publications to be included in the appendix. When publications are allowed, a limit of 3 publications, which are not publicly available, will be considered in the initial peer review (see below for further details and check the FOA for any specific instructions). A summary listing all of the items included in the appendix is encouraged, but not required. When including a summary, it should be the first file on the CD. Applications that do not follow the appendix requirements may be delayed in the review process.

Applicants are prohibited from using the appendix to circumvent page limits in any section of the application for which for which a page limit applies. For additional information regarding Appendix material and page limits refer to NOT-OD-11-080, http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-080.html.

Five identical CDs containing all appendix material must be submitted in the same package with the application. When preparing CDs:

- Use PDF format. Where possible, applicants should avoid creating PDF files from scanned documents. NIH recommends producing the documents electronically using text or word-processing software and then converting to PDF. Scanned documents are generally of poor quality and difficult to read.
- 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.

The following materials may be included in the appendix to New, Revision, Renewal and Resubmission applications (note, however, that some FOAs do not permit publications):

- Up to 3 publications of the following types. In each case include the entire document:
    - Manuscripts and/or abstracts accepted for publication but not yet published.
    - Manuscripts and/or abstracts published, but a free, online, publicly available journal link is not available.
    - Patents directly relevant to the project.

  (Do not include unpublished theses or abstracts/manuscripts **submitted**, (but not yet accepted), for publication.)
- Surveys, questionnaires, and other data collection instruments, clinical protocols, and informed consent documents.
- Photographs or color images of gels, micrographs, etc., **are no longer accepted as Appendix material**. These images must be included in the Research Strategy PDF. However, images embedded in publications are allowed.
- For materials that cannot be submitted on CD (e.g., medical devices, prototypes), applicants should contact the Scientific Review Officer for instructions following notification of assignment of the application to a SRG. Applicants are encouraged to be as concise as possible and submit only information essential for the review of the application.

Publications that are publicly accessible must not be included in the appendix. For such publications, the URL or PMC submission identification numbers along with the full reference should be included as

appropriate in the Bibliography and References Cited/Progress Report Publication List section, and/or the Biographical Sketch section.

6. The Peer Review Process

Overview

NIH policy is intended to ensure that applications for funding submitted to the NIH are evaluated on the basis of a process that is fair, equitable, timely, and conducted in a manner free of bias. The NIH dual peer review system is mandated by statute in accordance with section 492 of the Public Health Service Act and federal regulations governing "Scientific Peer Review of Research Grant Applications and Research and Development Contract Proposals" (42 CFR Part 52h).

The first level of review is carried out by a Scientific Review Group (SRG) composed primarily of non-federal scientists who have expertise in relevant scientific disciplines and current research areas. The second level of review is performed by Institute and Center (IC) National Advisory Councils or Boards. Councils composed of both scientific and lay members are chosen for their expertise, interest, or activity in matters related to health and disease. Only applications that are favorably recommended by both the SRG and the Advisory Council may be recommended for funding. Only the NIH Institute or Center may make actual funding decisions.

A detailed description of what happens to a research project grant application after it is received for peer review can be found at the following location: http://grants.nih.gov/grants/peer_review_process.htm. Additional information about charters and membership of SRGs, Councils, and Boards can be obtained from the appropriate agency. Information on CDC review procedures is located at http://www.cdc.gov/od/science/PHResearch/peerreview.htm.

Streamlining

The initial scientific peer review of most applications will also include a process in which only those applications deemed by the reviewers to have the highest scientific and technical merit, generally the better half of the applications under review, will be discussed at the SRG meeting, assigned an impact score, and receive a second level review. Applications in the lower half are reviewed by SRG members but they are not discussed or scored at the SRG meeting. This process allows the reviewers to focus their discussion on the most meritorious applications.

Before the review meeting, each reviewer and discussant assigned to an application will give a separate score for each of the five core review criteria and a preliminary impact score for that application (see below). The preliminary impact scores will be used to determine which applications will be discussed.

Scoring

SRG members are instructed to evaluate research applications by addressing the five core review criteria (see below) and additional review criteria as applicable for the application. However, Requests for Applications (RFAs) and other types of funding opportunities (e.g., construction grants and fellowship applications) may list different and/or additional review criteria and considerations.

For each application that is discussed, a final overall impact score will be given by each eligible committee member (without conflicts of interest) following the panel discussion. Each member's impact score will reflect his/her evaluation of the overall impact of the project in its entirety, rather than an arithmetic formula applied to the reviewer's scores given to each criterion. The final impact score for each discussed application will be determined by calculating the arithmetic average of all the eligible members' impact scores, and multiplying the average by 10.

As part of the initial merit review, and regardless of whether an application is discussed or not discussed (streamlined), all applicants will receive a written critique, called a Summary Statement, unless stated otherwise in the FOA. The Summary Statement represents a combination of the reviewers' written comments and scores for individual criteria. The Summary Statement for discussed applications includes the Scientific Review Officer's summary of the members' discussion during the SRG meeting; the final impact score; the recommendations of the SRG, including budget recommendations; and administrative notes of special considerations. For applications that are not discussed by the full committee, the scores of the assigned reviewers and discussants for the five core criteria will be reported individually on the Summary Statement. Final impact scores are not given for applications that are not discussed.

Research Project Evaluation Criteria

Overall Impact. Reviewers will provide an overall impact/priority score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following five core review criteria, and additional review criteria (as applicable for the project proposed).

Core Review Criteria. Reviewers will consider each of the five review criteria below in the determination of scientific and technical merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance. Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Investigator(s). Are the PD/PIs, collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

Innovation. Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Approach. Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?

If the project involves clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

Environment. Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

Additional Review Criteria. As applicable for the project proposed, reviewers will consider the following additional items in the determination of scientific and technical merit, but will not give separate scores for these items.

Protections for Human Subjects. For research that involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials.

Inclusion of Women, Minorities, and Children. When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children.

Vertebrate Animals. The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For additional information see http://grants.nih.gov/grants/olaw/VASchecklist.pdf.

Resubmission Applications. When reviewing a Resubmission application (formerly called an amended application), the committee will evaluate the application as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the project.

Renewal Applications. When reviewing a Renewal application (formerly called a competing continuation application), the committee will consider the progress made in the last funding period.

Revision Applications. When reviewing a Revision application (formerly called a competing supplement application), the committee will consider the appropriateness of the proposed expansion of the scope of the project. If the Revision application relates to a specific line of investigation presented in the original application that was not recommended for approval by the committee, then the committee will consider whether the responses to comments from the previous scientific review group are adequate and whether substantial changes are clearly evident.

Biohazards. Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

Additional Review Considerations. As applicable for the project proposed, reviewers will address each of the following items, but will not give scores for these items and should not consider them in providing an overall impact/priority score.

Budget and Period Support. Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

Select Agent Research. Reviewers will assess the information provided in this section of the application, including 1) the Select Agent(s) to be used in the proposed research, 2) the registration status of all entities where Select Agent(s) will be used, 3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

Applications from Foreign Organizations. Reviewers will assess whether the project presents special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions that exist in other countries and either are not readily available in the United States or augment existing U.S. resources.

Resource Sharing Plans. Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: 1) Data Sharing Plan (http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm); 2) Sharing Model Organisms (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html); and 3) Genome Wide Association Studies (GWAS) (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-088.html).

Dual-Level Peer Review

The second level of review will usually be performed by the Advisory Council or Board of the potential awarding component (Institute, Center, or other unit). Council or Board recommendations are based not only on considerations of scientific merit, as judged by the SRGs, but also on the relevance of the proposed study to an Institute/Center's mission, programs and priorities.