U.S. Department of Health and Human Services

Public Health Service

Grant Application (PHS 398)

PART I

Instructions

Form Approved Through 09/30/2007
OMB No. 0925-0001

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FOREWORD

The PHS 398 instructions contain information for preparing grant applications to the National Institutes of Health (NIH) and other Public Health Service agencies for:

Public Health Service (PHS) Research Grants

Career Development Awards (K-awards)

Institutional Ruth L. Kirschstein National Research Service Awards (NRSA) (Training Grants)

Small Business Innovation Research (SBIR) Grants

Small Business Technology Transfer (STTR) Grants

The PHS 398 is required for all applications for new, revised, competing continuation, and supplemental research grant, and research training grants, changes of grantee institution, and cooperative agreement applications.

Please be sure to bookmark this website (http://grants.nih.gov/grants/funding/phs398/phs398.html) for future reference and for instructions on submitting just-in-time Other Support information.

This edition of the PHS 398 has been extensively rewritten with special emphasis on clarity and special emphasis on simplicity and plain language. It has been reorganized into three distinct parts, each of which is available as a separate file in the MS Word and PDF versions. Principal investigators and institutions will need to use all three parts of the instructions in order to prepare a complete and acceptable application.

Part I: Instructions for Preparing the Application (MS Word) (PDF)

Part II: Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan (MS Word) (PDF)

Part III: Policies, Assurances, Definitions and Other Information (MS Word) (PDF)

The three files may be opened in your browser, or may be saved locally to your hard drive. If saved locally, the three files must be saved to the same folder/directory for the links between the files to function. (Refer to the Instructions for Downloading Documents and Electronic Forms http://grants.nih.gov/grants/edocs.htm and select Saving Files Locally.)

Within each part are links to pertinent sections of the PHS 398 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 the Application

Section I: Preparing your application

Section II: Submission and review of your application

Section III: Information pertinent to career development awards

Section IV: Information pertinent to institutional training grants

Section V: Information pertinent to SBIR and STTR applications

Part II: Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan (MS Word) (PDF)

Part II of the PHS 398 is to be used if your proposed research will involve human subjects. These instructions assist you in determining whether human subjects are involved and include six possible scenarios and detailed instructions to assist you in completing Item e. of the Research Plan (Human Subjects Research).

Part III: Policies, Assurances, Definitions and Other Information (MS Word) (PDF)

Part III of the PHS 398 includes information on policies, assurances, definitions, and other information relating to submission of applications for traditional, solicited and unsolicited, investigator-initiated, research project grants, and cooperative agreements to the PHS. Applicants should refer to this document as well as the PHS 398 instructional materials, Grants Information (GrantsInfo), and

Grants Policy Statement sections for additional sources of information.

The PHS 398 grant application instructions and interactive forms are available in electronic format. 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 09/2004) 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 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, many grant programs, in particular, grant programs of PHS agencies other than NIH, have additional specific instructions. Applicants should contact an official listed in the table of PHS agencies to obtain the most current information and instructions.

NIH Extramural Research and Research Training Programs

The NIH Office of Extramural Research Grants homepage (http://grants.nih.gov/grants/oer.htm) provides an array of helpful information. Applicants are encouraged to bookmark this site and visit it often.

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 mechanisms, the peer review system, and application procedures. Grants Information (GrantsInfo) is a communication service within the DEOIR. Information about the NIH extramural research and research training programs, funding opportunities, and the grant application process, can be obtained by e-mailing your request to: GrantsInfo@nih.gov or by calling (301) 435-0714.

Quick References

Applicants New to NIH: Getting Started

grants.nih.gov/grants/useful_links.htm

Award Data

(CRISP, extramural research grants, award trends, training and career awards)
grants1.nih.gov/grants/award/award.htm

Contact Information for an NIH Staff Person

directory.nih.gov
NIH locator: (301) 496-4000

Grants Information

grants.nih.gov/grants/giwelcome.pdf
E-mail: GrantsInfo@nih.gov
Telephone: (301) 435-0714

Grant Writing Tips and Sample Applications

http://grants1.nih.gov/grants/grant_tips.htm

eRA Commons

Institutions are invited to register with the eRA Commons. Registered Principal Investigators (PIs) can check assignment/contact information, review outcome, and other important information. **https://commons.era.nih.gov/commons/index.jsp**. At this time the eRA Commons is available to NIH grantees only. Plans are underway to incorporate data for other HHS agencies.

NIH Office of Extramural Research Human Subjects Website

This site provides, in one place, HHS and NIH requirements and resources for the extramural community involved in human subjects research http://grants.nih.gov/grants/policy/hs/index.htm.

Office for Human Research Protections

(Human Subject Protections, Institutional Review Boards, or related assurances)
http://www.hhs.gov/ohrp
Telephone: 1-866-447-4777 or (301) 496-7005

Office of Laboratory Animal Welfare (OLAW)

(Animal Welfare and related regulations and assurances)
grants.nih.gov/grants/olaw/olaw.htm
Telephone: (301) 496-7163

Receipt/Referral of an Application

Division of Receipt and Referral
Center for Scientific Review
http://www.csr.nih.gov/EVENTS/AssignmentProcess.htm
Telephone: (301) 435-0715
TTY: (301) 451-0088
Fax: (301) 480-1987

Specific Application: Before Review

Telephone or e-mail the Scientific Review Administrator named on the electronically-generated "notification of assignment" that is mailed to you upon assignment of your application.

Specific Application: Post Review

Telephone or e-mail the NIH Program Official named on the summary statement of your application.

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) from NIH and other PHS agencies. The *Guide* also contains vital information about policies and procedures. To subscribe to the Guide, visit http://grants.nih.gov/grants/guide/listserv.htm.

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 institutions on behalf of a principal investigator to facilitate the pursuit of a scientific objective when the idea for the research is initiated by the investigator. If the funding IC anticipates substantial program involvement during 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. 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 mechanisms, see Part III: Policies, Assurances, Definitions, and Other Information.

Grant and Cooperative Agreement Solicitations

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 of PAs and RFAs are as follows:

Program Announcement (PA): A formal statement about a new or ongoing extramural activity or mechanism. It may serve as a reminder of continuing interest in a research area, describe modification in an activity or mechanism, 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.

Specific PAs 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 Grants.gov "Find grant funding opportunities" (http://www.grants.gov/Find). Read the RFA or PA carefully for special instructions. The instructions in the RFA or PA may differ from the general instructions, and they supersede the general instructions. Each RFA or PA 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 RFA or PA.

Research Grant Mechanisms and Program Guidelines

A partial list of research grant mechanisms is provided below. As noted in the descriptions in Part III: Policies, Assurances, Definitions, and Other Information, not all awarding components use all programs. For a complete listing of program guidelines, visit the OER Grants website http://grants1.nih.gov/grants/funding/funding_program.htm.

Research Grants:

- Basic Research Grant (R01)
- Small Research Grant (R03)
- Academic Research Enhancement Award (AREA) (R15)
- Exploratory/Developmental Grant (R21, R33, R21/R33)
- Small Business Innovation Research Grant (SBIR) (R43/R44)
- Small Business Technology Transfer Grant (STTR) (R41/R42)
- Program Project Grant (P01)
- Research Center Grant (P50)
- Scientific Meeting Support (R13, U13)
- Research Grants to Foreign Institutions and International Organizations

Training, Fellowships and Career Development Programs

- NIH Institutional Ruth L. Kirschstein National Research Service Award (T32)
- Individual Ruth L. Kirschstein National Research Service Award Fellowships (NRSA) (F31, F32, F33, F34, etc.)
- Research Career Development Award (K Award)

APPLICATIONS AVAILABLE FROM OTHER OFFICES

- International Research Fellowship Award Application (NIH 1541-1)
- Nonresearch Training Grant Application (PHS 6025)
- Health Services Project Application (5161-1)

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 staff phone numbers of relevant NIH awarding components and other PHS agencies are listed in the table below.

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

PHS Agency Contact Table

NATIONAL INSTITUTES OF HEALTH	
Fogarty International Center	301-496-1653
National Cancer Institute	301-496-3428
National Center for Complementary and Alternative Medicine	301-496-4792

PHS Agency Contact Table	
National Center on Minority Health and Health Disparities	301-402-1366
National Center for Research Resources	301-496-6023
National Eye Institute	301-451-2020
National Heart, Lung, and Blood Institute	301-435-0260
National Human Genome Research Institute	301-496-7531
National Institute on Aging	301-496-9322
National Institute on Alcohol Abuse and Alcoholism	301-443-4375
National Institute of Allergy and Infectious Diseases	301-496-7291
National Institute of Arthritis and Musculoskeletal and Skin Diseases	301-594-2463
National Institute of Biomedical Imaging and Bioengineering	301-435-6138
National Institute of Child Health and Human Development	301-496-0104
National Institute on Deafness and Other Communication Disorders	301-496-1804
National Institute of Dental and Craniofacial Research	301-594-7710
National Institute of Diabetes and Digestive and Kidney Diseases	301-594-8834
National Institute on Drug Abuse	301-443-2755
National Institute of Environmental Health Sciences	919-541-7723
National Institute of General Medical Sciences	301-594-4499
National Institute of Mental Health	301-443-3367
National Institute of Neurological Disorders and Stroke	301-496-9248
National Institute of Nursing Research	301-594-6906
National Library of Medicine	301-496-4621
CENTER FOR SCIENTIFIC REVIEW	301-435-0715 TTY (301) 451-0088
Study Section Information	
OTHER PHS AGENCIES WITHIN DHHS	
AGENCY FOR HEALTHCARE RESEARCH AND QUALITY	301-427-1457
CENTERS FOR DISEASE CONTROL AND PREVENTION	
National Institute for Occupational Safety and Health	404-639-3343
Procurement and Grants Office	404-842-6630
FOOD AND DRUG ADMINISTRATION	301-827-7185

PHS Agency Contact Table	
OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH	
Office of Adolescent Pregnancy Programs	301-594-4004
Office of Family Planning	301-594-4008
Agency for Toxic Substances and Disease Registry	404-842-6630
Indian Health Service	301-443-0578

BEFORE SUBMISSION

You may wish to contact NIH staff with a variety of questions before submitting an application.

Contact GrantsInfo and/or the Division of Receipt and Referral in CSR:

- To identify Institutes/Centers at NIH or other non-NIH agencies that might be appropriate for your application
- To learn about grant mechanisms
- To receive advice on preparing and submitting an application (e.g., format, structure)

Contact program staff in the relevant awarding component:

- To determine whether your proposed application topic would fit into the NIH Institute/Center's (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 whether you should respond to an RFA

Contact Scientific Review Administrators in the Center for Scientific Review to discuss requesting assignment to a Scientific Review Group (SRG).

AFTER SUBMISSION

If the initial assignment to an IC or SRG seems inappropriate, the principal investigator/program director 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 constitute a conflict of interest in the review process. Reviewers are required to notify the Scientific Review Administrator 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 your Scientific Review Administrator 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 your study section, conflicts, reviewers that may have bias).

AFTER PEER REVIEW

Feedback to applicants is very important. Once the principal investigator receives the Summary Statement, s/he may contact the appropriate awarding component program official (noted on the Summary Statement):

- 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

Grants Policy Statements

The *PHS 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 PHS grant awards, excluding NIH awards.

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.

Both publications are available from the following NIH website: http://grants1.nih.gov/grants/policy/policy.htm.

IMPORTANT CHANGES AND REMINDERS

CHANGES

Following is a summary of policy changes and notifications that have been implemented since the release of the last PHS 398 (05/01 version). These changes have been incorporated into this version of the PHS 398 application.

Title	NIH Guide Link
NIH ANNOUNCES REVISED POLICY: APPLICATIONS THAT INCLUDE CONSORTIUM/CONTRACTUAL FACILITIES AND ADMINISTRATIVE COSTS *Revised policy now applies to all applications involving consortium/contractual F&A costs, solicited & investigator-initiated, regardless budget amount or budget format.*	NOTICE: NOT-OD-05-004 http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-004.html
NIH ANNOUNCES UPDATED CRITERIA FOR EVALUATING RESEARCH GRANT APPLICATIONS *NIH Peer Review Criteria modified to better accommodate interdisciplinary, translational, and clinical projects.*	NOTICE: NOT-OD-05-002 http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-002.html
NIH POLICY ON SHARING OF MODEL ORGANISMS FOR BIOMEDICAL RESEARCH *New Policy on Sharing Model Organisms*	NOTICE: NOT-OD-04-042 http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html
PUBLICATION OF THE REVISED NIH GRANTS POLICY STATEMENT (REV. 12/03)	NOTICE: NOT-OD-04-009 http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-009.html
NIH SUPPORT FOR SCIENTIFIC MEETINGS AND CONFERENCES *NIH has established specific submission dates for conference grant applications (April 15, August 15, December 15) and requires advance approval from an IC for submission.*	PAR-03-176 http://grants.nih.gov/grants/guide/pa-files/PAR-03-176.html
REQUIREMENT OF DUNS NUMBER *A Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number is required on applications for Federal grants or cooperative agreements.*	NOTICE: NOT-OD-03-055 http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-03-055.html

Title	NIH Guide Link
REVISED NIH POLICY ON SUBMISSION OF A REVISED (AMENDED) APPLICATION *Eliminates the two-year time frame to submit up to two amended applications.*	NOTICE: NOT-OD-03-041 http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-041.html
REMINDER AND CLARIFICATION – DELIVERY OF COMPETING GRANT, COOPERATIVE AGREEMENT, AND FELLOWSHIP APPLICATIONS *Clarifies zip code for U.S. Postal Service express mail vs. courier service express mail.*	NOTICE: NOT-OD-03-040 http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-040.html NOTICE: NOT-OD-02-012 http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-012.html
NOTICE OF LEGISLATIVE MANDATES CONTAINED IN THE FY 2003 CONSOLIDATED APPROPRIATIONS RESOLUTION P.L. 108-07; SIGNED FEBRUARY 20, 2003 *Acknowledgment of Federal Funding; Anti-Lobbying; Continued Salary Limitation; Ban on Funding of Human Embryo Research; Purchase of American-Made Equipment and Products; Limitation on Use of Funds for Promotion of Legalization of Controlled Substances* *Restriction on Distribution of Sterile Needles; Restriction on Abortions*	NOTICE: NOT-OD-03-035 http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-035.html *NIH updates this notice annually in the NIH Guide for Grants and Contracts.*
FINAL NIH STATEMENT ON SHARING RESEARCH DATA *Applications with direct costs greater than $500,000 in any single year, or if specifically required by the RFA, must address data-sharing in the application.*	NOTICE: NOT-OD-03-032 http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html
RESUBMISSION OF UNPAID RFA APPLICATIONS AND RESUBMISSION OF APPLICATIONS WITH A CHANGED GRANT ACTIVITY MECHANISM *Changes policy on new vs. amended applications.*	NOTICE: NOT-OD-03-019 http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-019.html
LABORATORY ANIMAL WELFARE: CHANGE IN PHS POLICY ON HUMANE CARE AND USE OF LABORATORY ANIMALS *Implements Just-in-Time policy for Institutional Animal Care and Use Committee (IACUC) Approval Date.*	NOTICE: NOT-OD-02-064 http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-064.html

Title	NIH Guide Link
GRADUATE STUDENT COMPENSATION *NIH will provide reasonable amounts for graduate compensation, consistent with the requested budget for the position(s) and up to the currently effective NRSA zero postdoctoral stipend level.*	NOTICE: NOT-OD-02-017 http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-017.html
REVISED POLICY ON THE ACCEPTANCE FOR REVIEW OF UNSOLICITED APPLICATIONS THAT REQUEST $500,000 OR MORE IN DIRECT COSTS *Implements six week advance window for NIH acceptance.*	NOTICE: NOT-OD-02-004 http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-004.html
AMENDMENT: NIH POLICY AND GUIDELINES ON THE INCLUSION OF WOMEN AND MINORITIES AS SUBJECTS IN CLINICAL RESEARCH	NOTICE: NOT-OD-02-001 http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html
REQUIRED EDUCATION IN THE PROTECTION OF HUMAN RESEARCH PARTICIPANTS *Implements new requirement for education on the protection of human research participants for all individuals identified as Key Personnel.*	NOTICE: NOT-OD-01-061 http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-01-061.html
NIH POLICY ON REPORTING RACE AND ETHNICITY DATA: SUBJECTS IN CLINICAL RESEARCH	NOTICE: NOT-OD-01-053 http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-01-053.html

CHANGES TO INSTRUCTIONS

In an effort to simplify the instructions, the PHS 398 has been restructured into three distinct parts. Instructional information related to the preparation, submission and review of your application is included in this section, Part I. Information relating to human subjects research is now in a separate section of the PHS 398, Part II: Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan. Information relating to policies and assurances, definitions and other *non-instructional* information is now is a separate section, Part III: Policies, Assurances, Definitions, and Other Information.

Font Size Requirement: NIH now requires the use of Arial-11 or Helvetica-11 point font.

NIH Peer Review Criteria: The Review Criteria have been updated to better accommodate interdisciplinary, translational, and clinical projects.

CHANGES TO APPLICATION FORMS

NOTE: All Form Pages and Format Pages have been modified to be more compatible with existing software, and Microsoft Word (MS Word) files have replaced previous versions of Rich Text Format (RTF) files. Portable Document Files (PDF) of the form pages are offered as an alternative.

Form Page 1: Face Page

Item 1. The length of the title has been increased to 81 characters.

Item 3h. eRA Commons User Name field has been added. This data item is currently optional.

Item 4. Human Subjects Research box has been modified as follows:

- 4a: No/Yes check boxes for “Research Exempt”
- 4b: Human Subjects Assurance Number
- 4c: No/Yes checkboxes for Clinical Trial
- 4d: No/Yes checkboxes for NIH-Defined Phase III Clinical Trial

Form Page 2:

Form Page 2 is now two pages (Form Page 2 and Form Page 2-continued) which consist of five sections: Description, Performance Sites, Key Personnel, Other Significant Contributors, and Human Embryonic Stem Cells.

As part of the **Description**, instructions have been added to succinctly (2-3 sentences) describe the relevance of the proposed research to public health. This component of the Description should be prepared using concise terms and plain language that can be understood by a general, lay audience.

Key Personnel. A field has been added for the eRA Commons User Name. This data item is currently optional.

Other Significant Contributors. A category has been added to Form Page 2 that identifies individuals who have committed to contribute to the scientific development or execution of the project, but are not committing any specified measurable effort to the project. See Other Significant Contributors.

Human Embryonic Stem Cells. Instructions have been added regarding projects that involve human embryonic stem cells. Applicants must include the registration number of the specific cell line(s) from the stem cell registry (see http://stemcells.nih.gov/registry/index.asp).

Form Pages 4 and 5:

Budget pages have been modified to implement the new policy on Direct Cost Limitations. Specifically, the "Consortium/Contractual Direct Costs" budget row has been moved to above the "Subtotal Direct Costs" line. Instructions have been revised to implement the new policy.

Modular Budget Format Page:

The budget fields have been modified to fully implement the new policy on Direct Cost Limitations. Specifically, users must now separate the Consortium F&A costs from the other Direct Costs. Instructions have been revised to implement the new policy.

Biographical Sketch Format Page:

A field has been added for the eRA Commons User Name. This data item is currently optional.

Personal Data Form Page:

Applicants are now requested to provide **only** the last four digits of the Social Security Number. While providing this information remains voluntary, it is hoped that by limiting the data to only the last four digits, individuals will be more receptive to providing it. This data continues to provide the agency with vital information necessary for accurate identification, referral, and review of applications and for management of PHS grant programs.

Key Personnel Report Format Page:

The request for a Social Security Number is now limited to the last four digits.

Checklist Form Page:

A field has been added for “Change of Grantee Institution.”

The form page also includes two distinct options for grants at Foreign Institutions or Domestic Grants with Significant Foreign Involvement. Also, a text entry field has been added to list the countries involved.

Section III – Research Career Development Award Instructions:

The Checklist page is now required at the time of application submission.

Section V – SBIR/STTR Instructions:

Clarification has been provided on the preparation of the Final Progress Report.

REMINDERS

- Font and margin specifications must be followed; if not, application processing may be delayed or the application may be returned to the applicant without review.
- Prepare a succinct Research Plan. There is no requirement for applicants to use the maximum allowable pages allotted to the Research Plan (Items a-d). The remaining sections (e-j) of the Research Plan have no maximum allowable pages, but should be succinct.
- Several elements of an application are no longer required at the time the application is submitted. Instead, this information will be 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.

I. PREPARING YOUR APPLICATION

A. Introduction

Read all of the instructions thoroughly prior to preparing your application.

These instructions pertain to applications for research project grants. Use the additional instructions and sample pages included in sections III, IV, or V of this document when applying for Career Development Awards, Institutional Ruth L. Kirschstein National Research Service Awards, Small Business Innovation Research (SBIR) or Small Business Technology Transfer (STTR) Awards.

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.

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.

PAPERWORK BURDEN

The PHS estimates that it will take approximately 40 hours to complete this application for a regular research project grant. This estimate excludes time for development of the scientific plan. Items such as human subjects and vertebrate animals are cleared and accounted for separately. Therefore, these items are also 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.

B. General Instructions

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 in his/her application by 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 301-451-0088;
Fax: 301- 480-1987

- **Forms and Format Pages.**
  - Prepare the application using the PHS 398 MS WORD or PDF form pages and format pages as provided.

- *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.
- The face page must not have any shading/colors.
- 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 your application (e.g., Biographical Sketch; Introduction, if necessary; Literature Citations; and the Research Plan) must conform to the font requirements stated below.
- 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.

FORMAT SPECIFICATIONS

Follow type size and format specifications. Otherwise, application processing may be delayed, or the application may be returned to the applicant without review.

Font.

- Use Arial or Helvetica 11-point.
- Use standard size, black letters that can be clearly copied.
- The print must be clear and legible.

Page Margins.

- Use standard size (8 ½" x 11") sheets of paper.
- Use at least ½ inch margins (top, bottom, left, and right) for all pages, including continuation pages.

Application Paging.

- 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 unnumbered pages.

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

- You may use a smaller type size but it must be in black ink and readily legible.

Photographs and Images.

- 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 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.**
  - Original (signed by principal investigator and an authorized organizational official) and five exact, 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 five collated sets as appendices (see Section I-8_Appendix). Note: Full-sized glossy photographs may be included in the Appendix; however, a photo copy of each must also be included within the page limitations of the Research Plan.

- **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.

PAGE LIMITATIONS AND CONTENT REQUIREMENTS

All applications and proposals for NIH funding must be self-contained within specified page limitations.

Observe the page number limitations given in Table 1. Only in cases involving interdependent multiple subprojects (e.g., Program Projects and Multi-Center Clinical Trials) will the PHS accept applications that exceed the page number limitations. However, specific page number limits may apply to each subproject. For information pertaining to page number limits for such projects, contact the awarding component to which the application may be assigned. (See Agency Contact Table.) The page number limitations may also be different for other specialized grant applications (e.g., R03 and R21 applications). Consult and follow the additional instructions for those applications.

TABLE 1. PAGE LIMITATIONS AND CONTENT REQUIREMENTS

Section	Page Limit	Content
Introduction - New applications - Revised applications - Revised Phase I SBIR/STTR applications - Supplemental applications	Not required/Not to be submitted 3 1 1	See Instructions
Research Plan - Sections a-d - Sections e-j	25* * Some exclusions for competing continuation applications * SBIR/STTR: See **Section V** none	Text including all figures, charts, tables, and diagrams
Biographical Sketches	4	No more than four pages for each person listed as Key Personnel. Items A and B together may not exceed 2 pages.
Literature Cited	none	Complete citations, including titles and all authors
Appendix	none Phase I SBIR/STTR: Not permitted unless specifically requested by NIH.	No more than 10 publications (including *accepted* manuscripts); photographs (include a copy in the Research Plan); questionnaires; and other materials that do not photocopy well.
PAs and RFAs	Page limitations specified in the PA and RFA announcement in the *NIH Guide* take precedence.	See specific instructions in PAs and RFAs published in the *NIH Guide*.

REVISED APPLICATIONS

NIH allows the submission of up to two revised applications (with some exceptions, e.g., R03) but no longer restricts those submissions to a two-year timeframe. See NIH Policy on Submission of a Revised (amended) Application in Part III of the PHS 398.

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 Mechanism in Part III of the PHS 398.

Before a revised application can be submitted, the principal investigator must have received the Summary Statement from the previous review.

Acceptance of a revised application automatically withdraws the prior version, since two versions of the same application cannot be simultaneously pending.

Introduction to Revised Application. The revision must include an Introduction of not more than three pages that *summarizes* the substantial additions, deletions, and changes. The Introduction must also include responses to the criticisms and issues raised in the Summary Statement. **Insert the Introduction just before the very beginning of the Research Plan.**

Research Plan of Revised Application. A revised application must include substantial changes. Identify the changes in the Research Plan clearly by bracketing, indenting, or changing typography, unless the changes are so extensive as to include most of the text. This exception should be explained in the Introduction. **Do not underline or shade changes.** The Preliminary Studies/Progress Report section should incorporate any work done since the prior version was submitted.

Application processing may be delayed or the application may be returned if it does not comply with all of these requirements.

Investigators who have submitted three versions of an application and have not been successful often ask NIH staff how different the next application submitted needs to be to be considered 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 three reviews is expected to be substantially different in content and scope with more significant differences than are normally encountered in a revised 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 Design and Methods sections.

In the referral process, NIH staff look at all aspects of the application, not just the title and Description (abstract). 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.

COMPETING SUPPLEMENTAL APPLICATION

A competing supplemental application may be submitted to request support for a significant expansion of a project's scope or research protocol. Applications for competitive supplements 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 supplemental application **should not be submitted** until after the original application has been awarded and **may not extend beyond the term of the current award period.**

Provide a one-page introduction at the beginning of the Research Plan that describes the nature of the supplement and how it will influence the specific aims, research design, and methods of the current grant. Any budgetary changes for the remainder of the project period of the current grant should be

discussed under the budget justification. The body of the application should contain sufficient information from the original grant application to allow evaluation of the proposed supplement in relation to the goals of the original application.

If the supplemental 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 revisions 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 your approved application, but that were unforeseen when the new or competing continuation application was submitted. If you are contemplating supplemental funding, you must consult in advance with your designated Grants Management Officer and Program Official. It is important for you to submit a request before your grant expires. To be considered for an administrative supplement, you must submit a request in writing to the IC (not to CSR), signed by the Principal Investigator and the authorized Business Official, describing the need for additional funding and the categorical costs. In your letter, also be sure to point out what you will NOT be able to accomplish if such a request is denied.

C. Specific Instructions

1. FACE PAGE (MS WORD OR PDF)

The **entire** Face Page must be printed on a single page. The Face Page must not have any shading or colors.

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 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 principal investigator/program director. A *competing continuation or revised 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 *supplemental 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-04-007) 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.*

If an application is being submitted as a R03 or R21, a program announcement that includes this mechanism **must** be specified in Item 2. Note that not all Institutes and Centers use the R03 and/or R21 mechanisms; in addition, there may be Institute/Center specifications for these mechanisms.

In addition, if the application is for the Career Development Award, Academic Research Enhancement Award (AREA), Institutional Ruth L. Kirschstein National Research Service Award, or AIDS research, state that after the title.

For RFAs, attach the RFA label or a facsimile, including the RFA number, to the bottom of the Face Page of the original application. The RFA label is under the general mailing label, following the Checklist and Personal Data pages. Any special instructions in the RFA must be followed when preparing the application.

Item 3. Principal Investigator/Program Director

New Investigator. Check "Yes" in the "New Investigator" box *only* if the principal investigator has not previously served as such on any PHS-supported research project other than a small grant (R03), an Academic Research Enhancement Award (R15), an exploratory/developmental grant (R21), or

mentored career development awards for persons at the beginning of their research career (K01, K08, K22, and K23, K25). **If the principal investigator/ program director is not a new investigator, check "No."** Current or past recipients of Independent Scientist and other non-mentored career awards (K02, K05, K24, and K26) are not considered new investigators.

Item 3a. Name of Principal Investigator/ Program Director

Name of Principal Investigator/ Program Director. 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 principal investigators and institutional officials.** A supplemental application **must** have the same principal investigator/program director as the currently funded grant.

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 principal investigator/program director. 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 principal investigator 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 your organizational affiliation, such as Department of Medicine, Materials Research Laboratory, or Social Sciences Institute.

Item 3f. Major Subdivision

Indicate your 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

If the principal investigator is registered in the eRA Commons, enter the assigned Commons User Name. This data item is currently optional.

Item 4. Human Subjects

Questions in this section pertain to **Part II: Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan** (MS Word) (PDF).

Does your proposed research involve Human Subjects? See definition.

> Research involving the obtaining of identifiable private information or identifiable human biological specimens (such as blood and tissue samples) is considered 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 performance site or collaborating institution. "Yes" should be checked even if the research is exempt from regulations for the protection of human subjects (see Exemption Categories). If the application plans to involve human subjects, but does not have definite plans at the time of application, the principal investigator will need to provide the research plan, including section 7.e "Human Subjects Research" for approval by the awarding component before the research can occur.

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

Is your proposed research described by one or more of the exemptions in the HHS regulations (45 CFR Part 46)?

Check "Yes" if the activities proposed are exempt from the regulations. Insert the exemption number(s) corresponding to one or more of the six exemption categories listed in **Part II: Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan** (MS Word) (PDF). If the proposed research corresponds to one or more of the exempt categories, then the remaining parts of Item 4 of the Face Page are not applicable.

OHRP guidance states that Exemptions should be independently determined (http://www.hhs.gov/ohrp/humansubjects/guidance/irb71102.pdf). Institutions often designate their IRB to make this determination. Because NIH does not require IRB approval at time of application, the exemptions designated in item 4a often represent the opinion of the PI, and the justification provided for the exemption by the PI is evaluated during peer review.

Human Subjects Activities Not Exempt from HHS Human Subjects Regulations

Check "No" if 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) or Multiple Project Assurance (MPA) on file with the OHRP (http://www.hhs.gov/ohrp/) that covers the specific activity, insert the number in the space provided.

Insert "None" in Item 4b if the applicant organization does not have an approved assurance on file with OHRP. In this case, the applicant organization, by the signature on the Face Page, is declaring that it will comply with 45 CFR Part 46 and proceed to obtain a human subjects assurance (see http://www.hss.gov/ohrp). **Do not insert the human subjects assurance number of any collaborating institution in the space provided.**

NIH no longer requires IRB approval and certification of the 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 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.

To assist in filling out items 4c and 4d, see the Human Subjects Research Supplemental Instructions for definitions of clinical research and NIH-defined Phase III clinical trial.

Item 4c. Clinical Trial

Does your proposed research include a clinical trial?

Check "Yes" or "No" to indicate whether the project is a clinical trial.

Item 4d. NIH-Defined Phase III Clinical Trial

Does your proposed research meet criteria for an NIH-Defined Phase III Clinical Trial?

Check "Yes" or "No" to indicate whether the project is an NIH-Defined Phase III clinical trial.

Item 5. Vertebrate Animals

Check "No" if activities involving vertebrate animals are not planned at any time during the proposed project period. The remaining parts of Item 5 are then not applicable.

Check "Yes" if activities involving vertebrate animals are planned at any time during the proposed project period, either at the applicant organization or at any other performance site or collaborating institution.

Item 5a. IACUC Verification

NIH no longer requires Institutional Animal Care and Use Committee approval of the proposed research before NIH peer review of an application. See PHS policy section on Vertebrate Animals and http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-064.html. See also the Just-In-Time Policy.

This field is not necessary for application submission. However, the data must be

submitted to NIH consistent with the "just-in-time" process prior to award.

If the verification of IACUC approval is not submitted with the application, applicant organizations with "full" Animal Welfare Assurances on file with the Office of Laboratory Animal Welfare (OLAW) should enter "Pending" in the box requesting IACUC approval date. Following NIH peer review, applicants and their institutions will be notified of the need for IACUC review and verification for the proposed animal activity. The verification of IACUC approval from an official signing for the applicant organization must then be sent to and received by the Grants Management Office identified in the notice requesting IACUC verification. This IACUC verification must include: the PHS application number, title of the project, name of principal investigator/program director, institution, Animal Welfare Assurance number, date of IACUC approval, and appropriate signatures.

Any modification of the Research Plan section of the application, required by the IACUC, must be submitted with the follow-up verification. It is the responsibility of the principal investigator/ program director and the applicant organization to submit the follow-up verification.

Item 5b. Animal Welfare Assurance

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

Enter "None" in Item 5b if the applicant organization does not have an approved Animal Welfare Assurance on file with OLAW. **Do not enter the Animal Welfare Assurance number of any collaborating institution in the space provided**. By inserting "None" and, by the signing on the Face Page, the applicant organization is declaring that it will comply with PHS policy regarding the care and use of animals by submitting an Animal Welfare Assurance and verification of IACUC approval when requested to do so by OLAW.

Item 6. Dates of Proposed Period of Support

Request no more than 5 years of support. Note: Some mechanisms specify fewer years.

New application. Consult the schedule in Table 2 Submission, Review, and Award Cycles for an appropriate beginning date.

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

Supplemental application. **Submit a supplemental application only for a period within the current period of the active grant.** At the time of submission, the supplement 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 supplement's first budget period coincide with the ending date of the budget period that is to be supplemented, regardless of the supplement'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 Requested for Initial Budget Period

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

Modular, With Consortium/Contractual Costs. From the Modular Budget Format Page enter the "DC less Consortium F&A" for the initial period only.

Modular, Without Consortium/Contractual Costs. From the Modular Budget Format Page enter "Total Direct Costs" for the initial period only.

Item 7b. Total Costs Requested for Initial Budget Period

Non-Modular. 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.

Modular, With or Without Consortium/ Contractual Costs. Enter the sum of: 1) the "Total Direct Costs" for the initial period from the Modular Budget Format Page and 2) the Facilities and Administrative costs for the initial budget period, as calculated on the Checklist Form Page.

Note Item 7b represents total direct costs, including any consortium F&A costs.

Item 8. Costs Requested for Proposed Period of Support

Item 8a. Direct Costs Requested for Proposed Period of Support

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

Modular, With Consortium/Contractual Costs. From the Modular Budget Format Page, enter the "Sum Total" of "DC less Consortium F&A" for all years.

Modular, Without Consortium/Contractual Costs. From the Modular Budget Format Page, enter the "Sum Total" of "Total Direct Costs" for all years.

Item 8b. Total Costs Requested for Proposed Period of Support

Non-Modular. Enter the sum of: 1) "Total Direct Costs" from Form Page 5; and, 2) the Facilities and Administrative costs for the proposed period of support, as calculated on the Checklist Form Page.

Modular, With or Without Consortium/ Contractual Costs. Enter the sum of: 1) "Sum Total" from the Modular Budget Format Page; and, 2) the Facilities and Administrative costs for the proposed period of support, as calculated on the Checklist Form Page.

Note Item 8b represents total direct costs, including any consortium F&A costs.

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 definition in Part III: Policies, Assurances, Definitions and Other Information.

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 PRINCIPAL INVESTIGATOR'S SOCIAL SECURITY NUMBER,** as it is not appropriate for this item.

Data Universal Numbering System (DUNS) number. Enter the DUNS number. Applicant organizations must provide a DUNS number when applying for Federal grants or cooperative agreements. The DUNS, a Universal Identifier number, is a nine-digit number assigned by Dun and Bradstreet Information Services. An authorized organizational official should be consulted to determine the appropriate number to enter. If the organization does not have a DUNS number, an authorized organizational official should complete the electronic 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 principal investigators do not need to register for a DUNS.

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

organization. To locate your district visit 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. Principal Investigator/Program Director Assurance

An original signature, in ink, is required. "For" or "Per" signatures are not acceptable. Date of signature must be included.

Item 15. Applicant Organization Certification and Acceptance

Read this section carefully

An original signature, in ink, is required. "For" signatures are acceptable; i.e., if the official designated to sign for the applicant organization is not available to sign, only another institutional official with formal delegated authority to act in his/her behalf may sign as "acting for" such official. However, "Per" signatures (signing as the designated official or without the formal delegation) are not acceptable. The date of signature must be included. ***In signing the application Face Page, the duly authorized 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

Each application to the PHS requires that the following policies, assurances and/or certifications be verified by the signature of the Official Signing for Applicant Organization on the Face Page of the application. These assurances 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 your institution's research grant administrative office or the *NIH Grants Policy Statement* (available from the NIH website at 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 your project, program, or type of applicant organization:

Human Subjects

Research on Transplantation of Human Fetal Tissue

Women and Minority Inclusion Policy

Inclusion of Children Policy

Research Using Human Embryonic Stem Cells

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 and Human Gene Transfer Research

Financial Conflict of Interest (not applicable to Phase I SBIR/STTR)

Prohibited Research

Certification of Research Institution Participation (STTR only)

2. Description, Performance Sites, Key Personnel, Other Significant Contributors, and Human Embryonic Stem Cells

FORM PAGE 2 (MS WORD OR PDF)

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

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.

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 (Computer Retrieval of Information on Scientific Projects - CRISP) and will become public information.

Performance Site(s)

Indicate where the work described in the Research Plan will be conducted. If there is more than one performance site, list all the sites, including Department of Veterans Affairs (V.A.) facilities and foreign sites, and provide an explanation on the Resources Format Page of the application. 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 on the Checklist Form Page of the application. 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.

If a performance site is engaged in research involving human subjects, the applicant organization is responsible for ensuring that the performance site operates under an appropriate OHRP-approved 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 vertebrate animals, the applicant organization must ensure that all performance sites hold OLAW-approved assurances.

Key Personnel

In addition to the principal investigator (PI), 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 Key Personnel. **Consultants should also be included if they meet the same definition.**

Key Personnel must devote measurable effort to the project whether or not salaries are requested. "Zero percent" effort or “as needed” are not acceptable levels of involvement for those designated as Key Personnel.

Start with the principal investigator. List the principal investigator’s **last name first**. All other Key Personnel should be listed in **alphabetical order**, last name first. For each individual provide name, eRA Commons User Name (if known), organization name (their institutional affiliation), and role on the project. Under role on the project, indicate how the individual will function on the proposed project. *Use additional consecutively numbered pages as necessary.*

Other Significant Contributors. This category identifies individuals who have committed to contribute to the scientific development or execution of the project, but are not committing any specified measurable effort to the project. These individuals are typically presented at "zero percent" effort or "as needed" (individuals with measurable effort cannot be listed as Other Significant Contributors). Consultants should be included if they meet this definition. This would also be an appropriate designation for mentors on Career awards.

A biosketch, including Research Support information, will be required for these individuals as this highlights their accomplishments as scientists. Reviewers use these pages to address the "investigator" review criterion.

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

Should the level of involvement change for an individual listed in this category, they should be redesignated as "key personnel." This change should be made before any compensation is charged to the project.

Human Embryonic Stem Cells

If the proposed project involves human embryonic stem cells, list in this section the registration number of the specific cell line(s) from the stem cell registry found at: http://stemcells.nih.gov/registry/index.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.

3. Research Grant Table of Contents

FORM PAGE 3 (MS WORD OR PDF)

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. Budget Instructions

MODULAR FORMAT

The following instructions are applicable to research grant applications requesting **$250,000 or less per year for direct costs.** Modular budgets are simplified; therefore, detailed categorical information is not to be submitted with the application.

Note consortium/contractual F&A costs are not factored into this DC limit. They may be requested in addition to the $250,000 limit.

- Use for research grant applications requesting $250,000 or less in direct costs, exclusive of any consortium F&A costs.
- Applicable only to R01, R03, R15, and R21 applications.

- Submit only the Modular Budget Format Page (MS WORD or PDF).

- Do *not* submit Form Pages 4 and 5. Use these as internal "worksheets" only in the development of the total direct costs to be shown on the Modular Budget Format Page and in Item 7a of the Face Page.

- Refer to the Modular Budget Samples**:**

  Same Modules each year
  MS Word PDF

  Variable Modules each year
  MS Word PDF

Direct Costs.

Modular, With Consortium/Contractual Costs. On the Modular Budget Format Page, enter separately the Direct Costs less Consortium F&A, Consortium F&A, and Total Direct Costs requested for each year. The budget figures from the "DC less Consortium F&A" row are used for Face Page Items 7a. and 8a.

Modular, Without Consortium/Contractual Costs. If your budget does not include consortium/contractual costs complete only the "Total Direct Costs" row. From this row, use "Initial Period" figure for Face Page Item 7a, and "Sum Total" figure for Face Page Item 8a.

Request total direct costs in **modules of $25,000,** reflecting appropriate support for the project. There will be no future year escalations. A typical modular grant application will request the same number of modules in each year. Provide an additional narrative budget justification for any variation in the number of modules requested.

NIH may request (prior to award) additional budget justification in exceptional circumstances. For further information, see http://grants.nih.gov/grants/funding/modular/modular.htm and http://grants.nih.gov/grants/funding/modular/modular_review.htm.

Personnel. List **all** personnel, including names, percent of effort and roles on the project. No individual salary information should be provided. Since the modules should be a reasonable estimate of costs allowable, allocable, and appropriate for the proposed project, applicants must use the current legislatively imposed salary limitation when estimating the number of modules. For guidance on current salary limitations, see the *NIH Guide for Grants and Contracts* on the NIH grants website or contact your office of sponsored programs.

NIH grants also limit the compensation for graduate students. Compensation includes salary or wages, fringe benefits and tuition remission. This limit should also be used when estimating the number of modules. See: http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-017.html.

Consortium/contractual costs. Provide an estimate of total costs (direct plus Facilities and Administrative) for each year, rounded to the nearest $1,000. List the individuals/ organizations with whom consortium or contractual arrangements have been made. List all personnel, including percent of effort and roles on the project. No individual salary information should be provided. Indicate whether the collaborating institution is foreign or domestic. While only the direct cost for a consortium/contractual arrangement is factored into eligibility for using the modular budget format, the **total** consortium/contractual costs must be included in the overall requested modular direct cost amount.

While all NIH ICs use modular formats, not all of the other PHS agencies accept modular budgets. If you are submitting an application to an agency other than NIH, be sure to read the instructions in the funding announcement to determine whether the application should be submitted in the modular format, or contact an official at the appropriate PHS awarding component (see Agency Contact Table).

NON-MODULAR FORMAT

The following instructions are applicable to all applications requesting **more than $250,000 direct costs per year. Note consortium/ contractual F&A costs are no longer factored into this DC limit. If you exceed the $250,000 level by only the amount of consortium F&A costs, you are still required to use the modular format.** Detailed

categorical budget information for preparing the budget for the "Initial Budget Period" and the "Entire Proposed Period of Support" is to be submitted with the application.

- Use for research grant applications requesting more than $250,000 direct costs per year, exclusive of consortium F&A costs.
- Submit Form Page 4 and Form Page 5.
- **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.** Note 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.)
- Form Page 4 reflects the total direct costs, which includes the total costs of any contractual costs, requested for the *initial* (first 12 months) budget period. (F&A costs are requested on the Checklist Page.)
- Form Page 5 reflects the total direct costs for the *entire* project period. This form also is used to prepare the *narrative budget justification*.
- Submit a separate detailed budget (Form Page 4) for each participating consortium/contractual organization. For each, label that page accordingly. If consortium activity exceeds one year, also include Form Page 5. See Consortium/Contractual Costs for specific instructions.

If the proposed budget is $250,000 direct costs per year or less (excluding any consortium F&A costs), skip the following instructions for Form Page 4 and Form Page 5. Use the 'Modular Budget Format Page' only and follow the specific Budget Instructions for Modular Grant Applications.

DETAILED BUDGET FOR INITIAL BUDGET PERIOD

FORM PAGE 4 (MS WORD OR PDF)

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.

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 principal investigator, 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. This includes any "to-be-appointed" positions.

Type of Appointment/Months. List the number of months per year reflected in an individual's contractual appointment to the applicant organization. Unless otherwise noted, PHS staff assume that appointments at the applicant organization represent 12 months/100 percent time for each individual. If an appointment is less than full time, e.g., 50 percent time (i.e., 6 months), identify with an asterisk (*) and provide a full explanation under "Justification" on Form Page 5. Individuals may have consecutive appointments within a calendar year, for example for an academic period and a summer period. In this case, for each appointment, identify and enter the number of months on separate lines. In cases where

no contractual appointment exists with the applicant organization and salary is requested, enter the number of months for the requested period.

Percent of Effort on Project. For each individual at the applicant organization, list the percent of full-time effort to be spent on this project or use an asterisk (*) as described above if not full time.

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: Policies, Assurances, Definitions and Other Information.

Salary Requested. Enter the dollar amounts for each position for which funds are requested. The salary requested is calculated by multiplying the individual's institutional base salary by the percent of effort on this project. Explain under Justification on Form Page 5 if a lesser amount is requested (e.g., endowed position or institutional sources).

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 limitations, see the *Salary Cap Summary* on the NIH grants Web site or contact your 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://grants1.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 subcontractor(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: Joint University and Department of Veterans Affairs (V.A.) Appointments

Individuals with joint university and V.A. 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 V.A.; 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 boards or advisory committees to the project. 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, 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.

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. Costs for alterations and renovations are not allowed on grants made to foreign organizations or to foreign components on grants to domestic institutions.

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.

When F&A costs are requested by a consortium organization, enter the costs in the F&A cost category for each supplementary budget. Provide the F&A cost base and rate. Leave the direct cost category blank.

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

Supplemental Application

For a supplemental application, show only those items for which additional funds are requested. If the initial budget period of the supplemental application is less than 12

months, prorate the personnel costs and other appropriate items of the detailed budget.

Foreign Justification

If the applicant organization is a foreign institution or if your project includes a foreign component, provide a justification on Form Page 5 or, for Modular Applications, on the Modular Budget Format Page. Describe special resources or characteristics of the research project (e.g., human subjects, animals, disease, equipment, and techniques), whether similar research is being done in the United States and whether there is a need for additional research in this area. *For a definition of a substantial foreign component, see* Definitions section of Part III: Policies, Assurances, Definitions, and Other Information.

BUDGET FOR ENTIRE PROPOSED PERIOD OF SUPPORT

FORM PAGE 5 (MS WORD OR PDF)

Enter in the first column 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.

5. BIOGRAPHICAL SKETCH

FORMAT PAGE (MS WORD OR PDF)

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

If the individual is registered in the eRA Commons, include the assigned Commons User Name. This data item is currently optional. (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** (modular *and* other) grant applications.

The Biographical Sketch may not exceed four pages. Items A and B (together) may not exceed two of the four-page limit. See sample MS Word or PDF.

Complete the educational block at the top of the format page, and complete sections A, B, and C.

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

B. Selected peer-reviewed publications or manuscripts in press (in chronological order). Do not include manuscripts submitted or in preparation.

C. Research Support. List both selected ongoing and completed (during the last three years) research projects (Federal or non-Federal support). Begin with the projects that are most relevant to the research proposed in this application. Briefly indicate the overall goals of the projects and responsibilities of the key person identified on the Biographical Sketch. **Note: Do not include percent of effort or direct costs.**

Don't confuse "Research Support" with "Other Support." Though they sound similar, these parts of the application are very 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. NIH staff will request complete and up-to-date "other support" information from you *after* peer review. This information will be used to check that the proposed research has not already been Federally-funded.

Information on Other Support beyond that required in the biographical sketch should NOT be submitted with the application. Otherwise, the application processing may be delayed or the application may be returned to the applicant without review. For additional information and policy on Other Support, see *Part III: Policies, Assurances, Definitions and Other Information.*

6. RESOURCES

FORMAT PAGE (MS WORD OR PDF)

Follow the sample format and instructions on the Resources Format Page when completing information on resources available for the project. If there are multiple performance sites, then resources available at each site should be described. 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 employ useful collaborative arrangements.

7. RESEARCH PLAN

No Specific Form Page
Use Continuation Page (MS Word | PDF)

The Research Plan should include sufficient information needed for evaluation of the project, independent of any other document (e.g., previous application). The format for preparing this section is provided below. Be specific and informative, and avoid redundancies. For grant writing tips, see http://grants1.nih.gov/grants/grant_tips.htm.

Introduction (Revised or Supplemental Applications Only)

Refer to the section on Revised Applications. All revised (amended) and supplemental applications must include an Introduction. The Introduction may not exceed three pages for revised applications or one page for supplemental applications. *Insert the Introduction at the very beginning of the Research Plan*.

Page Limitations

Do not exceed 25 pages for *Items a-d*. All tables, graphs, figures, diagrams, and charts must be included within the 25-page limit. Be succinct and remember that there is no requirement to use all 25-pages allotted to *Items a-d* of the Research Plan.

Follow page limitations as specified in PAs and RFAs.

SBIR/STTR applicants: See Section V and the SBIR/STTR Solicitation for specific instructions.

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 that are glued or taped onto application pages are incompatible with the current duplication/scanning process.

Full-sized glossy photographs 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 limitations of the Research Plan (see Section I.C.8 Appendix).

All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, Internet website addresses (URLs) may not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Moreover, reviewers are cautioned that they should not directly access an internet site as it could compromise their anonymity.

The 25-page limit will be strictly enforced. Application processing may be delayed or the application may be returned to the applicant without review.

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 (*) in the left-hand margin and providing the page numbers before “a. Specific Aims” in the Research Plan.

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.

Content of Research Plan

The PHS recommends the following format and page distribution. Organize *Items a-d* of the Research Plan to answer these questions: *What do you intend to do? Why is the work important? What has already been done? How are you going to do the work?*

Do not exceed 25 pages for Items a-d, including all tables and figures.

a. Specific Aims

List the broad, long-term objectives and the goal of the specific 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. **One page is recommended.**

b. Background and Significance

Briefly sketch the background leading to the present application, critically evaluate existing knowledge, and specifically identify the gaps that the project is intended to fill. State concisely the importance and health relevance of the research described in this application by relating the specific aims to the broad, long-term objectives. If the aims of the application are achieved, state how scientific knowledge or clinical practice will be advanced. Describe the effect of these studies on the concepts, methods, technologies, treatments, services or preventative interventions that drive this field. **Two to three pages are recommended.**

c. Preliminary Studies/Progress Report

Preliminary Studies. For new applications, use this section to provide an account of the principal investigator/program director's preliminary studies pertinent to this application, including his/her preliminary experience with and outreach to the proposed racial/ethnic group members. This information will also help to establish the experience and competence of the investigator to pursue the proposed project.

Except for Exploratory/Development Grants (R21/R33), Small Research Grants (R03), and Phase I Small Business Research Grants (R41/R43), peer review committees generally view preliminary data as an essential part of a research grant application. Preliminary data often aid the reviewers in assessing the likelihood of the success of the proposed project.

Progress Report for Competing Continuation and Supplemental Applications. A Progress Report must be provided for competing continuation and supplemental applications. Provide the beginning and ending dates for the period covered since the project was last reviewed competitively. Summarize the previous application's specific aims and the importance of the findings. Discuss any changes in the specific aims as a result of budget reductions. Include the complete references to appropriate publications and manuscripts accepted for publication (not part of the page limitations). Include five collated sets, single-sided, of all Appendix material, in the same package with the application, following all copies of the application (see Section I.C.8).

If the competing continuation or supplemental application involves clinical research, then you must report on the enrollment of research subjects and their distribution by ethnicity/race and sex/gender.

See "What Form Should PIs Use for Population Tracking? (New Versus Old)" (PDF or MS Word) for more detailed instructions on which Target and Enrollment Report or Table to use.

Provide a succinct account of published and unpublished results, indicating progress toward their achievement.

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

last reviewed competitively. Up to 10 such publications may be included in the five collated sets of appendices.

The publications portion of the competing continuation and supplemental applications Progress Report is not included in the 25-page limit.

Six to eight pages are recommended for the narrative portion of the Preliminary Studies/ Progress Report.

d. Research Design and Methods

Describe the research design conceptual or clinical framework, procedures, and analyses to be used to accomplish the specific aims of the project. Unless addressed separately in Section i, include how the data will be collected, analyzed, and interpreted as well as the data-sharing plan as appropriate. Describe any new methodology and its advantage over existing methodologies. Describe any novel concepts, approaches, tools, or technologies for the proposed studies. Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims. As part of this section, provide a tentative sequence or timetable for the project. Point out any procedures, situations, or materials that may be hazardous to personnel and the precautions to be exercised.

Although no specific number of pages is recommended for the Research Design and Methods section, be as succinct as possible. There is no requirement that all 25 pages allotted for *items a-d* be used.

e. Human Subjects Research

The following human subject information applies even if you are obtaining specimens from collaborators or if you are subcontracting the human research to another organization.

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

For all research involving human subjects, a part of the peer review process will include careful consideration of protections from research risks, as well as the appropriate inclusion of women, minorities, and children. The Scientific Review Group (SRG) will assess the adequacy of safeguards of the rights and welfare of research participants, and the appropriate inclusion of women, minorities, and children, based on the information in the application. This evaluation will be a part of the Approach criterion. The evaluation of the inclusion plans will be factored into the overall score that the SRGs award for scientific and technical merit of the application.

Much of the information on the protection of human subjects that you are required to provide in this section of the PHS 398 is identical to information that you will be required to provide for IRB review at your own institution.

To assist you in filling out this section of the application, a Decision Table is provided below that presents six possible scenarios, and links to instructions for providing information on human subjects protection from research risks, and the inclusion of women, minorities and children. All research will fall into one of these six scenarios.

Determining which scenario best matches your proposed research depends on your answers to the following five questions:

Question 1: Does your proposed research involve human subjects?

Question 2: Is your proposed research described by one or more of the exemptions in the Department of Health and Human Services (HHS) Regulations (45 CFR Part 46)?

Question 3: Does your proposed research include Clinical Research?

Question 4: Does your proposed research include a Clinical Trial?

Question 5: Does your proposed research meet criteria for an NIH-Defined Phase III Clinical Trial?

DECISION TABLE FOR HUMAN SUBJECTS RESEARCH, PROTECTION AND THE INCLUSION OF WOMEN, MINORITIES, AND CHILDREN

	Criteria and Answers to Questions 1 thru 5				
Scenarios with linked instructions	1. Human Subjects Research	2. Exempt from HHS Human Subjects Regulations	3. Clinical Research	4. Clinical Trial	5. NIH-Defined Phase III Clinical Trial
A No Human Subjects	No	N/A	N/A	N/A	N/A
Requirements for Scenario A: - Indicate "No Human Subjects Research"					
B Human Subjects/E-4	Yes	Yes Exemption: 4	No	N/A	N/A
Requirements for Scenario B: - Indicate Exemption 4 (E-4) and include justification that E-4 is appropriate.					
C Human Subjects/ Other Exemptions	Yes	Yes Exemptions: 1, 2, 3, 5, 6	Yes	N/A	N/A
Requirements for Scenario C: - Indicate Exemption number(s) and include justification that the designated exemption(s) is appropriate. - Address “Inclusion of Women and Minorities” - Address “Inclusion of Children”					
D Clinical Research	Yes	No	Yes	No	N/A
Requirements for Scenario D: - Address Protection of Human Subjects - Address “Inclusion of Women and Minorities” - Address “Inclusion of Children” “Targeted/Planned Enrollment Table(s)” for each new study/ protocol (New applications; Competing Continuation applications; Competing Supplements) - “Inclusion Enrollment Report Table(s)” (Competing Continuations; Competing Supplements)					
E Clinical Trials	Yes	No	Yes	Yes	No
Requirements for Scenario E: - All requirements in Scenario D - Data and Safety Monitoring Plan - Note: Some trials may require a Data and Safety Monitoring Board, based on risk					
F NIH-Defined Phase III Clinical Trial	Yes	No	Yes	Yes	Yes
Requirements for Scenario F: - All requirements in Scenario E Increased requirements for Inclusion of Women and Minorities in Clinical Research					

Click on the questions, and when you have the answer for the five questions proceed to the table above, and select the scenario that best matches your responses. Follow the instructions provided for the scenario you choose. If you need additional guidance then click on the questions, the column heading in the table below, or links within the scenario and you will be provided additional information and guidance.

For Clinical Research, place the Target/Planned Enrollment Table(s) under the heading "Inclusion of Women and Minorities," immediately in front of the heading "Inclusion of Children." See Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan.

When you have completed this section of the application proceed to Section f Vertebrate Animals.

Relevant Human Subjects Research policies and information:

Protection of Human Subjects (45 CFR Part 46)

Required Education in the Protection of Human Research Participants

Inclusion of Women and Minorities in Clinical Research

NIH Policy on Inclusion of Children

NIH Policy on Reporting Race and Ethnicity Data: Subjects in Clinical Research

Vulnerable Populations

Research Using Human Embryonic Stem Cells

Completing the Population Tracking Tables

f. Vertebrate Animals.

If you have marked Item 5 on the Face Page of the application "Yes," create a section heading entitled "Vertebrate Animals." Place it immediately following the Research Design and Methods section of the application (or after Item e, if applicable.)

Failure to address the following elements will result in the application being designated as incomplete and it will be grounds for the PHS either to defer the application from the peer review round or to potentially negatively affect the application's priority score.

Under the Vertebrate Animals heading address the following five points. In addition, when research involving vertebrate animals will take place at collaborating site(s) or other performance site(s), provide this information before discussing the five points. Although no specific page limitation applies to this section of the application, be succinct.

1. Provide a detailed description of the proposed use of the animals in the work outlined in the Research Design and Methods 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 reasons for its selection. State whether this method is consistent with the recommendations of the Panel on Euthanasia of the American Veterinary Medical Association. If not, present a justification for not following the recommendations.

g. Literature Cited.

List all references. The list may include, but may not replace, the list of publications required in the Progress Report for competing continuation applications.

Each reference must include the title, names of all authors, book or journal, volume number, page numbers, and year of publication.

See example at:
http://www.niaid.nih.gov/ncn/grants/app/app.pdf

The reference 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.

h. Consortium/Contractual Arrangements.

Explain the programmatic, fiscal, and administrative arrangements to be made between the applicant organization and the consortium organization(s). If consortium/ contractual activities represent a significant portion of the overall project, explain why the applicant organization, rather than the ultimate performer of the activities, should be the grantee.

The signature of the authorized organizational official 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 NIH consortium agreement policy and are prepared to establish the necessary inter-organizational agreement(s) consistent with that policy. A separate statement is no longer required.

i. Resource Sharing.

(1) *Data Sharing Plan*: Investigators seeking $500,000 or more in direct costs in any year must include a brief 1-paragraph description of how final research data will be shared, or explain why data-sharing is not possible. Applicants are encouraged to discuss their data-sharing plan with their program contact at the time they negotiate an agreement with the Institute/Center (IC) staff to accept assignment of their application. See Data-Sharing Policy or http://grants1.nih.gov/grants/policy/data_sharing/index.htm.

(2) *Sharing Model Organisms*: All applications, regardless of the amount requested, where the development of model organisms is anticipated are to include a description of a specific plan for sharing and distributing unique model organism research resources or state appropriate reasons why such sharing is restricted or not possible. Note unlike the data sharing requirement above, this requirement is for **all** applications. See Sharing Model Organisms Policy.

These descriptions are not included in the Research Plan page limits.

j. Consultants.

Attach appropriate letters here from all individuals confirming their roles in the project and rate/charge for consulting services. **Do not place these letters in the Appendix**.

8. APPENDIX

Include **five collated sets**, single-sided, of all Appendix material, in the same package with the application, following all copies of the application. Identify each item with the name of the principal investigator. **Do not intermingle Appendix materials with the application.**

New, revised, competing continuation and supplemental applications **may** include the following materials in the Appendix:

- Up to 10 publications, manuscripts (*accepted* for publication), abstracts, patents, or other printed materials directly relevant to this project. These may be stapled as sets. *Do not include manuscripts **submitted** for publication.*

- Surveys, questionnaires, data collection instruments, clinical protocols, and informed consent documents. These may be stapled as sets.

- Original glossy photographs or color images of gels, micrographs, etc., provided that a photocopy (may be reduced in size) is also included within the 25-page limit of *Items a-d* of the research plan. *No photographs or color images may be included in the*

Appendix that are not also represented within the Research Plan.

Do not use the Appendix to circumvent the page limitations of the research plan. Graphs, diagrams, tables, and charts that do not need to be in a glossy format to show detail must not be included in the Appendix. An application that does not observe these limitations will be returned. These Appendix limitations may not apply to specialized grant applications. Request and follow the additional instructions for those applications.

The Appendix will not be duplicated with the application and will be sent only to certain members of the SRG who will serve as the primary reviewers of the application.

9. CHECKLIST

CHECKLIST FORM PAGE (MS WORD OR PDF)

Type of Application

Check all that apply.

Inventions and Patents (Competing Continuation 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 the *Policies, Assurances and Definitions and Other Information*.

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 Grant Award will provide specific instructions regarding the use of such income.

Assurances/Certifications

Each application to the PHS requires that the policies, assurances, and certifications listed on the Checklist be verified by the signature of the official signing for the applicant organization on the Face Page of the application.

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 HHS policy. F&A costs will NOT be paid on construction grants, grants to Federal organizations, grants to individuals, and conference grants. Follow any additional instructions provided for Career Development Awards, Institutional Ruth L. Kirschstein National Research Service Awards, SBIR/STTR Awards, foreign grants, and specialized grant applications.

Special Instructions for Modular Applications

Applicant institutions should calculate the F&A costs using the current negotiated F&A rate, less exclusions, for the initial budget period and all future budget periods. It is not necessary to list the exclusions on the Checklist or anywhere in the application. However, the direct cost base used for the calculation of the F&A costs must be listed for each year. Show rate used in calculation for F&A costs.

10. PERSONAL DATA

FORM PAGE (MS WORD OR PDF)

Follow instructions on the form. Place the form at the end of the original application. **Do not copy.**

11. KEY PERSONNEL REPORT

(KEY PERSONNEL FORM PAGE (MS WORD or PDF); for Competing Continuation Applications Only)

Use only when requested by the awarding component.

List all Key Personnel, salaried and unsalaried, at the applicant organization or elsewhere, who participated in the project during the current budget period. Include all degrees, role on project, date of birth, annual percent of effort, and the last four digits of the Social Security number. When requesting this portion 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.

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 now meet the definition of "key personnel."

II. SUBMISSION AND REVIEW OF YOUR APPLICATION

This section provides instructions for assembling your grant application, the application mailing address, and a schedule of the PHS grant application submission, review and award cycles. It also provides an overview of what happens to your application after submission and the peer review process.

Cover letter. Applicants are encouraged to include a cover letter with the application. The letter may contain any of the following information that applies to the application:

- Application title
- PA or RFA title, if you are responding to an NIH initiative
- Request of an assignment and referral to a particular awarding component(s) or Scientific Review Group (SRG). (The PHS makes the final determination.)
- List of people (e.g., competitors) who should not review your application and why
- Disciplines involved, if multidisciplinary
- Statement that you have enclosed the required NIH IC approval documentation for an application over $500,000
- Statement that you have enclosed the required NIH institute approval documentation for a Conference Grant or Cooperative Agreement application (R13 or U13)

Submit a complete application. Incomplete applications will be grounds for the PHS to return the application without peer review. An application will be returned if it is illegible, if the instructions were not followed, or if the material presented is insufficient to permit an adequate review.

The application must be complete and accurate at the time of submission as there is no guarantee that the Scientific Review Administrator will accept or the peer reviewers will consider late material.

Similar, Essentially Identical, or Identical Applications

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

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 principal investigator are the original work of the principal investigator 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 and not by disease or disease state. 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 be returned to the applicant without review.

Essentially identical applications will not be reviewed except for: 1) individuals submitting an application for an Independent Scientist Award (K02) proposing essentially identical research in an application for an individual research project; and 2) individuals submitting an individual research project identical to a subproject that is part of a program project or center grant application.

A. Number of Copies

Original Plus 5 Copies

Submit the **original and five** exact, legible, single-sided photocopies of each application. The **original** must be signed by the principal investigator and an authorized organizational official.

B. Bindings and Packaging

Submit the following materials in one package:

- cover letter;
- original application;
- five copies of the application;
- five sets of Appendix materials.

Do NOT include more than one application set (original plus 5 copies and appendices) in each mailing envelope.

The original application. The original application must be single-sided, with both required signatures on the Face Page. Do **not** staple or otherwise bind the original application. Use rubber bands or clips. Assemble the pages in the order specified in the table of contents. Place the Personal Data page at the end of the application; it is not to be duplicated. If appropriate, attach the RFA label provided in the application kit or a facsimile to the Face Page.

Five exact, single-sided copies of the original application. Make the copies **after** both individuals have signed the Face Page so that their signatures are present on the copies. Do not staple or otherwise bind the five copies of the original application. Rubber bands are acceptable.

Five collated sets of appendix material. The appendix material, and only the appendix material, may be stapled or bound. Do not use notebooks or 3-ring binders. Items should be stapled or bound where appropriate, and each marked with the name of the principal investigator. A summary sheet, listing all of the items included in the Appendix, is encouraged.

C. Submission of Supplementary or Corrective Information

Unless specifically required by these instructions (e.g., vertebrate animals verification), do not send supplementary or corrective material after the submission date unless the Scientific Review Administrator of the Scientific Review Group solicits or agrees to accept this information.

D. Application Mailing Address

Use the mailing labels provided at the end of the forms (MS WORD or PDF).

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
Bethesda, MD 20892-7710
(United States Postal Service (USPS) Express or Regular mail)
or
Bethesda, MD 20817 **(Express/Courier Non-USPS Service)**

The telephone number is (301) 435-0715
TTY (301) 451-0088.

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 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-02-012.html.

There may be additional instructions for submission of responses to RFAs.

E. Application Submission Dates

Applications submitted for the dates listed in Table 2 will be 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/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 holiday, the submission date will be extended to the following workday. The

application will be on time if it is sent on the following workday.

RFAs and PAs. Applications that are being submitted for special dates that are not listed in Table 2 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, and the proof-of-mailing date is not later than 1 week prior to the deadline date. If the date is listed in Table 2, then it is a submission or "send by" date. If a special date is specified, then the application must arrive at NIH by that date.

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, you must include with the signed, completed application a cover letter explaining the reasons for the delay. 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.

Submission, Review and Award Cycles

The PHS submission, review, and award schedule is provided in Table 2.

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

Table 2. Submission Dates, Review, and Award Cycles

Types of Applications	Cycle I	Cycle II	Cycle III
Application Submission Dates			
Institutional Ruth L. Kirschstein National Research Service (Kirschstein-NRSA) Awards* (**All** new, competing continuation, supplemental and revised applications)	January 10	May 10	September 10
Academic Research Enhancement Award (AREA) (**All** new, competing continuation, and revised applications *except* those involving AIDS-related research)	January 25	May 25	September 25
New Research Grants (e.g., R01) and Career Development Awards (K series)	February 1	June 1	October 1
Program Project Grants and Center Grants (P series) (**All** new, competing continuation, supplemental and revised applications)	February 1	June 1	October 1
Competing Continuation, Supplemental and Revised: Research Grants and Career Development Awards**	March 1	July 1	November 1
Small Business Innovation Research (SBIR), Small Business Technology Transfer (STTR) Grants (**All** new, supplemental, and revised applications *except* AIDS and AIDS-Related applications)	April 1	August 1	December 1
Conference Grants and Conference Cooperative Agreements (**All** new, competing continuation, supplemental and revised applications)	April 15	August 15	December 15
AIDS and AIDS-Related Grants (**All** new, competing continuations, supplemental and revised applications; *includes* AIDS and AIDS-Related SBIR/STTR)	May 1	September 1	January 2

Types of Applications	Cycle I	Cycle II	Cycle III
RFAs and PARs	**Special submission dates: Check the specific NIH Guide announcement.**		
Review and Award Schedule			
Scientific Merit Review	June - July	Oct - Nov	Feb - Mar
Advisory Council Review	Sept - Oct	Jan - Feb	May - June
Earliest Project Start Date* **	December	April	July

* Many NIH Institutes and Centers use only one or two of the submission dates for Institutional NRSA awards. Please check the program announcement for "Institutional Research Training Grants (T32)" at http://grants.nih.gov/training/nrsa.htm.

** Some ICs have different submission dates for revised Career Development Award applications. Check with the appropriate IC.

***Awarding components may not always be able to honor the requested start date of an application. Therefore, applicants should make no commitments or obligations until confirmation of the start date by the awarding component.

Application Assignment Information

Competing grant applications submitted to the PHS agencies must be submitted through the Division of Receipt and Referral, CSR, NIH unless otherwise stated. Administrative information about the application is entered into a computer system. The application is then assigned to an appropriate Scientific Review Group and Institute(s). Assignment is based on the scientific content of the application using established referral guidelines.

After the submission date, usually within 6 weeks, the PHS will send the principal investigator/program director and the applicant organization the application's assignment number; the name, address, and telephone number of the Scientific Review Administrator of the Scientific Review group to which the application has been assigned; and the assigned Institute contact and phone number.

If you do not receive applicant assignment information within six 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; TTY (301) 451-0088. If there is a change in assignment, you will receive another notification.

For those investigators registered with the eRA Commons, assignment information as well as review outcome and other important information is available in the Commons.

All institutions are invited to register with the eRA Commons. By joining the Commons, you can create user accounts for your institution's staff and check the status of current grant applications in no time. You can start in immediately with STATUS and the administrative functions, and soon you will be able to use e-SNAP. To join the eRA Commons, go to https://commons.era.nih.gov/commons/registration/registrationInstructions.jsp. For other information, go to the Commons home page.

Applicant investigators 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 and conflicts-of-interest in the peer review process. From the time of assignment to the time the review of your application is complete, you must direct all questions to the Scientific Review Administrator. This individual is in charge of the review group and is identified in the assignment notice that is mailed to you.

F. The Peer Review Process

A description of what happens to your research project grant application after it is received for peer review can be found at the following location: http://www.csr.nih.gov/Welcome/Grant_Application.htm.

Overview

Most applications submitted to the PHS will be reviewed through a two-tier system. The first level of review will be performed by a Scientific Review Group, often called a study section or review committee. The purpose of the SRG is to evaluate the scientific and technical merit of applications. The SRG does not make funding decisions. Additional detailed information on review procedures for scientific review group meetings is located at: http://www.csr.nih.gov/guidelines/proc.pdf. The CSR homepage provides a complete listing of Rosters for the Scientific Review Groups (SRGs) managed by CSR. See http://www.csr.nih.gov/Committees/rosterindex.asp.

Streamlining

The initial scientific peer review of most research applications also will include a process in which only those applications deemed by the reviewers to have the highest scientific merit, generally the top half of the applications under review, will be discussed at the Scientific Review Group meeting, assigned a priority score, and receive a second level review. Applications in the lower half are not discussed or scored at the Scientific Review Group meetings. This process allows the reviewers to focus their discussion on the most meritorious applications.

SRG members will be instructed to evaluate research applications by addressing five review criteria (see below) and assigning a single, global score for each scored application. The score will reflect the overall impact that the proposed research could have on the field. Requests for Applications (*RFAs) and other types of grants may have different and/or additional review criteria.*

As part of the initial merit review and regardless of whether an application is scored or unscored (streamlined), all applicants will receive a written critique, called a Summary Statement. The Summary Statement represents a combination of the reviewers' written comments and, for non-streamlined applications, it includes the SRA's summary of the members' discussion during the study section meeting as well as the recommendations of the study section, a recommended budget, and administrative notes of special considerations.

Information about charters and membership of SRGs, Councils, and Boards can be obtained from the appropriate agency.

Research Project Evaluation Criteria

Significance: Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge or clinical practice be advanced? What will be the effect of these studies on the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Approach: Are the conceptual or clinical framework, design, methods, and analyses adequately developed, well-integrated, well-reasoned, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

In conducting an evaluation of the scientific assessment of Approach criterion, SRGs will also evaluate the involvement of human/animal subjects, the proposed plans for inclusion of minorities and members of both sexes/genders. The evaluation will be factored into the overall score for scientific and technical merit of the application.

Innovation: Is the project original and innovative? For example: Does the project challenge existing paradigms or clinical practice; address an innovative hypothesis or critical barrier to progress in the field? Does the project develop or employ novel concepts, approaches or methodologies, tools, or technologies for this area?

Investigator: Are the investigators appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers? Does the investigative team bring complementary and integrated expertise to the project (if applicable)?

Environment: Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed studies benefit from unique features of the scientific environment, or subject populations, or employ useful collaborative arrangements? Is there evidence of institutional support?

While these review criteria are intended for use primarily with unsolicited research project applications (e.g., R01 or P01), to the extent reasonable, they will also form the basis of the review of solicited applications and non-research activities. However, for some activities (e.g., construction grants), use of these criteria as stated may not be feasible.

Note: In addition to the above criteria, the following items will be considered in the determination of scientific merit and the priority score.

Human Subjects: Protection from Research Risks: In conducting peer review for scientific and technical merit, SRGs also will evaluate the involvement of human subjects and proposed protections from research risk relating to their participation in the proposed non-exempt research plan according to the following four review criteria: (1) Risk to Subjects, (2) Adequacy of protection against risks (3) Potential benefits of the proposed research to the subjects and others and (4) Importance of the knowledge to be gained.

When human subjects are involved in research that involves one of the six categories of research that are exempt under 45 CFR Part 46, the SRG will evaluate the justification for the exemption and (1) Human Subjects Involvement and Characteristics, and (2) Sources of Materials.

Inclusion of Women, Minorities, and Children in Clinical Research: When human subjects are involved in the proposed clinical research, the SRG will also evaluate the proposed plans for inclusion of minorities and members of both sexes/genders, as well as the inclusion of children in clinical research, as part of the scientific assessment of Approach criterion.

Vertebrate animals: As part of the peer review process, the SRG will evaluate the proposed involvement and protection of vertebrate animals as part of the scientific assessment of Approach and Environment criteria and according to the following five points: (1) detailed description of the proposed use of the animals; (2) justification for the use of animals and for the appropriateness of the species and numbers proposed; (3) adequacy of proposed veterinary care; (4) procedures for limiting pain and distress to that which is unavoidable; and (5) methods of euthanasia.

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. **-**

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

INDIVIDUAL RESEARCH CAREER DEVELOPMENT AWARD (CDA) APPLICATION
"K" SERIES

III. PREPARING AN INDIVIDUAL CDA APPLICATION

A. Introduction

This section includes additional instructions to be used when applying for an individual Research Career Development Award (CDA), and includes a summary of current CDA mechanisms, a **substitute** Table of Contents (CDA Substitute Form Page 3), and guidelines for letters of reference. The instructions in this section of the PHS 398 application should be used along with the instructions in the preceding sections.

These instructions do not cover applications for program awards (K12 and K30), which provide support for institutional career development programs. Institutions planning such applications should contact the potential awarding component concerning eligibility, award criteria, and application procedures.

B. Individual Career Development Award Mechanism

Summary of Research Career Development Award Mechanisms			
Program	**Description**	**Sponsor (Mentor)**	**Reference Letters**
K01	Mentored Research Scientist Development Award	Yes	Yes
K02	Independent Scientist Award	No	No
K05	Senior Scientist Award	No	No
K07	Academic Career Award	*	*
K08	Mentored Clinical Scientist Development Award	Yes	Yes
K18	Career Enhancement Award for Stem Cell Research	Yes	Yes
K22	Career Transition Award (see specific IC)	*	Yes
K23	K23 Mentored Patient-Oriented Research Career Development Award	Yes	Yes
K24	Mid-Career Investigator Award in Patient Oriented Research	No	No
K25	Mentored Quantitative Research Career Development Award	Yes	Yes

Summary of Research Career Development Award Mechanisms			
Program	**Description**	**Sponsor (Mentor)**	**Reference Letters**
K26	Midcareer Investigator Award in Mouse Pathobiology Research	No	No

*Varies with career status and source of award. Check the program announcement (PA).

Before applying for a CDA, applicants should carefully review the guidelines in the NIH program announcement or request for applications for the specific career award(s) of interest, noting especially the eligibility requirements, award provisions, requirements for a sponsor, and review criteria. NIH program announcements and requests for applications for career awards are issued periodically in the *NIH Guide for Grants and Contracts*. The PAs and other guidelines are available on the NIH website http://grants.nih.gov/training/careerdevelopmentawards.htm.

The eligibility criteria, support levels, and other important aspects of specific career awards, including availability, may vary among NIH Institutes or Centers and other PHS agencies. For this reason, it is strongly recommended that applicants contact the program director of the appropriate awarding component prior to the preparation of an application. For NIH career awards, the program contacts are listed in the individual program announcements for CDAs (see http://grants.nih.gov/training/careerdevelopmentawards.htm). For non-NIH career awards, applicants should read the instructions of the appropriate funding announcement carefully or contact an official. (See the Agency Contact table.)

C. Letters of Reference

Letters are required for all new and revised mentored CDA applications (see table of Career Development Award Mechanisms, Section B). **Applications with fewer than three reference letters may be delayed or may be returned without review**. These letters should be from individuals not directly involved in the application, but who are familiar with your qualifications, training, and interests. **The sponsor/mentor of this application cannot be counted as a reference.**

3 required

The letters are critically important and should address the candidate's competence and potential to develop into an independent biomedical or behavioral investigator. Only those individuals who can make the most meaningful comments about the candidate's professional training and qualifications for a research career should be used as referees. Where possible, some referees who are not from the candidate's current department or organization, but are knowledgeable about their qualifications, should be selected.

Request reference letters only from individuals who will be able to return them to you in time for submission with the application.

Complete the upper section of the **CDA Reference Guidelines Format Page (MS Word or PDF)** including the application submission deadline. Then send copies of the CDA Reference Guidelines Format Page to those who have agreed to serve as referees. Referees should be provided with postage-paid return envelopes *addressed to the candidate* with the following words in the front bottom left corner "DO NOT OPEN PHS USE ONLY." **Attach unopened envelopes to the Face Page of the original application and submit the entire package by the submission deadline**. **Applicants reapplying must include a new set of reference letters.**

D. Basic Administrative Data

1. FORM PAGE 1 (MS WORD OR PDF)

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

Check "Yes." Provide appropriate K Award PA or RFA number (see previous section) and title for the specific type of CDA requested.

Item 3. Principal Investigator/Program Director

Provide the name of the candidate. Indicate the doctoral degree(s) in 3b. If the candidate is not located at the applicant organization at the time the application is submitted, the mailing and e-mail addresses (Item 3d) and telephone (Item 3g) should indicate where the applicant can be reached prior to the requested award date; items 3c, 3 e, and 3f should reflect the candidate's projected position at the applicant organization.

Item 6. Dates of Proposed Period of Support

The period of support must be within specified limits for the type of CDA requested. If the application involves a change of applicant organization for an active CDA awardee, indicate the time remaining in the original award.

2. DESCRIPTION, PERFORMANCE SITES, KEY PERSONNEL, OTHER SIGNIFICANT CONTRIBUTORS, AND HUMAN EMBRYONIC STEM CELLS

FORM PAGE 2 (MS WORD OR PDF)

Description: Project Summary and Relevance

The first major component of the Description is a **Project Summary**.

Provide an abstract of the whole application (candidate, environment, and research). Include the candidate's immediate and long-term career goals, research career development plan, and a description of the research project.

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.

Performance Site(s)

Indicate where the work described in the Research and Career Development Plans will be conducted. If there is more than one performance site, list all the sites, including Department of Veterans Affairs (V.A.) facilities and foreign sites, and provide an explanation on the Resources Format Page of the application. If the use of a performance site will involve research using human subjects, it is the responsibility of the applicant organization to assure that the performance site complies with the human subject protection regulations in 45 CFR Part 46 and other NIH human subject related policies described in the PHS 398 and GPS. For research involving vertebrate animals, the applicant organization must ensure that all performance sites hold OLAW-approved assurances.

Key Personnel and Other Significant Contributors

Name the candidate and, if applicable, the sponsor/mentor(s), co-sponsor(s), consultants, and contributors as Key Personnel or as Other Significant Contributors as described in Section I.C.2. Individuals identified as Key Personnel must devote measurable effort to the proposed project whether or not salaries are requested. Individuals who have committed to contribute to the scientific development and execution of the project, but are not committing any specified measurable effort to the proposed project should be identified as Other Significant Contributors. Please note that for Mentored Career Development Awards, modified Other Support Pages must be submitted for sponsor(s) and co-sponsor(s) (see Section 7).

For CDAs with no sponsor, the candidate's department head or other senior staff member should be named who is responsible for ensuring that the candidate's time is protected for the expressed goals of the award.

Human Embryonic Stem Cells

If your research plan involves the use of human embryonic stem cells, read and follow the instructions in Section I.C.2.

3. Table of Contents

CDA SUBSTITUTE FORM PAGE 3 (MS WORD OR PDF)

Use the **substitute** Table of Contents for CDAs.

Citizenship

All applicants must provide information regarding citizenship at the bottom of the substitute Table of Contents. The Candidate must be a citizen or non-citizen national of the United States or its possessions and territories, or must have been lawfully admitted to the United States for permanent residence by the time of the award.

4. Detailed Budget for Initial Budget Period

FORM PAGE 4 (MS WORD OR PDF)

Form Page 4 is not required at the time of application. Should Form Page 4 be requested prior to award, specific instructions will be provided.

If you are submitting an application to an agency other than NIH, be sure to read the instructions in the funding announcement to determine whether the application should be submitted in the modular format; or contact an appropriate official. (See PHS Agency Contact Table.)

5. Budget for Entire Proposed Period of Support

FORM PAGE 5 (MS WORD OR PDF)

Do not fill in the budget table on Form Page 5. Provide only the total direct costs requested for each year and total direct costs for the entire proposed period of support. **(Consult the relevant PA or RFA for guidelines on allowable costs and budget limitations.)**

Begin the budget justification in the space provided; use continuation pages as needed.

Budget Justification

List the name, role on project, and percent effort for all project personnel (salaried or unsalaried) and provide a narrative justification for each person based on his/her role on the project and proposed level of effort.

Identify all consultants by name and organizational affiliation, and describe the services to be performed.

Provide a narrative justification for any major budget items, other than personnel, that are requested for the conduct of the project that would be considered unusual for the scope of research. **No specific costs for items or categories should be shown.**

6. Biographical Sketch

FORMAT PAGE (MS WORD OR PDF)

A biographical sketch (***limited to four pages for each person***) is required for the candidate, sponsor(s), co-sponsor(s), and other Key Personnel. Biographical sketches should follow the order listed on Form Page 2.

Sponsor(s), co-sponsor(s), and other Key Personnel should follow the Biographical Sketch Format Page.

Candidates should follow the instructions below.

Education

Provide the month and year for each degree conferred. For non-degree education, indicate the time period covered. List professional certifications received within the last 10 years.

Research and/or Professional Experience

Use the headings given below instead of the instructions on the Biographical Sketch Format Page. Identify each heading.

Employment

Start with the first position held following the baccalaureate and give a consecutive record to date. Indicate the department and

organization, department head or supervisor, rank, tenured or non-tenured, status (full- or part-time), and inclusive dates. Where applicable, include information on military service, internships, residencies, research assistantships, fellowships, etc.

Honors

List academic and professional honors chronologically.

Professional Societies

Identify professional societies and related organizations in which membership has been held within the last 10 years, giving dates.

Publications

List all publications (chronologically), divided into the following groups:

- Original research and theoretical treatises;
- Non-experimental articles, e.g., review of literature in field, book chapters, etc.;
- Books, pamphlets, etc.
- If the list of publications cannot be accommodated within the four-page limit, select the most pertinent publications. If a copy of a publication is being submitted with the application, indicate with an asterisk and footnote "copies sent." For competing continuation applications, also identify with a double asterisk and appropriate footnote all papers published during the concluding period of support.

7. OTHER SUPPORT FORMAT PAGE (MS WORD OR PDF)

For mentored CDAs (see Summary of Award Mechanisms table)**:** Submit modified Other Support Page(s) for the sponsor(s) and co-sponsor(s), but not for the candidate. Provide information for the following selected items on the sponsor's and co-sponsor's current and pending research **support relevant to the candidate's research plan**.

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.

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.

Do not include information on overlap and level of effort.

For non-mentored CDAs: Do not submit Other Support Pages at the time of application unless specified to do so in the corresponding career award announcement (e.g., K24).

Updated information on all active support for the candidate, sponsor(s), co-sponsor(s), and Key Personnel may be requested by the awarding component prior to award.

8. RESOURCES

RESOURCES FORMAT PAGE (MS WORD OR PDF)

Provide a detailed description of the institutional resources available to you, following instructions on the Resources Format Page. The information provided is of major importance in establishing the feasibility of the goals of the career development plan.

E. Additional Information for Revised Applications

Use **CONTINUATION FORMAT PAGES (MS WORD OR PDF)** to complete the sections below.

1. Introduction to Revised Application (for revised applications only)

All revised applications must include an Introduction to Revised Application, **not to exceed three pages.**

List each area of concern noted in the Summary Statement for the previous application, and provide a detailed response to each concern. Summarize clearly the changes that have been made in the revised application. Do not include an extensive description of each change in the introduction. In the body of the application, highlight paragraphs with significant changes by bracketing, indenting, or changing the typography. If the changes are so extensive as to include most of the text, this exception should be explained in the Introduction to the Revised Application. Do not underline or shade changes.

F. Career Development Plan

Use **CONTINUATION FORMAT PAGES (MS WORD OR PDF)** to complete the sections below.

1. The Candidate

Candidate's Background

Use this section to provide any additional information not described in the Biographical Sketch Format Page such as research and/or clinical training experience.

Career Goals and Objectives: Scientific Biography

Describe your past scientific history, indicating how the award will fit into past and future research career development. If there are consistent themes or issues that have guided previous work, these should be made clear; if your work has changed direction, the reasons for the change should be indicated. It is important to justify the award and how it will enable you to develop or expand your research career.

Career Development/Training Activities During Award Period

Stress the new, enhanced research skills and knowledge you will acquire as a result of the proposed award. If you have considerable research experience in the same areas as the proposed research, reviewers may determine that the application lacks potential to enhance your research career. For mentored awards, describe structured activities, such as course work or technique workshops, which are part of the developmental plan.

Training in the Responsible Conduct of Research

All CDA applications must describe a plan to acquire (or provide) training in the responsible conduct of research. There are no specific curriculum or format requirements for this instruction; however, conflict of interest, responsible authorship, policies for handling misconduct, policies regarding the use of human and animal subjects, data management, and data-sharing are areas that are strongly suggested for consideration. Applicants may wish to consult the NIH web site (http://www.nih.gov/sigs/bioethics/researchethics.html) for additional guidance.

Briefly discuss each of the activities, except research, in which you expect to participate. Include a percentage of time involvement for each activity by year, and explain how the activity is interrelated with the proposed research and the career development plan.

2. Statements by Sponsor, Co-Sponsor(s), Consultant(s), and Contributor(s)

This section is to be completed by the sponsor, co-sponsor(s), consultant(s), and contributor(s), as appropriate.

For mentored awards (see Summary of Career Development Award Mechanisms table), the sponsor must explain how the award will enhance the development of the candidate's research career. Provide in detail the plan for the candidate's training and research career development. This description must include not only research, but also other developmental activities, such as seminars, scientific meetings,

training in the responsible conduct of research, and presentations. It should discuss expectations for publications over the entire period of the proposed project.

The sponsor should explain the nature and extent of supervision and commitment to the candidate's development that will occur during the award period and the source or anticipated support for the candidate's research project for each year of the award period. The sponsor should describe previous experience as a mentor, including type of mentoring (e.g., graduate students, career development awardees, postdoctoral students), number of persons mentored, and career outcomes.

The sponsor should describe the candidate's anticipated teaching load for the period of the award (number and types of courses or seminars), clinical responsibilities, committee and administrative assignments, and the portion of time available for research.

All mentored career development applications should identify all co-sponsors, consultants and collaborators involved with the proposed research and career development program. Briefly describe their roles and anticipated contributions that they will provide. A co-sponsor must specifically address the nature of his/her role in the career development plan and how the responsibility for the candidate's development is shared with the sponsor. Describe respective areas of expertise and how they will be combined to enhance the candidate's development. Describe previous experience as a mentor. Also describe the nature of any resources committed to this CDA. Letters from the sponsor, co-sponsor(s), consultant(s), and contributor(s) documenting their role and willingness to participate in the project must be included in this section of the application. Do not place these letters in the Appendix.

Non-mentored career development award applications should also list any contributors or consultants. Briefly describe research materials, data, guidance, or advice they will provide. **Letters** from consultant(s) and contributor(s), documenting their willingness to participate in the project and describing their roles, **must be included in this section of the application as well.**

3. Environment and Institutional Commitment to the Candidate

Description of Institutional Environment

The sponsoring institution must document a strong, well-established research program related to the candidate's area of interest, including the names of key faculty members relevant to the candidate's proposed developmental plan. Referring to the resources description (Resources Format Page), indicate how the necessary facilities and other resources will be made available for career enhancement as well as the research proposed in this application. Describe opportunities for intellectual interactions with other investigators, including courses offered, journal clubs, seminars, and presentations.

Institutional Commitment to the Candidate's Research Career Development

Introduction

The institutional commitment should document the agreement of the institution to provide adequate time and support for the candidate to devote the proposed protected time to research and career development for the entire period of the proposed award. The institution should provide the equipment, facilities, and resources necessary for a structured career development experience. It is essential to document the institution's commitment to the retention, development, and advancement of the candidate during the period of the award.

Because of the diverse types of K awards, applicants should contact the appropriate awarding component program director listed in the specific PA or RFA to determine the level of commitment required for this application.

Agreement

The applicant organization must:

a. Agree to release the candidate from other duties and activities to devote the required percentage of time for development of a research career. For most K awards, commitment of at least 75 percent of time is required. Describe actions that will be taken to ensure this; e.g., reduction of the candidate's teaching load, committee and administrative assignments, and clinical or

other professional activities for the current academic year. Describe the candidate's academic appointment, bearing in mind that it must be full-time, and that the appointment (including all rights and privileges pertaining to full faculty status if in an academic setting) and the continuation of salary are not contingent upon the receipt of this award. Describe the proportion of time currently available for the candidate's research experience and what the candidate's institutional responsibilities will be if an award is made;

b. Provide the candidate with appropriate office and laboratory space, equipment, and other resources and facilities (including access to clinical and/or other research populations) to carry out the proposed research plan; and

c. Provide appropriate time and support for any proposed sponsor(s) and/or other staff consistent with the career development plan.

Signatures

The institutional commitment must be dated and signed by the person who is authorized to commit the institution to the agreements and assurances listed above. In most cases, this will be the dean or the chairman of the department. "Per" signatures are not acceptable.

The signature must appear over the signer's name and title at the end of the statement. If the candidate will be working away from the home institution, signatures from both the home and the host institution are required.

The sponsoring institution, through its signatures on the Face Page and in the institutional commitment section, certifies that all items outlined above will be provided and that the institution will abide by the applicable assurances and PHS policies.

4. RESEARCH PLAN

A Research Plan is required for all types of individual K awards. The Research Plan is the major component of the research career development plan. It is important to relate the research to the candidate's scientific career goals. Describe how the research, coupled with other developmental activities, will provide the experience, knowledge, and skills necessary to launch and conduct an independent research career, or enhance an established research career.

For most types of research, the plan should include: a specific hypothesis; a list of the specific aims and objectives that will be used to examine the hypothesis; a description of the methods/approaches/techniques to be used in each aim; a discussion of possible problems and how they will be avoided; and, when appropriate, alternative approaches that might be tried if the initial approaches do not work.

The plan should be appropriate to develop skills needed by a researcher. Projects that lack a clearly stated aim or hypothesis, such as studies involving routine data gathering to see where leads might develop and other types of descriptive projects, usually do not receive favorable recommendations from peer reviewers. This also applies to projects that are overly ambitious and describe more work than can be done in the requested time, as well as more routine projects that might be done, in large part, by a skilled technician.

Although candidates for mentored K awards are expected to write the Research Plan, the sponsor should review a draft of the plan and discuss it in detail with the candidate. Review by other knowledgeable colleagues is also helpful.

Follow the research plan format and instructions described in Section I, Item 7 of the main instructions, except as noted below.

The headings for the first four sections of the Research Plan are:

a. Specific Aims

b. Background and Significance

c. Preliminary Studies/Progress Report

d. Research Design and Methods

Note: The total number of pages for Item 1 (The Candidate) and a-d of Item 4 (Research Plan) combined may not exceed 25 pages. In many cases, CDA applications will be shorter than the limit.

Although it is understood that CDA applications do not require the extensive detail usually incorporated into regular research applications, a fundamentally sound Research Plan and a reasonably detailed methods section should be provided.

In general, less detail will be expected in descriptions of research planned for the future years of the proposed CDA, but there should be sufficient detail to enable the peer reviewers to determine that the plans for those years, including the methods to be used, are worthwhile and are likely to enhance development of the candidate.

e. Human Subjects Research

If your research plan involves Human Subjects Research, read and follow the full instructions in Section I. **For new Clinical Research, place the Target/Planned Enrollment Table(s) in section e.**

f. Vertebrate Animals

If your research plan involves Vertebrate Animals, follow the instructions in Section I.

g. Literature Cited

Follow the instructions in Section I.

h. Consortium/Contractual Arrangements

Follow the instructions in Section I.

i. Resource Sharing

Follow the instructions in Section I.

j. Consultants

Omit this section.

5. APPENDIX

Submit no more than five publications and manuscripts accepted for publication. Do not submit abstracts or unpublished theses. Submit five collated sets.

6. CHECKLIST

CHECKLIST FORM PAGE (MS WORD OR PDF)

Submit the Checklist Page with the application.

Type of Application

Check all that apply.

Inventions and Patents (Competing Continuation 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 the *Policies, Assurances and Definitions and Other Information*.

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 Grant Award will provide specific instructions regarding the use of such income.

Assurances/Certifications

Each application to the PHS requires that the policies, assurances, and certifications listed on the Checklist be verified by the signature of the

official signing for the applicant organization on the Face Page of the application.

Facilities and Administrative (F&A) Costs

These costs will be reimbursed at 8 percent of modified total direct costs.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE

Institutional Ruth L. Kirschstein National Research Service Award (NRSA) Application

IV. INSTRUCTIONS FOR PREPARING AN NRSA APPLICATION

Sequential Guide for Preparing an Institutional Kirschstein-NRSA Application (Requires use of both the General and Kirschstein-NRSA Instructions.)	
Web Document Links	**Page References**
FORM PAGE 1	
Item 1. Specific PHS 398 Instructions	PHS 398-17
Item 2. Kirschstein-NRSA Instructions and Specific PHS 398 Instructions	NRSA-55 PHS-17
Item 3. Specific PHS 398 Instructions	PHS 398-17
Item 4. Kirschstein-NRSA Instructions	NRSA-55
Item 5. Kirschstein-NRSA Instructions	NRSA-55
Item 6. Kirschstein-NRSA Instructions and Specific PHS 398 Instructions	NRSA-56 PHS 398-20
Item 7. Specific PHS 398 Instructions	PHS 398-20
Form Pages 2-3: Kirschstein-NRSA Instructions (Form Page 2) and (Form Page 3)	NRSA-56
Form Page 4: Kirschstein-NRSA Instructions and Stipends	NRSA-57
Form Page 5: Kirschstein-NRSA Instructions	NRSA-57
Biographical Sketch Format Page: Kirschstein-NRSA Instructions	NRSA-57
Resources Format Page: Kirschstein-NRSA Instructions	NRSA-57
Research Training Program Plan: Kirschstein-NRSA Instructions	NRSA-58

A. Introduction

This section includes instructions to be used when applying for a competing (new, competing continuation, and supplemental) PHS Institutional Ruth L. Kirschstein National Research Service Award (Kirschstein-NRSA), substitute form pages for the Table of Contents and both budget pages, and instructions for the Research Training Program Plan. Begin by reading the General Instructions in Section I-B, and then follow both sets of instructions using the Sequential Guide for Preparing an Institutional Kirschstein-NRSA Application. (See table on previous page.)

Prior to preparing an application, consult with the appropriate PHS awarding component. Also review the current T32, T34 or T35 Kirschstein-NRSA Program Announcement (PA) available at (http://grants.nih.gov/training/nrsa.htm). Note especially the eligibility requirements, submission dates, award provisions, payback provisions, and review criteria. PAs are also issued periodically by the individual NIH Institutes or Centers in the *NIH Guide for Grants and Contracts*. This information is available from the appropriate PHS agency, from grantee offices of sponsored programs, or equivalent offices.

Please note that the training grant director must explain the terms of the payback service requirement to all prospective postdoctoral training candidates. A complete description of the service payback obligation is available in the NRSA Program Announcement or the NIH Grants Policy Statement.

B. Specific Instructions

1. Face Page (MS WORD or PDF)

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

Indicate "Institutional Ruth L. Kirschstein NRSA" and the specific PHS awarding component and/or specialized program area, if applicable.

Item 4. Human Subjects

Check “Yes” if training plans include involvement of trainees in projects that include human subjects. If the applicant organization has an approved Federal Wide Assurance (FWA) or other Assurance on file with the Office for Human Research Protections (OHRP), insert the FWA or other number in Item 4b. If an award is made, human subjects may **not** be involved and trainees may not participate in human subjects related research until a certification of the date of IRB approval or a designation of exemption has been submitted to and accepted by the PHS agency, and NIH requirements for human subjects research have been addressed (see instructions in Section I, Human Subjects Research, and the GPS).

In many instances, trainees supported by institutional training grants will be participating in research supported by research project grants for which the IRB review of human subjects is already complete or an exemption is already designated. This review or exemption designation is sufficient, provided the IRB determines that the research would not be substantially modified by the participation of a trainee. The appropriate grants must be identified along with their IRB review dates or exemption designation in Section F of the Research Training Plan.

These policies apply to all Performance Sites.

Item 5. Vertebrate Animals

Check “Yes” if training plans include trainee participation in projects involving vertebrate animals. If the applicant organization has an approved Animal Welfare Assurance on file with the Office of Laboratory Animal Welfare (OLAW), insert the assurance number in Item 5b. If at the time of application, plans for the involvement of vertebrate animals are so indefinite that Institutional Animal Care and Use Committee (IACUC) review and approval are not feasible, insert "Indefinite" at Item 5a.-

In many instances, trainees supported by institutional training grants will be participating

in research supported by research project grants for which the IACUC review is already complete. This review is sufficient, provided the IACUC determines that the research would not be substantially modified by the participation of a trainee. The appropriate grants must be identified along with their IACUC approval dates in Section G of the Research Training Program Plan.

If an award is made, vertebrate animals may not be used and trainees may not participate in vertebrate animal related research until a verification of the date of IACUC approval has been submitted to the PHS awarding component.

These policies apply to all Performance Sites.

Item 6. Dates of Entire Proposed Period of Support

The usual starting date for an institutional Kirschstein-NRSA is July 1, but there are other possible starting dates. Consult the review and award schedule in Section I of the general instructions (Table 2. Submission, Review, and Award Cycles). Many PHS awarding components restrict submission and review dates to once a year. **Applicants are strongly encouraged to contact appropriate awarding component staff before submitting an application.**

2. Description, Performance Sites, Key Personnel, Other Significant Contributors, and Human Embryonic Stem Cells

FORM PAGE 2 (MS WORD OR PDF)

Description: Project Summary and Relevance

The first and major component of the Description is a **Project Summary**. Summarize the objectives, rationale and design of the research training program. Provide information regarding the research areas and scientific disciplines encompassed by the program. Include a brief description of the level(s) and duration of the proposed training, the projected number of participating trainees and their anticipated levels of experience.

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.

Performance Sites. List all of the locations where training, program management, and the research experiences described in the Program Plan will be performed. If a performance site is participating in research using human subjects, it is the responsibility of the applicant organization to assure that the performance site complies with the human subject protection regulations in 45 CFR Part 46 and other NIH human subject related policies described in the PHS 398 and GPS. For research involving vertebrate animals, the applicant organization must ensure that all performance sites hold OLAW-approved assurances.

Key Personnel and Other Significant Contributors. The Program Director, training faculty and any other individuals whose contributions are critical to the development, management and execution of the Training Program in a substantive, measurable way (whether or not salaries are reimbursed) should be identified as Key Personnel. Since these efforts are not project related research endeavors, they should not be identified in Other Support information. The Other Significant Contributors section is not relevant for NRSA applications.

Human Embryonic Stem Cells. For each trainee utilizing human embryonic stem cells in a research project, list project title, mentor, and specific cell line(s) from the registry.

3. Table of Contents

KIRSCHSTEIN-NRSA SUBSTITUTE FORM PAGE 3 (MS WORD OR PDF)

Use the substitute Table of Contents for Kirschstein-NRSA.

4. Detailed Budget for Initial Budget Period

INSTITUTIONAL KIRSCHSTEIN-NRSA SUBSTITUTE FORM PAGE 4 (MS WORD OR PDF)

If you are requesting a budget of $500,000 directs costs or more for any year, contact the awarding component to determine whether you must obtain prior approval before submitting the application. Some Institutes/Centers do not require prior approval. (See Policy on the Acceptance for Review of Unsolicited Applications That Request $500,000 or More in Direct Costs.)

Use the Institutional Kirschstein-NRSA Substitute Form Page 4 and Institutional Kirschstein-NRSA Substitute Form Page 5 and follow the instructions below. **Refer to the relevant PA or consult the PHS awarding component for current allowable costs and stipend levels**. Provide information where possible on the substitute Institutional Kirschstein-NRSA Substitute Form Page 4, with additional details starting in the budget justification block on the substitute Kirschstein-NRSA Substitute Form Page 5.

Stipends

Enter the number of trainees and total stipend amount for each trainee category as appropriate. Use the current Institutional Kirschstein-NRSA stipend schedule, (http://grants.nih.gov/training/nrsa.htm). If a category contains different stipend levels, e.g., for varying levels of postdoctoral experience and/or varying appointment periods, itemize. Enter the total stipends for all categories.

Tuition, Fees, and Health Insurance

Explain in detail the composition of this item. Itemize tuition, individual fees, and medical insurance. If tuition varies, (e.g., in-state, out-of-state, student status) identify these separately. Tuition at the postdoctoral level is limited to that required for specified courses. Tuition and fees (including self-only or family health insurance) may be requested only to the extent that the same resident or nonresident tuition and health insurance fees are charged to regular non-Federally supported students and postdoctorate fellows. Grantees should request full needs. A formula will be applied by the NIH awarding component at the time an award is calculated.

Trainee Travel

State the purpose of any travel, giving the number of trips involved, the destinations, and the number of individuals for whom funds are requested, bearing in mind that PHS policy requires coach class air travel be used. Justify foreign travel in detail, describing its importance to the training experience.

Training Related Expenses

Funds to defray other costs of training, such as staff salaries, consultant costs, equipment, research supplies, staff travel, etc., are requested as a lump sum based on the amounts specified in the Program Announcement for each predoctoral and postdoctoral trainee. Give the number of trainees at the predetermined rate and enter the total dollar figure. No further itemization or explanation is required.

5. Budget for Entire Proposed Period of Support

INSTITUTIONAL KIRSCHSTEIN-NRSA FORM PAGE 5 (MS WORD OR PDF)

Use the Institutional Kirschstein-NRSA Substitute Form Page 5.

6. Biographical Sketch

BIOGRAPHICAL SKETCH FORMAT PAGE (MS WORD OR PDF)

There is no Form Page for biographical sketches. Follow the format on the Biographical Sketch Format Page. Include biographical sketches, not to exceed four pages each, for all professional personnel contributing to the training program. Assemble sketches with the program director first and others following in alphabetical order.

7. Resources

RESOURCES FORMAT PAGE (MS WORD OR PDF)

Follow the format and instructions on the Resources Format Page. Describe the facilities and resources that will be used in the proposed training program. Indicate in what ways the applicant organization will support the program (e.g., supplementation of stipends).

8. Research Training Program Plan

Introduction (Revised/Supplemental Applications Only)

If you are preparing a **revised** or **supplemental** application, complete the Introduction section first (see instructions provided earlier in Section I, Revised Applications or Competing Supplements).

Follow the outline below for all applications to describe the Research Training Program Plan. **Do not exceed 25 pages of narrative for sections A-D.** The information provided in tables (see below) will not be counted toward the page limitation; however, these tables should be numbered consecutively and each given a title. Number the table pages at the bottom of the page according to their placement within the narrative or contiguously at the end of the narrative to maintain the continuity of the application.

Before completing the training plan, contact the appropriate PHS awarding component, which may have further advice or suggestions for organizing the relevant data into particular formats.

A. Background

Give the rationale for the proposed research training program, relevant background history, and the need for the research training proposed. Indicate how the proposed program relates to current training activities at the applicant institution.

Summarize the research training activities of the major participating unit(s) and department(s) represented in the proposed program. **In a table (Table 1),** provide the current number of faculty members in each unit and department, as well as the total numbers of current predoctoral students and postdoctoral trainees.

In a table (Table 2), list all current and pending training support available to the participating faculty and department(s). For each grant, include status (active or pending), funding source, complete identifying number, dates of the entire project period, annual direct costs, name of the program director, title of the training program, and number of training positions (predoctoral and postdoctoral). List participating faculty members who are also named in this application, and indicate their percent effort in those programs.

B. Program Plan

1. **Program Administration**. Describe the program director's qualifications for providing leadership of the program, including relevant scientific background, current research areas, and experience in research training. Indicate the program director's percent effort in the proposed program.

   Describe the administrative structure of the program and the distribution of responsibilities within it, including the means by which the program director will obtain continuing advice with respect to the operation of the program.

2. **Program Faculty**. List each training faculty member, his/her primary departmental affiliation, and role in the proposed program. Describe each faculty member's research that is relevant to this program and indicate how trainees will participate in this research. Describe the extent to which participating faculty members cooperated, interacted, and collaborated in the past, including joint publications and joint sponsorship of student research.

   In a table (Table 3), for each participating faculty member, list active and pending research grant and contract support from all sources (including Federal, non-Federal, and institutional research grant and contract support) that will provide the context for research training experiences. If none, state "None." Include the source of support, grant number and title, dates of the entire project period, and annual direct costs. If part of a larger project, identify the principal investigator and provide the

above data for both the parent grant and the subproject.

In a table (Table 4), for each participating faculty member, list all past and current students for whom the faculty member was/is the thesis advisor or sponsor (past 10 years only). For each student indicate: 1) whether predoctoral or postdoctoral; 2) the training period; 3) previous institution, degree, and year awarded prior to entry into training; 4) title of the research project; and 5) for past students, their current positions, and for current students, their source of support.

For **new applications**, list representative recent publications of some of the above students or postdoctorates.

In competing continuation applications, denote trainees who were or are supported by this training grant with an asterisk. Individuals who were trained at sites other than the applicant organization may be included but should be specifically identified. Publications of trainees should be listed in the Progress Report of this application (see instructions for Progress Report below).

3. **Proposed Training**. Describe the proposed training program. State the training level and number of trainees. For postdoctoral trainees, indicate the proposed distribution by degree (e.g., M.D., Ph.D.). Describe course work and research opportunities, the extent to which trainees will participate directly in research, and the duration of training, i.e., usual period of time required to complete the training offered.

   Indicate how the individual disciplinary and/or departmental components of the program are integrated and coordinated and how they will relate to an individual trainee's experience.

   For training programs that emphasize research training for clinicians, describe the interactions with basic science departments and scientists. Include plans for ensuring that the training of these individuals will provide a substantive foundation for a competitive research career. Generally, a minimum of 2 years of research training is required for all postdoctoral trainees with health professional degrees. Describe fully any trainee's access to and responsibility for patients, including time commitment.

   Provide representative examples of programs for individual trainees. Include curricula, degree requirements, didactic courses, laboratory experiences, qualifying examinations, and other training activities, such as seminars, journal clubs, etc. Describe how the preceptor and research problems are chosen, how each trainee's program will be guided, and how the trainee's performance will be monitored and evaluated.

4. **Training Program Evaluation.** Program directors are encouraged to develop methods for ongoing evaluation of the quality of the training program. Describe any plans for such an evaluation, e.g., plans to obtain feedback from current and former trainees to help identify weaknesses in the training program and to provide suggestions for program improvements.

5. **Trainee Candidates**. Describe recruitment plans, including the sources and availability of trainees; the qualifications of prospective trainees; and the criteria and procedures by which trainees will be selected.

   Create **a table(s) (Table 5a, b, etc.)** for each participating department/unit for each of the past 5 years. Include the following information: 1) number of individuals who have formally applied for training; 2) number offered admission; 3) number who entered training; 4) number who completed or are currently in training; and 5) number who left the program.

   Indicate whether these individuals were applying for predoctoral or postdoctoral training; for postdoctoral fellows, identify their degrees (e.g., M.D., Ph.D.).

   Prospective predoctoral trainees. **In a table (Table 6)**, anonymously indicate the credentials and application outcomes of the predoctoral applicant pool for the most recent year for each participating department and unit. For each applicant (identified with a number in sequence,

rather than by name, to safeguard privacy) indicate the previous institution attended, Graduate Record Examination scores, and grade point average. Indicate whether applicants were or were not offered admission, which applicants matriculated, and whether applicants were U.S. citizens or had permanent resident status.

Prospective postdoctoral trainees. In a table (Table 7), present the qualifications of prospective postdoctoral trainees in the most recent applicant pool. Provide the degree(s) and year awarded, previous institution, thesis research topic, preceptor, citizenship or permanent resident status, and residency training (when appropriate) for each prospective applicant to the program. Indicate whether applicants were or were not offered admission and which applicants entered the program.

C. Minority Recruitment and Retention Plan

The NIH promotes broad and systematic efforts to recruit individuals from minority groups currently underrepresented in biomedical and behavioral research. The accomplishments of Kirschstein-NRSA programs, with respect to recruiting and retaining individuals from underrepresented groups, will ensure that minority scientists are progressively better represented in the national research effort.

Applications without a description of minority recruitment efforts will be considered incomplete and will be returned to the applicant without peer review.

Describe the program's previous efforts and plans to recruit and train graduate students and/or postdoctoral trainees from ethnic or racial groups underrepresented in biomedical and behavioral research. Organize the information as follows:

History. Describe efforts to recruit minority students into the existing training program. In **competing continuation applications**, also describe past efforts to recruit and retain underrepresented minority students into Kirschstein-NRSA training positions.

Achievements. In a table (Table 8), summarize recruitment data for the program and/or each of the participating departments or units in each of the past 3 years. Provide the number of minority individuals who applied; number offered admission; and number who entered the program. For those who entered the program, indicate current status (i.e., in training, graduated or completed training) and all sources of support. For those who have left the program or completed training, include information about their subsequent career development or employment. In competing continuation applications, indicate which individuals were supported by the Kirschstein-NRSA grant.

Proposed plans. Describe steps to be taken during the proposed award period regarding the identification, recruitment, and retention of graduate students and postdoctorates from underrepresented groups. Consider the success and/or failures of recruitment strategies used in the past. In particular, describe the specific efforts to be undertaken by the training program and how these might relate to the recruitment efforts of the medical school, graduate school, and/or the university at large. In most cases, institutional efforts alone will not satisfy the requirement to recruit individuals from underrepresented groups.

D. Plan for Instruction in the Responsible Conduct of Research

Applications lacking a plan for instruction in the responsible conduct of research will be considered incomplete and will be returned to the applicant without review.

Every Kirschstein-NRSA trainee **must** receive instruction in the responsible conduct of research. Describe a plan to provide trainees with formal and informal instruction on scientific integrity and ethical principles in research. The plan must address the rationale for the instruction, the format and subject matter, the degree of faculty participation, trainee attendance, plans to assess the quality and the frequency of instruction. For **competing continuation applications**, describe the type of instruction provided in the current project period, the degree of student participation, the results of any assessments and other relevant information.

There are no specific curriculum or format requirements for this instruction; however, conflict of interest, responsible authorship,

policies for handling misconduct, policies regarding the use of human and animal subjects, data management, and data-sharing are areas that are strongly suggested for consideration. Applicants may wish to consult the NIH web site (http://www.nih.gov/sigs/bioethics/researchethics.html) for additional guidance.

E. Progress Report (Competing Continuation Applications Only)

State the period covered. Briefly describe the accomplishments of the training program. **In a table (Table 9)**, for each year of the grant since the last competing application, provide the following: 1) total number of positions awarded in each training category; 2) number of predoctoral trainees appointed and months of support committed; and 3) number of postdoctoral trainees appointed, with what degrees, at what levels, and for how many months. If any trainee positions were not filled, explain the reason.

In a table (Table 10), list all trainees who were, or are, supported by this training grant (past 10 years only, if applicable). For each student provide: 1) name; 2) year of entry into the training program; 3) prior institution and degree at entry; 4) source of support during each year of training, e.g., this training grant, another training grant (specify), research grant, university fellowship, individual fellowship (specify), etc.; 5) name of research mentor; 6) research topic; and 7) for trainees who have completed the program, their current positions and institutional affiliations.

In the narrative section of the Progress Report, list each trainee supported during the period covered and indicate in parentheses the preceptor/mentor. Briefly summarize the research conducted by each trainee and list all publications (full citation) that resulted from the work done during training. If any postdoctoral trainee with a health professional degree who was appointed to the grant during the most recent award period received less than 2 years of research training, explain why. Where possible for past trainees, describe the extent of their current involvement in research, including research grant support and representative recent publications. This information will be used to track the pattern of support of trainees and the subsequent research career development of former trainees.

Describe any specific effects of this training program on curriculum and/or research directions. Describe how the funds provided under Training Related Expenses were used to benefit the program.

F. Human Subjects

As indicated earlier in these instructions (Item 4 on the Face Page), where appropriate, include a list of already reviewed research project grants (grant number, principal investigator, project title) and their IRB approval dates or exemption designations.

G. Vertebrate Animals

As indicated earlier in these instructions (Item 5 on the Face Page), where appropriate, include a list of already reviewed research project grants (grant number, principal investigator, project title) and their IACUC approval dates.

H. Consortium/Contractual Arrangements

Describe any programmatic, fiscal, or administrative arrangements between the applicant organization and other participating organizations. See Section 1.C.7.h for additional guidance.

I. Resource Sharing

Not applicable to Institutional Training Grants. Omit this section.

9. APPENDIX

Appendix material is generally not needed with training grant applications. Oversized documents, brochures, and catalogues may be exceptions. Five collated sets should be submitted.

10. CHECKLIST

CHECKLIST FORM PAGE (MS WORD OR PDF)

Inventions and Patents

Not applicable.

Facilities and Administrative Costs

Facilities and Administrative (F&A) costs under Institutional Kirschstein-NRSAs, other than those issued to state or local government agencies, will be awarded at 8 percent of total allowable direct costs (exclusive of tuition and related fees). Equipment and consortium costs are also excluded from the F&A costs on those training grants, where Training Related Expenses are not calculated and awarded on a lump-sum basis, such as the Minority Access to Research Careers Program (MARC) or Career Opportunities in Research (COR) Undergraduate Research Training Program. State and local government agencies will receive the full F&A cost rate.

11. KEY PERSONNEL REPORT

Not applicable.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

SMALL BUSINESS INNOVATION RESEARCH (SBIR) AND SMALL BUSINESS TECHNOLOGY TRANSFER (STTR) GRANT APPLICATIONS

V. INSTRUCTIONS FOR PREPARING SBIR AND STTR GRANT APPLICATIONS

A. Introduction

This section includes instructions to be used when applying for a competing (new Phase I or Phase II) PHS Small Business Innovation Research (SBIR) or Small Business Technology Transfer (STTR) grant. Also use the current SBIR/STTR grant solicitation available at: http://grants.nih.gov/grants/funding/sbir.htm. Note especially the eligibility requirements, page limitations, review criteria, and reporting requirements.

Prior to preparing an application, consult with the appropriate PHS awarding component.

The applicant organization and the principal investigator are jointly responsible for the accuracy and validity of all the administrative, fiscal and scientific information in the application. Deliberate withholding, falsification, or misrepresentation of information could result in administrative actions such as withdrawal of an application or the suspension and/or termination of an award, as well as possible criminal penalties.

B. General Instructions

Use the Public Health Service Grant Application forms (PHS 398) for all SBIR and STTR applications (Phase I, Phase II, and Phase I/Phase II Fast Track) **in accordance with** the *NIH, CDC, and FDA Omnibus Solicitation for SBIR/STTR Grant Applications* or the *Phase II SBIR/STTR Grant Application Instructions*:

- **Phase I** NIH, CDC, and FDA Grant Application Instructions and Preparation Requirements (PDF or MS Word)
- **Phase II** NIH, CDC, FDA SBIR/STTR Grant Application Instructions (PDF or MS Word)

The following PHS 398 forms (MS Word or PDF) apply specifically to SBIR and STTR applicants:

Full Set: (MS WORD)

Individual Form Files:

Form Page 1: Face Page (MS WORD PDF)

Form Page 2: Description, Performance Sites, Key Personnel, Other Significant Contributors, and Human Embryonic Stem Cells (MS WORD PDF)

Form Page 3: Research Grant Table of Contents (MS WORD PDF)

Form Page 4: Detailed Budget for Initial Budget Period (MS WORD PDF)

Form Page 5: Budget for Entire Proposed Period of Support (MS WORD PDF)

Modular Budget Format Page (MS WORD PDF)

Biographical Sketch Format Page (MS WORD PDF)

Resources Format Page (MS WORD PDF)

Checklist Form Page (MS WORD PDF)

Personal Data Form Page (MS WORD PDF)

Continuation Page (MS WORD PDF)

Targeted/Planned Enrollment Format Page

(MS WORD PDF) (if Human Subjects research is proposed)

Enrollment Report Format Page (MS WORD PDF) (if Human Subjects research is proposed)

Mailing Address, RFA and SBIR/STTR Labels (MS WORD PDF)

STTR Research Institution Budget Form Page (MS WORD PDF)

STTR Research Institution Certification Format Page (Modular STTR Budgets Only) (MS WORD PDF)

There is NO FORM PAGE for the Research Plan.

C. Highlighted Changes to Form Page 2

Form Page 2 is now two pages (Form Page 2 and Form Page 2-continued) which consist of five sections: Description, Performance Sites, Key Personnel, Other Significant Contributors, and Human Embryonic Stem Cells.

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.

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 (Computer Retrieval of Information on Scientific Projects - CRISP) and will become public information.

Performance Site(s)

Indicate where the work described in the Research Plan will be conducted. If there is more than one performance site, list all the sites, including Department of Veterans Affairs (V.A.) facilities and foreign sites, and provide an explanation on the Resources Format Page of the application. 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 on the Checklist Form Page of the application. 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.

If a performance site is engaged in research involving human subjects, the applicant organization is responsible for ensuring that the performance site operates under an appropriate OHRP-approved 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 vertebrate animals, the applicant organization must ensure that all performance sites hold OLAW-approved assurances.

Key Personnel

In addition to the principal investigator (PI), 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 Key Personnel. **Consultants should also be included if they meet the same definition.**

Key Personnel must devote measurable effort to the project whether or not salaries are requested. "Zero percent" effort or “as needed” are not acceptable levels of involvement for those designated as Key Personnel.

Start with the principal investigator. List the principal investigator’s **last name first**. All other Key Personnel should be listed in **alphabetical order**, last name first. For each individual provide name, eRA Commons User Name (if known), organization name (their institutional affiliation), and role on the project. Under role on the project, indicate how the individual will function on the proposed project. *Use additional consecutively numbered pages as necessary.*

Other Significant Contributors. This category identifies individuals who have committed to contribute to the scientific development or execution of the project, but are not committing any specified measurable effort to the project. These individuals are typically presented at "zero percent" effort or "as needed" (individuals with measurable effort cannot be listed as Other Significant Contributors). Consultants should be included if they meet this definition. This would also be an appropriate designation for mentors on Career awards.

A biosketch, including Research Support information, will be required for these individuals as this highlights their accomplishments as scientists. Reviewers use these pages to address the "investigator" review criterion.

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

Should the level of involvement change for an individual listed in this category, they should be redesignated as "key personnel." This change should be made before any compensation is charged to the project.

Human Embryonic Stem Cells

If the proposed project involves human embryonic stem cells, list in this section the registration number of the specific cell line(s) from the stem cell registry found at: http://stemcells.nih.gov/registry/index.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.

D. Limitations on Length of Application

PHASE I SBIR/STTR

Observe the page number limitations. Otherwise, application processing may be delayed or the application may be returned without review. Items a-d of the Phase I Research Plan are limited to a total of 15 pages for Phase I applications.

The entire SBIR/STTR Phase I application *may not exceed 25 single-spaced standard size (8 ½" x 11") pages, **excluding** the following*:

- Cover letter.
- One-page “Introduction” required when submitting a revised application.
- Biographical Sketch Format Page(s) (*maximum* of 4 pages for each key person).
- Sections *e-l* of the Research Plan.
- Checklist Form Page.
- Personal Data on principal investigator Form Page.
- Letters of commitment from collaborators and consultants.
- STTR Research Institution Budget Form Page (non-Modular) or Research Institution Certification Format Page (Modular).
- Page(s) furnishing information required under “Prior SBIR/STTR Phase II Awards” (located in Section IV, Grant Application Instructions and Requirements, Item 9. Research Plan), if applicable.

The 25-page limit includes all other form pages and “continuation” pages suggested by these instructions or application form pages. Unless

specifically solicited by NIH, Phase I appendices are not permitted and will not be considered in the review of the application.

PHASE II SBIR/STTR

- *Items a-d* of the Phase II Research Plan are limited to 25 pages.
- "Introduction" (maximum three pages) required when submitting a revised application.

There is no further limitation on the total number of pages for the entire Phase II application.

E. Final Report Requirements

You must submit a Final Report within 90 days of the project period end date. Submit the **original and one copy** of the report to the **Grants Management Office** of the awarding component (IC) within **90 days** of the termination of the grant.

Final reports serve as an important source of material for staff of the awarding component in preparing annual reports, for planning purposes, and in communicating scientific accomplishments achieved through the SBIR/STTR program.

There is no "form page" for a Final Report. It may be typed on plain white paper (or you may use the PHS 398 Continuation Page). *The recommended length for the narrative portion is 10 pages*. See the instructions for completion of the "Research Plan" regarding the presentation of the accomplishments of the Phase I effort.

PHASE I FINAL REPORT

Phase I grantees that (1) do not intend to seek Phase II support or (2) are not prepared to submit a Phase II application within four months following the expiration of the Phase I budget period, must submit a final report of their Phase I effort. Otherwise, the Phase I Final Report is a part of the Phase II application.

The format for the Phase I Final Report is as follows:

1. State the beginning and ending dates for the period covered by the SBIR **Phase I** grant.
2. List all key personnel who have worked on the project during that period, their titles, dates of service, and number of hours devoted to the project.
3. Summarize the specific aims of the Phase I grant.
4. Provide a succinct account of published and unpublished results, indicating progress toward their achievement. Summarize the importance of the findings. Discuss any changes in the specific aims of Phase I since the project was initiated. Include the Inclusion Enrollment Report with the final enrollment data for clinical research (MS Word or PDF).
5. List titles and complete references to publications, and manuscripts accepted for publication, if any, that resulted from the Phase I effort. Submit *five copies* of such items, except patent and invention reports, as an *Appendix*.
6. List patents, copyrights, trademarks, invention reports and other printed materials, if any, that resulted from the Phase I or describe patent status, trade secrets or other demonstration of IP protection.
7. Describe the technology developed from this SBIR/STTR, its intended use and who will use it.
8. Describe the current status of the product (e.g., under development, commercialized, in use, discontinued).
9. If applicable, describe the status of FDA approval for your product, process, or service (e.g., continuing pre-IND studies, filed an IND, in Phase I (or II or III) clinical trials, applied for approval, review ongoing, approved, not approved).
10. Describe how your company has benefited from the program and/or the technology developed (e.g., firm's growth, follow-on funding, increased technical expertise, licensing agreements, spin-off companies,

public offering [include stock exchange and symbol]).

11. List of the generic and/or commercial name of product, process, or service, if any, that resulted from SBIR/STTR funding. If applicable, indicate the number of products sold.

12. Provide the current number of employees (total full time equivalents [FTEs]).

PHASE II FINAL PROGRESS REPORT

A Phase II Final Progress Report is required to close out your Phase II grant.

The format for the Phase II Final Progress Report is as follows:

1. State the beginning and end dates for the period covered by the SBIR/STTR **Phase II** grant.

2. List all key personnel who worked on the project during that period (include titles, dates of service, and number of hours devoted to the project).

3. Summarize the specific aims of the Phase II grant.

4. Provide a succinct account of published and unpublished results, indicating progress toward achievement of the originally stated aims. Include the Inclusion Enrollment Report with the final enrollment data for clinical research (MS Word or PDF).

5. List titles and complete references to publications, and manuscripts accepted for publication, if any, that resulted from the Phase II.

6. List patents, copyrights, trademarks, invention reports and other printed materials, if any, that resulted from the Phase II or describe patent status, trade secrets or other demonstration of IP protection.

7. Describe of the technology developed from this SBIR/STTR, its intended use and who will use it.

8. Describe the current status of the product (e.g., under development, commercialized, in use, discontinued).

9. If applicable, describe the status of FDA approval for your product, process, or service (e.g., continuing pre-IND studies, filed an IND, in Phase I (or II or III) clinical trials, applied for approval, review ongoing, approved, not approved, not ready to submit for FDA approval).

10. Describe how your company has benefited from the program and/or the technology developed (e.g., firm's growth, follow-on funding, increased technical expertise, licensing agreements, spin-off companies, public offering [include stock exchange and symbol]).

11. List of the generic and/or commercial name of product, process, or service, if any, that resulted from SBIR/STTR funding. If applicable, indicate the number of products sold.

12. Provide the current number of employees (total full time equivalents [FTEs]).

The recommended length for the *narrative portion is 10 pages*.

F. SBIR/STTR Policy and Additional Guidance

All SBIR and STTR applications (Phase I, Phase II, and Phase I/Phase II Fast-Track) must be submitted using the Public Health Service Grant Application Forms (PHS 398) in accordance with the instructions in the SBIR/STTR Omnibus Grant Solicitation:

(MS Word)
http://grants.nih.gov/grants/funding/sbirsttr1/index.doc

(PDF)
http://grants.nih.gov/grants/funding/sbirsttr1/index.pdf.

SBIR/STTR applicants should also refer to **Part II (Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan)** (MS Word) (PDF) and **Part III**

(Policies, Assurances, Definitions and Other Information) (MS Word) (PDF) of the PHS 398 for important information relating to submission of research grant applications to NIH.