U.S. Department of Health and Human Services

National Institutes of Health and
Agency for Healthcare Research and Quality

Ruth L. Kirschstein National Research Service Award Individual Fellowship Application (PHS 416-1)

Instructions for PHS 416-1
Rev. 08/2012

Form Approved Through 08/31/2015
OMB No. 0925-0001

TABLE OF CONTENTS

PART I

Instructions

1. Foreword

The PHS 416-1 instructions contain information for preparing Fellowship applications to the National Institutes of Health (NIH) and the Agency for Healthcare Research and Quality (AHRQ).

Applicants to PHS agencies other than NIH should contact the agency using the PHS Agency Contacts Table in 1.5 below because some awarding components have application requirements that differ from those for NIH.

NIH continues to transition grant mechanisms to the SF424 (R&R) and electronic submission through Grants.gov. This PHS 416-1 is required for use until the Fellowship mechanisms are transitioned to the SF424 (R&R). Once the Fellowship mechanisms have transitioned to electronic submission the applicant must apply through Grants.gov using the SF424 (R&R) and electronic PHS Fellowship Supplemental components that will be provided as part of the electronic application forms.

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

Bookmark this website http://grants.nih.gov/grants/funding/416/phs416.htm for easy electronic access to this document.

Summary of Changes

These instructions include numerous clarifications and updates. The following table is a summary of policy changes and notifications implemented since the 6/2009 revision of the PHS 416-1 application.

TITLE	NIH GUIDE LINK
Ruth L. Kirschstein National Research Service Award (NRSA) Stipends, Tuition/Fees and Other Budgetary Levels Effective for Fiscal Year 2012	NOTICE OD-12-033 http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-033.html
Ruth L. Kirschstein National Research Service Awards (NRSA) and Other Fellowship Applications: New Policy on Post-Submission Information on Sponsor's Research Funding	NOTICE OD-12-022 http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-022.html
Revised Policy: Managing Conflict of Interest in the Initial Peer Review of NIH Grant and Cooperative Agreement Applications	NOTICE OD-11-120 http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-120.html
Review of Grants Information for Fiscal Year 2011	NOTICE OD-11-117 http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-117.html
Resubmission of Applications with Pending Appeals of NIH Initial Peer Review	NOTICE OD-11-101 http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-101.html

TITLE	NIH GUIDE LINK
Modification of Eligibility Criteria for Ruth L. Kirschstein National Research Service Awards (NRSA) for Individual Postdoctoral Fellows (Parent F32)	NOTICE OD-11-097 http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-097.html
NIH, AHRQ, CDC, FDA and NIOSH to Release Updated Electronic Application Forms – ADOBE-FORMS-B2	NOTICE OD-11-096 http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-096.html
Reminder: Compliance with NIH Application Format and Content Instructions	NOTICE OD-11-080 http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-080.html
Ruth L. Kirschstein National Research Service Award (NRSA) Stipends, Tuition/Fees and Other Budgetary Levels Effective for Fiscal Year 2011	NOTICE OD-11-067 http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-067.html
Appeals of NIH Initial Peer Review	NOTICE OD-11-064 http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-064.html
Modification of the Fellowship Biographical Sketch in NIH Grant Application Form SF424 (R&R) to Permit a Description of Factors that may have Resulted in a Hiatus in Training or Reduced Productivity	NOTICE OD-11-050 http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-050.html
Notice of Change in Policy on the Submission of Reference Forms (Letters of Reference) for Kirschstein-NRSA Fellowship (F) Applications	NOTICE OD-11-047 http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-047.html
Advanced Notice of Change in Policy on the Submission of Letters of Reference for Kirschstein-NRSA Fellowship (F) and Career Development (K) Applications	NOTICE OD-11-036 http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-036.html
Reminder: Policies Affecting Submission of NIH Grant Applications for Due Dates on or after January 25, 2011	NOTICE OD-11-021 http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-021.html
Updated Electronic Application Forms Required for F, K, T, and D Submissions with Due Dates of January 25, 2011 and Beyond	NOTICE OD-11-008 http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-008.html
New Time Limit for NIH Resubmission Applications	NOTICE OD-10-140 http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-140.html
NIH, AHRQ, and NIOSH to Eliminate Error Correction Window for Due Dates On or After January 25, 2011	NOTICE OD-10-123 http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-123.html

TITLE	NIH GUIDE LINK
Enhancing Peer Review: Updated Processes for the Review of all Ruth L. Kirschstein National Research Service Award (NRSA) Fellowship Applications	NOTICE OD-10-071 http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-071.html
Review Considerations for Applications and Awards under the New NIH Guidelines for Human Stem Cell Research	NOTICE OD-10-056 http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-056.html
Clarification of SF424 (R&R) Application Instructions for Resubmissions of Revision and Renewal Applications	NOTICE OD-10-052 http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-052.html
Ruth L. Kirschstein National Research Service Award (NRSA) Stipends, Tuition/Fees and Other Budgetary Levels Effective for Fiscal Year 2010	NOTICE OD-10-047 http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-047.html
Update on the Requirement for Instruction in the Responsible Conduct of Research	NOTICE OD-10-019 http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-019.html
Restructured Application Forms and Instructions for Submissions for FY2011 Funding	NOTICE OD-09-149 http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-149.html
Two Critical Issues for Recent Submissions of Applications for Ruth L. Kirschstein National Research Service Awards (NRSA) Individual Fellowships – References and Designation of Sponsor	NOTICE OD-09-144 http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-144.html

Important Reminders for all Applicants

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. NIH requires the use of one of four approved fonts and a font size of 11 points or larger. The approved font options include two serif fonts (Palatino and Georgia) and two sans serif fonts (Arial and Helvetica). A symbol font may be used to insert Greek letters or special characters; the font size requirement still applies. A smaller font size may be used for figures, graphs, diagrams, charts, tables, figure legends, and footnotes, but this type must follow the font typeface requirement and be readily legible.

Prepare a *succinct* Research Training Plan. There is no requirement for applicants to use the maximum allowable pages allotted to the Research Training Plan (Sections 2-5). The remaining sections of the Research Training Plan have no maximum allowable pages, but should also be succinct.

Several elements of an application are not required at the time the application is submitted. This information is requested later in the review cycle (i.e., just-in-time) to ensure that it is current. See Just-In-Time Policy in Part III. 1.5.

1.1 Application Guide Format

This edition of the PHS 416-1 is organized into three parts, and is available in two different formats: MS Word and PDF. Within each Part are links to pertinent sections of the application, other documents, or NIH web pages. To use these links in the MS Word version effectively, you must enable the "web" tool bar in order to have a “back button” to return to a page after using a link. The three parts of the 416-1 are described below:

Part I: Instructions for Preparing and Submitting an Application

Part I includes instructions on submitting a grant application, completing the PHS 416-1 forms and format pages, submission and review of your application,

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

Part II of the PHS 416-1 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 8 of the Research Training Plan (Human Subjects Research).

Part III: Policies, Assurances, Definitions and Other Information

Part III of the PHS 416-1 includes information on policies, assurances, definitions, and other information relating to submission of applications to the PHS. Applicants should refer to this as well as the PHS 416-1 instructional materials, Grants Information (GrantsInfo), and *Grants Policy Statement* sections for additional sources of information.

THESE INSTRUCTIONS AND APPLICATION FORMS (revised 06/2012) SUPERSEDE ALL PREVIOUS EDITIONS. Carefully read the instructions. Submission of an application that fails to meet the PHS requirements will be grounds for the PHS to delay the review or to return the application without peer review. A properly prepared application will facilitate the administrative processing and peer review that must occur before an award can be made.

While the instructions are generally applicable, many fellowship programs have additional specific instructions. Applicants should contact an official listed in the table to obtain the most current information and instructions.

Bookmark this website **http://grants.nih.gov/grants/forms.htm** for easy electronic access to the forms and instructions.

1.2 NIH and AHRQ 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.

Information about the NIH extramural research and research training programs, funding opportunities, and the grant application process, can be obtained by emailing your request to: GrantsInfo@nih.gov or by calling (301) 435-0714, TTY (301) 451-5936.

Guidelines for Kirschstein-NRSA Individual Fellowships and non-NRSA may be found on the NIH Web Site at http://grants.nih.gov/training/nrsa.htm. Guidelines for the AHRQ fellowships may be found on the AHRQ Web Site at http://www.ahrq.gov/fund/hhspolicy.htm.

1.3 Fellowship Mechanisms and Program Guidelines

The Kirschstein-NRSA program helps ensure that a diverse pool of highly trained scientists is available in adequate numbers and in appropriate research areas to carry out the Nation's biomedical and behavioral research agenda. Kirschstein-NRSA fellowships are awarded as a result of national competition for research training in specified health-related areas. Certain specialized individual fellowships, such as the predoctoral fellowships (F31 and F30), postdoctoral fellowships (F32), Senior Fellowships (F33), and other institute-specific fellowship programs are provided under this authority. For individual predoctoral fellowships, NIH Institutes and Centers (ICs) have differing requirements. All NIH ICs except Fogarty International Center (FIC) and National Library of Medicine (NLM) award Kirschstein-NRSA fellowships. FIC and NLM have unique funding authorities for fellowships that are not under the Kirschstein-NRSA authority.

This Application Guide contains information for preparing applications for Individual Fellowships available from the National Institutes of Health (NIH) and the Agency for Healthcare Research and Quality (AHRQ). These fellowships are available at the predoctoral, postdoctoral, and senior fellowship levels. These include both Ruth L. Kirschstein National Research Service Award (NRSA) and non-NRSA programs. It is important to note that not all predoctoral, postdoctoral, and senior fellowships are supported by each IC and AHRQ. Therefore, individuals interested in this type of award are strongly encouraged to consult with the appropriate NIH IC and AHRQ before submitting an application. (For example, Postdoctoral (F32) fellowships are provided by the NIH ICs and AHRQ. AHRQ does not provide senior fellowships.) *This action is of utmost importance because applications with marginal or no relevance to the mission of the participating ICs or AHRQ will not be accepted for review or funding.* Thus, specific FOAs always should be consulted for guidance.

Contact information can be found in each Funding Opportunity Announcement (FOA) published as a program announcement or request for applications and below in the Interactions with PHS Staff section.

For more information, see the NIH Research Training and Career Development website at http://grants.nih.gov/training/extramural.htm and the AHRQ Research Training website at http://www.ahrq.gov/fund/training/rsrchtng.htm.

A partial list of research training and career development award 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://grants.nih.gov/grants/funding/funding_program.htm.

Kirschstein-NRSA Programs:

Individual Ruth L. Kirschstein National Research Service Award Fellowships (NRSA) (F30, F31, F32, F33, F34, etc.)

Other Individual Fellowship (non-NRSA) Programs:

Information for other non-NRSA Fellowship programs can be found at http://grants.nih.gov/training/extramural.htm

1.4 Interactions with PHS Staff

NIH and AHRQ encourage applicants to communicate with staff throughout the entire application, review and award process. Web site addresses and staff phone numbers of NIH and AHRQ contacts are listed below. A list of contacts specifically for extramural training at the NIH ICs can also be found at: http://grants.nih.gov/training/ tac_training_contacts.doc. Individuals are encouraged to always check this website for the most current contact information.

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

PHS Agency Contacts

PHS AGENCY (LINK TO WEB SITE)	AWARDING COMPONENT (LINK TO WEB SITE)	TELEPHONE NUMBER
NATIONAL INSTITUTES OF HEALTH (NIH)	*Eunice Kennedy Shriver* National Institute of Child Health and Human Development	301-496-0104
NIH	Fogarty International Center	301-496-1653
NIH	National Cancer Institute	301-496-3428
NIH	National Center for Complementary and Alternative Medicine	301-496-4792
NIH	National Center for Research Resources	301-496-6023
NIH	National Eye Institute	301-451-2020
NIH	National Heart, Lung, and Blood Institute	301-435-0260
NIH	National Human Genome Research Institute	301-496-7531
NIH	National Institute on Aging	301-496-9322
NIH	National Institute on Alcohol Abuse and Alcoholism	301-443-4375
NIH	National Institute of Allergy and Infectious Diseases	301-496-7291
NIH	National Institute of Arthritis and Musculoskeletal and Skin Diseases	301-594-2463
NIH	National Institute of Biomedical Imaging and Bioengineering	301-451-4792
NIH	National Institute on Deafness and Other Communication Disorders	301-496-1804
NIH	National Institute of Dental and Craniofacial Research	301-594-4800
NIH	National Institute of Diabetes and Digestive and Kidney Diseases	301-594-8834
NIH	National Institute on Drug Abuse	301-443-2755
NIH	National Institute of Environmental Health Sciences	919-541-7723
NIH	National Institute of General Medical Sciences	301-594-4499
NIH	National Institute of Mental Health	301-443-3367

PHS AGENCY (LINK TO WEB SITE)	AWARDING COMPONENT (LINK TO WEB SITE)	TELEPHONE NUMBER
NIH	National Institute on Minority Health and Health Disparities	301-402-1366
NIH	National Institute of Neurological Disorders and Stroke	301-496-9248
NIH	National Institute of Nursing Research	301-594-6906
NIH	National Library of Medicine	301-496-4621
NIH	Center For Scientific Review	301-435-0715 TTY 301-451-5936
AGENCY FOR HEALTHCARE RESEARCH AND QUALITY	Agency for Healthcare Research and Quality	301-427-1447

Before Submission

You may wish to contact NIH or AHRQ staff with a variety of questions before submitting an application. Each FOA includes names of staff members.

Contact GrantsInfo and/or the Division of Receipt and Referral, Center for Scientific Review (CSR), NIH:

- To identify Institutes/Centers (ICs) at NIH or other non-NIH agencies and/or a Scientific Review Group (SRG) that might be appropriate for your application. Note requests for assignment to an Institute/Center and/or SRG may be made in a cover letter at the time of application submission.
- 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 IC's or AHRQ's programmatic area.
- To learn about programmatic areas of interest to the IC or AHRQ.
- To find out about requesting an assignment to an IC.
- To discuss whether you should respond to an RFA.
- To receive scientific guidance on preparing and submitting an application
- To discuss appropriate fellowship level, particularly predoctoral and senior fellowships

Contact Scientific Review Officers in the CSR to discuss requesting assignment to a SRG.

After Submission

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

Division of Receipt and Referral
Center for Scientific Review
National Institutes of Health
6701 Rockledge Drive, Suite 2030, MSC 7720
Bethesda, MD 20892-7720
Fax requests (301-480-1987) are also acceptable

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

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

After Assignment

Contact your Scientific Review Officer 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 PD/PI reviews the Summary Statement in the eRA Commons, the appropriate awarding component program official (noted on the Summary Statement) may be contacted:

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

A paper copy of the Peer Review Outcome Letter and Summary Statement will not be mailed to the Applicant Fellow and may only be accessed through the eRA Commons.

1.5 Grants Policy Statements

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

AHRQ uses the *HHS Grants Policy Statement* in administering its grant awards. It 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 awards, excluding NIH awards.

1.6 Quick References

Applicants New to NIH: Getting Started

grants.nih.gov/grants/useful_links.htm

Award Data

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

Contact Information for an AHRQ Staff Person

training@ahrq.hhs.gov
Technical Assistance: Telephone: (301) 427-1349

Contact Information for an NIH Staff Person

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

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

Grant Writing Tips and Frequently Asked Questions

http://grants.nih.gov/grants/planning_application.htm
http://grants.nih.gov/grants/writing_application.htm
http://grants.nih.gov/training/faq_fellowships.htm

eRA Commons

Institutions are invited to register with the eRA Commons and to register individuals. Registered Applicants/Fellows can check assignment/contact information, review outcome, and other important information. Note this is the only way Applicants/Fellows can now access information on review and Institute assignments, review outcomes, and summary statements. This information is no longer mailed to the Applicants/Fellows.

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 DHHS agencies.

NIH Office of Extramural Research Human Subjects Website

This site provides, in one place, DHHS 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://cms.csr.nih.gov/ResourcesforApplicants/Submission+And+Assignment+ Process.htm
Telephone: (301) 435-0715
TTY: (301) 451-5936
Fax: (301) 480-1987

Specific Application: Before Review

Telephone or e-mail the Scientific Review Officer named on the electronically-generated "notification of assignment" that is available in the eRA Commons. **In order to avoid delays in the e-notification process, it is vital that all Individual Fellows are registered in the eRA Commons and e-mail addresses are checked periodically for accuracy.**

Specific Application: Post Review

Telephone or e-mail the NIH or AHRQ Program Official named on the summary statement of your application which can be viewed in the eRA Commons.

1.7 Authorization

NIH and AHRQ request the information described in these instructions pursuant to the statutory authorities contained in Section 487 of the PHS Act, as amended (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 to review an application and to monitor the awardee's performance.

The statutory authorities for the Fellowship programs are contained in the following:

F30, F31, F32, F33 Authority: Sections 301(a) and 487 of the PHS Act, as amended (42 USC 241a and 42 USC 288), 42 CFR Part 66.

F05 Authority: Section 307, 42USC 2421 and 42 CFR Part 63a.

F37 Authority: Section 472, 42 USC 286B-3 and 42 CFR Part 61.

AHRQ Authority: Section 487,Sections 304, 902, and 935 of the PHS Act, 42 USC 242b, 299, and 299c-4 and 42 CFR 67, Subpart A.

1.8 Paperwork Burden

NIH, which maintains this application form and instructions, estimates that it will take approximately 20 hours to complete. This estimate does not include time for development of the research training plan. Items such as human subjects and vertebrate animals have separate clearances and are not included in this estimate. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. If you have comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, send comments to: NIH Project Clearance Office, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0001). *Do not send applications to this address*.

2. General Instructions

2.1 Introduction

Read all of the instructions thoroughly before preparing your application.

Use this application to apply for new and competing continuation (renewal) Kirschstein-NRSA Individual Fellowships from NIH or AHRQ. Applications for these Individual Fellowships will not be accepted on other forms.

Further details on policies governing the Kirschstein-NRSA program are available on the NIH web site at http://grants.nih.gov/training/nrsa.htm, by contacting GrantsInfo@nih.gov, or by calling (301) 435-0714, TTY (301) 451-5936.

Read and follow these instructions carefully to avoid delays, misunderstandings, and possible return of applications. 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 301-451-5936; Fax: 301- 480-1987

2.2 Registration Processes

2.2.1 (Reserved)

2.2.2 DUNS Registration for Applicant Organization

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

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

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

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

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

2.2.3 Central Contractor Registration (CCR) for the Applicant Organization

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

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

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

2.2.4 eRA Commons Registration

The applicant organization and the PD/PI (i.e. Applicant Fellow) must also complete a **one-time** registration in the eRA Commons. Access to the Commons is vital for all steps in the process after application submission. An organization and PD/PI must be registered in the Commons before they can take advantage of retrieval of grant information. Institutional/organizational officials are responsible for registering the Fellow in the eRA Commons. Fellows should work with their AOR (also known as the Signing Official in the eRA Commons) to determine their institutional/organizational process for registration.

IMPORTANT: The eRA Commons registration process should be started at least **two (2) weeks** prior to the submission date. A valid PD/PI eRA Commons user name ID must be entered in item 4b of the Face Page.

2.2.4.1 Commons Registration for the Organization

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

To register an Organization in the eRA Commons:

1. Open the eRA Commons homepage (https://commons.era.nih.gov/commons/).
2. Click Grantee Organization Registration (found in "About the Commons" links on the right side of the screen).

3. Follow the step-by-step instructions. Remember to fax in the registration signature page to eRA.
4. Click Submit. The organization is registered when the NIH confirms the information and sends an email notification of registered Signing Official (SO) account (userid/password).

This registration is independent of Grants.gov and may be done at any time.

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

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

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

2.2.4.2 Commons Registration for the Applicant Fellow (designated as Project Director/Principal Investigator; or PD/PI)

The individual Fellow for whom support is being requested is to be designated as the PD/PI on the application, and must also be registered in the Commons. The PD/PI must hold a PI account **and** be affiliated with the applicant organization. **This registration must be done by an organizational official (or delegate) who is already registered in the Commons.** To register PDs/PIs in the Commons, refer to the eRA Commons System Users Guide (http://era.nih.gov/Docs/COM_UGV2630.pdf).

Once the PD/PI has received email confirming his/her registration within the Commons, the PD/PI must verify, review, and update as needed, all Personal Information located within the Personal Profile tab in the eRA Commons System. These data must contain the most recent information in order for the application to be processed accurately.

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

It is important to note that if a PD/PI is also an NIH peer-reviewer with an Individual DUNS and CCR registration, that particular DUNS number and CCR registration are for the individual reviewer only. These are different than any DUNS number and CCR registration used by an applicant organization. Individual DUNS and CCR registration should be used only for the purposes of personal reimbursement and should not be used on any grant applications submitted to the Federal Government.

For additional information on how to prepare for electronic submission, see: http://grants.nih.gov/grants/ElectronicReceipt/preparing.htm.

Guidance for Affiliating Individual Fellows in the eRA Commons

In October 2006, NIH issued "Guidance to Applicant Organizations about Registering Research Fellows in the eRA Commons" (Notice Number: NOT-OD-07-003; see http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-003.html). The purpose of this Notice is to remind applicant organizations that they should register in the eRA Commons any individual research fellows who are submitting applications to NIH and AHRQ. Many individuals who are submitting Individual Fellowship applications have the unique circumstance of actually submitting an application through a Sponsoring Organization that is different than their current organization. This is perfectly appropriate considering the nature of Individual Fellowship programs. However, this does pose a complexity with respect to eRA Commons registration. Many prospective individual fellows have already been registered in the eRA Commons by their current organization. However, to be able to view the records for an application submitted through a different organization, that individual must also be "affiliated" with the new sponsoring organization. Note a separate eRA Commons registration is NOT required. However, the proposed sponsoring organization must take steps to affiliate the prospective fellow.

This process assumes the Prospective Fellow has already been registered in the eRA Commons by another organization and assigned the PI Role. If a Prospective Fellow has not yet been registered in the eRA Commons, they should work with the appropriate officials within the sponsoring organization to be properly registered. When the sponsoring organization handles the initial eRA Commons registration, no further affiliation is required.

To Affiliate a Prospective Fellow with a Different Sponsoring Organization:

1) Prospective Fellow gives Commons user ID and email address to the administrator of the new sponsoring organization. (The email address must be the one that is contained in the Personal Profile for the Fellow.)
2) Administrator of the new sponsoring organization logs into the Commons. (The administrator can be the Signing Official, Administrative Official, or the Accounts Administrator.)
3) Administrator selects "Administration" tab and then "Accounts" tab.
4) Administrator selects "Create Affiliation" tab.
5) Administrator enters the Commons User ID and Email address into the appropriate fields and clicks "Submit."

Note: The account cannot have any other roles attached to it other than the PD/PI and IAR (Internet Assisted Review). For additional information on Creating Affiliations for Users in the eRA Commons, see: https://commons.era.nih.gov/commons-help/175.htm.

2.3 (Reserved)

2.4 Funding Opportunities

Grants for health-related research and research training projects or activities make up the largest category of funding provided by the NIH Institutes/Centers (ICs) and other non-NIH agencies. Most applications for support originate with individual investigators who develop proposed plans for research or research training within an area that is relevant to the NIH.

2.4.1 NIH Guide for Grants and Contracts

The *NIH Guide for Grants and Contracts*, a weekly electronic publication (http://grants.nih.gov/grants/guide), contains announcements about funding opportunities, such as Requests for Applications (RFAs) and Program Announcements (PAs) from the 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.

2.4.2 Funding Opportunities Announcements (FOAs)

An NIH IC or AHRQ may issue Funding Opportunity Announcements (FOAs) in the form of program announcements (PAs) or requests for applications (RFAs) soliciting Kirschstein-NRSA Individual Fellowship applications. The PA/RFAs are available from the sponsoring IC or AHRQ and are issued in the *NIH Guide for Grants and Contracts* (http://grants.nih.gov/grants/guide/index.html).

Before preparing an application, applicants should thoroughly review the pertinent PA/RFA, noting the research area(s), eligibility requirements, any program-specific instructions, application receipt date, award provisions, and service payback provisions.

Definitions 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 Opportunities" (http://www.grants.gov/applicants/find_grant_opportunities.jsp). 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 Grant Opportunities, or other public document contains contact information under *Inquiries* in addition to information specific to the RFA or PA.

Individual Fellowship RFAs and PAs are also located at http://grants.nih.gov/training/nrsa.htm.

2.5 (Reserved)

2.6 Format Specifications

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

Font

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

Paper Size and Page Margins

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

Page Formatting

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

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

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

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 two (2) submitted copies provided such images are printed directly on the application page and are critical to the content of the application.

Copies

- Send the original application (signed by authorized organizational official) and two 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 the appendix. Note: Photographs may be included in the appendix; however, a photocopy of each must also be included within the page limitations of the Research Training 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 for NIH or AHRQ funding must be self-contained within the specified page limitations (see table below).

Unless otherwise specified in an NIH or AHRQ PA or RFA, internet Web site 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.

SECTION	PAGE LIMIT	CONTENT
Research Proposal—Description (Form Page 2, Item 17)	Limited to space provided on form	Succinct and accurate description of proposed work when separated from application
Applicant/Fellow Biographical Sketch	4 (no limits on subsections)	See Instructions
Previous Research Experience (Form Page 5) Doctoral Dissertation and Other Research Experience	2	See Instructions

SECTION	PAGE LIMIT	CONTENT
Research Training Plan Introduction Sections 2-5 only (Sections 6-21 are not included in the 10-page limit)	1 10	Required for Resubmission Applications only Text plus all figures and tables
Sponsor/Co-Sponsor Biographical Sketch	4 (per person)	May use Biographical Sketch in PHS 398

2.7 Resubmission Applications

For all original new (i.e. never submitted) Individual Fellowship applications intended for the April 2009 due dates and beyond, NIH will accept only a single amendment application (now known as a "Resubmission" application) and there is no time limit for the resubmission application. Any second resubmission will be administratively withdrawn and not accepted for review. A new application following two reviews is expected to be substantially different in content and scope with more significant differences than are normally encountered in a resubmission application. For original new applications submitted prior to April 2009, applicants are permitted two resubmissions. For these "grandfathered" applications, any second resubmission must be submitted no later than January 7, 2011 and NIH will not accept any second resubmissions after that date. See NIH Policy on Submission of a Revised/Resubmission (amended) Application in Part III.

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.

There are four requirements for a Resubmission application:

- The Summary Statement must be available in the eRA Commons (http://commons.era.nih.gov/commons/).
- The Fellow must make significant changes to the application.
- An Introduction of no more than one page must be included that summarizes the substantial additions, deletions and changes to the application. The Introduction must also include a response to the issues and criticism raised in the Summary Statement. The Introduction should be placed immediately before item 2 of the Research Training Plan.
- The substantial scientific changes must be marked in the text of the Research Training Plan by bracketing, indenting, or change of typography. Do not underline or shade the changes. Deleted sections should be described but not marked as deletions. If the changes are so extensive that essentially all of the text would be marked, explain this in the Introduction.

A resubmission application will be returned without review if it does not comply with all of these requirements.

Acceptance of a resubmission application will not automatically withdraw the prior version. As of February 2008, eRA keeps all versions (e.g., 01, A1) of a grant application active and provides an internal MAA ("Multiple Active Applications") flag for each application in an active cluster. The cluster allows applicants to identify quickly all versions of one application. If any version in a cluster is awarded, all other applications within the cluster will be automatically withdrawn without any additional action by applicants or staff.

Reference Letters for Resubmission Application. Applicants must resubmit three sealed reference letters with the application. See Reference Letter instructions for additional details.

2.8 Revision Applications

Revision applications (formerly called a competing supplement) are submitted to request support for a significant expansion of a project's scope or research protocol. Revision applications are not appropriate when the sole purpose is to restore awards to the full SRG-recommended level if they were administratively reduced by the funding agency. **Revision applications are generally not applicable to individual fellowships supported by NIH and AHRQ.**

Administrative Supplements

An administrative supplement provides additional funding to meet increased costs that are within the scope of an approved application, but that were unforeseen when the new or competing Renewal application was submitted. If considering administrative supplemental funding, consult in advance with the designated Grants Management Officer and Program Official. It is important to submit a request before the grant expires. To be considered for an administrative supplement, submit a request in writing to the Institute/Center, **not** to the Division of Receipt and Referral, Center for Scientific Review. The request must be signed by the authorized Business Official and describe the need for additional funding and the categorical costs. In the letter, point out what will NOT be accomplished if such a request is denied. Administrative supplements are **not** submitted using the 416-1 Application.

2.9 Similar, Essentially Identical, or Identical Applications

Submissions of identical applications to one or more components of the PHS are not allowed, and the NIH will **not** accept similar grant applications with essentially the same research training 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 Applicant Fellow are the original work of the Applicant Fellow 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.

2.10 (Reserved)

2.11 (Reserved)

2.12 (Reserved)

2.13 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 Officer of the Initial Review Group's study section solicits or agrees to accept this information.

2.14 Application Submission Dates

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

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

Funding Opportunity Announcements (RFAs and Pas). Applications in response to announcements with special receipt dates **must be received at NIH by the** specified **date.** However, an application received after the deadline may be acceptable if it carries a legible proof-of-mailing date assigned by the carrier not later than 1 week prior to the deadline date. Note: This differs from the procedures for submitting applications for those dates listed in the table, which are considered submission or "send by" dates.

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 business day. The application will be on time if it is sent on the following business day.

Late applications. Permission is not granted in advance for submission of a late application. Late applications are accepted only in extenuating circumstances. If an application is submitted late, a cover letter explaining the reasons for the delay must be included with the signed, completed application. Late applications are evaluated on an individual basis considering the reasons provided. Contacting the Division of Receipt and Referral in advance will not influence the acceptance of a late application. For additional information on late applications, see NOT-OD-08-027, dated January 4, 2008 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-027.html) and clarification in NOT-OD-08-111, dated September 2, 2008 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-111.html).

2.15 Submission and Review Cycles

The PHS submission, review, and award schedule is provided at this website: http://grants.nih.gov/grants/dates.htm. Note that many funding mechanisms have transitioned to electronic submission and the SF424 (R&R) application and instructions. The PHS 416-1 is not scheduled to transition until April, 2009 so applicants should continue to use this version of the instructions and forms. Applicants should refer to the OER Electronic Submission of Grant

Applications website, http://grants.nih.gov/grants/ElectronicReceipt/ for details on the transition to electronic submission.

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

Application Assignment Information

Competing grant applications submitted to the PHS agencies 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 (SRG) and Institute(s). Assignment is based on the scientific content of the application using established referral guidelines.

After the submission date, usually within four (4) weeks, the applicant/fellow and the sponsoring organization will be able to access in the eRA Commons the application's assignment number; the name, address, and telephone number of the Scientific Review Officer (if the review takes place in CSR) or the review official of an IC Scientific Review Group to which the application has been assigned; and the assigned Institute contact and phone number. Review outcome and other important information are also available in the Commons.

If applicant assignment information is not available in the eRA Commons within two weeks of the submission date, contact the Division of Receipt and Referral, Center for Scientific Review (CSR), National Institutes of Health, Bethesda, MD 20892-7720, (301) 435-0715; TTY (301) 451-5936. If there is a change in assignment, you will receive another notification.

Applicant investigators must not communicate directly with any study section or 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 Officer or review official outside of CSR. This individual is in charge of the review group and is identified in the eRA Commons.

2.16 Resources for Finding Help

2.16.1 (Reserved)

2.16.2 Finding Help for the eRA Commons Registration

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

eRA Commons Helpdesk: http://grants.nih.gov/support

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

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

2.16.3 Finding Help for Application Preparation

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

GrantsInfo Phone:	301-435-0714 301-451-5936 (TTY)
GrantsInfo Email:	GrantsInfo@nih.gov

3. Submission of the Grant Application

Submit a complete application. 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. There is no guarantee that the Scientific Review Officer will accept or the peer reviewers will consider late material.

3.1 Cover Letter

Fellowship applicants are required to include a cover letter with the application. The cover letter is only for internal use and will not be shared with peer reviewers. The cover letter must contain the list of referees (including name, departmental affiliation, and institution). It should also contain any of the following information that applies to the application:

- Application title.
- Funding Opportunity Announcement (PA, RFA or Parent Announcement title, if applicable).
- Request of an assignment (referral) to a particular IC or Scientific Review Group (SRG). While requests are given careful consideration, the PHS makes the final determination for assignments. (See suggested format below.)
- List of individuals (e.g., competitors) who should not review the application and why.
- Disciplines involved, if multidisciplinary.
- Statement that any required NIH approval documentation for the type of application submitted is enclosed.
- **List of Referees:** All Fellowship applicants must include a list of referees in the Cover Letter. The list must include the names, degrees, and affiliations of the individuals from whom you have asked to submit reference letters.

  At least three reference letters are required. Your references should be carefully selected. Only those individuals who can make the most meaningful comments about your qualifications

for a research career should be used. ***The sponsor of this application cannot be counted as a reference. The sponsor's recommendation is included as part of the application (see Sponsor/Co-Sponsor information).*** Whenever possible, select at least one referee who is not in your current department. If not submitting a reference from the dissertation advisor or chief of service, provide an explanation.

For postdoctoral applications, references from graduate school or medical school are preferred over those from undergraduate school.

Request reference reports only from individuals who will be able to submit them in time. Consider any factor (e.g., illness or extended vacation) that might cause an inordinate delay. See Section 5.9 for additional information and instructions for referees. Give these reference forms to the referees well in advance of the application date.

Failure to provide references may delay processing of your application or may result in the application being returned to you without review.

Suggested Cover Letter Format

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

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

Examples:

Please assign this application to the following:

Institutes/Centers

National Cancer Institute - NCI

National Institute for Dental and Craniofacial Research – NIDCR

Scientific Review Groups

Molecular Oncogenesis Study Section – MONC

Cancer Etiology Study Section – CE

Please do not assign this application to the following:

Scientific Review Groups

Cancer Genetics Study Section – CG

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

3.2 Number of Copies

Submit the **original and two** identical, legible, single-sided photocopies of each application. The **original must be signed** by the Official Signing for Sponsoring Institution on the Face page.

3.3 Binding and Packaging

Submit the following materials in *one* package:

- cover letter (original only);
- original application, including the Personal Data page at the end of the application;
- two copies of the application, made after the original has been signed and **not** including the Personal Data Page;
- at least 3 sealed letters of reference;
- Appendix materials – five identical CDs of all appendix material in PDF format.

Do not include more than one application (original plus 2 copies and appendices) in each mailing envelope.

The original application. The original application must be single-sided, with the required signature on the Face Page. Do *not* staple or otherwise bind the original application. 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 original 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.

Two identical, single-sided copies of the original application. Make the copies **after** the Official Signing for Sponsoring Institution has signed the Face Page so the signature is present on the copies. Do **not** staple or otherwise bind the two copies of the original application. Rubber bands are acceptable.

Letters of reference. At least **three sealed letters** of reference attached firmly to the Face Page of the original application.

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

- Use PDF format.
- Label each disk with the Applicant Fellow name and application title.
- If burning CD-ROM disks on a Mac, select the ISO 9660 format.

- Do not use compression techniques for the electronic files.
- Do not use password protection, encryption, digital signature and/or digital certification in the PDF files.

3.4 Application Mailing Address

Use the mailing labels provided with the PHS 416-1.

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

Center for Scientific Review
National Institutes of Health
6701 Rockledge Drive, Suite 1040
MSC 7710
Bethesda, MD 20892-7710
(United States Postal Service (USPS) Express or Regular mail)
or
Bethesda, MD 20817 **(Express/Courier Non-USPS Service)**

The telephone number is (301) 435-0715
TTY (301) 451-5936.

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

All applications and other deliveries to the Center for Scientific Review must come either via courier delivery (e.g. Federal Express, DHL, UPS) or via the USPS. Applications delivered by individuals to the Center for Scientific Review will not be accepted. For additional information see **http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-040.html.**

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

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

4. Completing the PHS 416-1 Forms and Format Pages

- Prepare the application using the PHS 416-1 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 416-1 form pages vary due to field or space limitations. The PHS 416-1 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 Training 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.

Specific Instructions for Applicant Fellow

This application is mostly completed by the applicant with extensive consultation with the sponsor and co-sponsor (if any), and institutional officials at the sponsoring institution. Certain information is completed by the sponsor and sponsoring institution administrative officials. Items to be completed by anyone other than just the applicant are clearly marked.

This application consists of three Sections:

Section I: To be completed by you the Applicant/Fellow. Sections of Section I are to be completed with appropriate consultation with your sponsor, co-sponsor (if any) and sponsoring institutional officials when applicable. These items are clearly marked. Section I includes:

- Face Page (Form Page 1)
- Form Page 2
- Form Page 3
- Form Page 4, Table of Contents
- Applicant/Fellow Biosketch
- Form Page 5, Previous Research Experience
- Research Training Plan, Sections 1 - 21, some with sponsor consultation
- Checklist, A, C, and D
- Personal Data on Kirschstein-NRSA Individual Fellowship Applicant Page

Section II: To be completed by the Sponsor (and Co-Sponsor when applicable)

- Sponsor and Co-Sponsor Biosketch(es)
- Sponsor and Co-Sponsor Information (see instructions)

Section III: References: To be completed by your chosen referees and included in sealed envelopes along with this application.

All sections must be submitted together in the same envelope; otherwise, the application will be returned without review.

This application is used for all types of Kirschstein-NRSA Individual Fellowships—Predoctoral, Postdoctoral, and Senior. Special instructions may apply to Predoctoral or Senior Fellowships. The following table summarizes where instructions differ for these types of fellowships.

Special Instructions for Predoctoral and Senior Fellowships Applicants

PREDOCTORAL FELLOWSHIPS	
Face Page Item 2, Level of Fellowship	Special Instructions
Face Page Item 3, Response to PA/RFA	Special Instructions
Form Page 3, Activities Planned Under This Award	Special Instructions
Applicant/Fellow Biosketch C. Scholastic Performance	Special Instructions
Form Page 5, Item 24a & b, Thesis/Dissertation Title and Advisor. Item 25, Doctoral Dissertation and Other Research Experience	Omit Special Instructions
Checklist, C	Omit
Checklist, D, Tuition, Fees, Health Insurance	Special Instructions
References	Special Instructions
Kirschstein-NRSA Payback Assurance	Does not apply

SENIOR FELLOWSHIPS	
Face Page, Item 2, Level of Fellowship	Special Instructions
Face Page, Item 3, Response to RFA/PA	Special Instructions
Applicant/Fellow Biosketch	Do not use. Use traditional biosketch found in the PHS398
Form Page 5, Item 24a & b, Thesis/Dissertation Title and Advisor	Omit
Research Training Plan, Section 20. Selection of Sponsor and Institution	Special Instructions
Checklist, C	Special Instructions
Checklist, D. Tuition, Fees, Health Insurance	Omit

The applicant completes Section I of the application (see list above) in consultation with the sponsor. The application should then be provided to the sponsor and sponsoring institution, along with these instructions and any other information required for completion and submission. *This includes the sealed reference letters*. The sponsor should review the specific instructions for and complete Section

II, Sponsor's Information. The applicant and sponsor should verify that the application has been properly completed, assembled, and paginated, and that appropriate institutional approvals and signatures have been obtained.

Kirschstein-NRSA Individual Fellowships provide a stipend to the awardee plus an allowance to the sponsoring institution to defray some of the fellow's training expenses. Individuals sponsored by foreign institutions may also receive travel funds. Detailed information is provided in the Kirschstein-NRSA section of the *NIH Grants Policy Statement* at http://grants.nih.gov/grants/policy/nihgps_2012/index.htm.

The only budget information requested in the application is that related to tuition and fees for courses which support the research training experience, health insurance (self-only or family) for predoctoral applicants, and stipend/salary information for senior fellowship applicants (see Checklist, instructions for Section I, Items C and D). Other budget items are fixed, based on a formula or determined at time of award, and the applicant need not provide any information.

4.1 Face Page (Form Page 1) (Application Section I)

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

Item 1, Title of Research Training Proposal

Do not exceed **81 characters***, including the spaces between words and punctuation*. Choose a descriptive title that is specifically appropriate. The title should not be worded in a way that could easily be misconstrued if quoted out of context. A *new* application must have a different title from any other PHS project with the same individual applicant. A *resubmission application or renewal* should normally have the same title as the previous application or grant. If the specific aims of the project have significantly changed, choose a new title.

Item 2, Level of Fellowship

Indicate the level of fellowship requested in the Individual Fellowship application (predoctoral, postdoctoral, senior). Postdoctoral fellowships are provided by the NIH ICs and AHRQ.

Predoctoral fellowships are provided by a limited number of NIH ICs and AHRQ. Therefore, individuals interested in this type of award are strongly encouraged to consult with the appropriate IC or AHRQ before submitting an application. **This action is of utmost importance because applications with marginal or no relevance to the mission of the participating NIH ICs or AHRQ will not be accepted for review or funding.**

Senior fellowships are provided by a limited number of NIH ICs and some ICs have specific criteria for accepting this type of fellowship. Therefore, individuals interested in this type of award are strongly encouraged to consult with the appropriate IC before submitting an application. (AHRQ does not provide senior fellowships.) Eligibility for a senior fellowship includes possession of a doctoral degree for at least 7 years and an established research career.

Item 3, Program Announcement /Request for Applications

If you are applying for a postdoctoral fellowship through the NIH-wide postdoctoral program, leave this section blank. However, if you are applying for a specific program announced by a particular Institute, check Yes, and enter the appropriate PA number (e.g., PA-05-###) and title.

If you are applying for a predoctoral fellowship program, check Yes, and enter the appropriate PA number (e.g., PA-05-###) and title. Predoctoral PA numbers are listed at: http://grants.nih.gov/training/nrsa.htm#fellowships.

If you are applying for the senior fellowship program, check Yes, and enter the appropriate PA number. Instead of the complete PA title, it is OK to enter "Senior Fellowship" in the PA title field.

For responses to 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 at the end of the forms section. Any special instructions in the RFA must be followed when preparing the application.

Item 4a, Name of Applicant

Insert the name of the individual applying for the fellowship (applicant). Provide last name followed by a comma, first name, and middle name.

Item 4b. eRA Commons User Name

If you are registered in the eRA Commons, enter the assigned Commons User Name. The Commons User Name is the ID assigned to and used by you to access the Commons. This data item is now required.

Item 4c, Highest Degree(s) at Activation

Indicate up to three academic and professional degrees held or expected to be held on the start date of the requested fellowship. For foreign degrees, give the U.S. equivalent.

Item 4d, Present Mailing Address

Provide complete information (including room number, building, and street address) necessary for postal delivery of the address where the applicant can be reached at any time before the beginning date of the requested fellowship. Changes should be reported promptly in writing.

Item 4e, Permanent Mailing Address

If the information given in Item 4d is not a permanent address, provide the complete address where you can always be contacted. Changes should be reported promptly in writing. If this address is the same as in 4d, indicate "same".

Items 4f to 4j

Self-explanatory.

Item 4k, Citizenship

Candidates must check the appropriate box. To be eligible for a Kirschstein-NRSA Individual Fellowship (F30, F31, F32, F33), the candidate must be a U.S. citizen, a non-citizen national, or have been lawfully admitted to the U.S. for permanent residence before the award is issued. U.S. non-citizen nationals are persons born in lands that are not States but are under U.S. sovereignty, jurisdiction, or administration, e.g., American Samoa. Individuals on temporary student visas are not eligible for NRSA support.

If the candidate has been lawfully admitted for permanent residence, i.e., is in possession of an Alien Registration Receipt Card or other legal verification of such status, the candidate should check the "Permanent Resident of U.S." box. Before the award is issued, a permanent resident will be required to submit a notarized statement that a licensed notary has seen the applicant's Alien Registration Receipt Card or some other valid verification from the U.S. Immigration and Naturalization Service of legal admission to the U.S. as a permanent resident.

If the candidate is a non-citizen of the U.S. who has applied for, but not yet been granted legal admission to the U.S. as a permanent resident, the candidate should check the "Permanent Resident of U.S. Pending" box, understanding that no award will be issued until such time as the required permanent residency has been established and the required documentation submitted to the NIH IC.

If the candidate is applying for a non-NRSA fellowship program supported by the NIH, for which citizenship or permanent residency is not required (e.g., Fogarty International Center programs), the candidate must have in his/her possession a valid visa allowing him/her to remain in the U.S. (or in a foreign research training setting, if applicable) long enough to be productive on the proposed fellowship project. It is the responsibility of the sponsoring institution to determine and retain documentation indicating that the individual candidate's visa will allow him/her to reside in the proposed research training setting for the period of time necessary to complete the proposed fellowship. The candidate should check the "Non-U.S. Citizen with temporary U.S. visa" box. This information may be requested by the NIH IC prior to issuance of an award except in certain circumstances, such as for F05 applicants, who would have a temporary U.S. visa pending since a visa application cannot be submitted until the grant is awarded. In general, it is highly recommended that all non-U.S. citizens need to adhere to specific requirements as stated in the FOA or contact the appropriate individual listed on the FOA.

Item 5, Training Under Proposed Award

List the proposed area of research training according to the Fields of Training in Section 7 of these instructions. The Fields of Training listing indicates several major areas, each with subcategories. Select the subcategory that corresponds to the proposed area of research training. Provide *both* the number and name of the subcategory, e.g., 2470 Virology. If the Fields of Training listing does not provide a good descriptor, use the closest subcategory from the list.

This information is used for reporting purposes only and is not used for study section assignments.

Item 6, Prior and/or Current Kirschstein-NRSA Support (Individual or Institutional)

If "Yes," refer to Item 22 (Form Page 5).

Item 7a, Dates of Proposed Award

Indicate the start and end dates of the requested support period. The earliest possible start date and the length of Kirschstein-NRSA support that can be provided are shown in a specific solicitation (i.e., PA/RFA) or in Part I, Section 3.5 of these instructions, "Application Submission Dates."

Item 7b, Proposed Award Duration

Indicate the number of months (2 digits) covered by the dates in Item 7a.

Item 8, Degree Sought During Proposed Award

Complete if applicable. Completion of the degree requirements should be coordinated with the sponsor.

Items 9 through 14 are completed in consultation with the Sponsor and Administrative Officials at the Sponsoring Institution)

Item 9, 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 9 are then not applicable.

Human Subjects Involved

Check "Yes" if activities involving human subjects are planned at any time during the proposed project period, either at the applicant organization or at any other Project/Performance Site or collaborating institution. Check "Yes" if the research is exempt from DHHS regulatory requirements for the protection of human subjects (see Exemption Categories).

If you plan to conduct research involving human subjects, but do not have definite plans at the time of application, you will need to include this information in Item 8 of the Research Training Plan. Certification of IRB review and approval must be provided and accepted by the awarding component before the research may occur.

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

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

Regulatory requirements (Federal and state) to protect human subjects may apply to research using human specimens and/or data, such as use of:

- Bodily materials, such as cells, blood or urine, tissues, organs, hair or nail clippings, from living individuals who are individually identifiable to the investigator(s), even if these materials were collected by others;

- Residual diagnostic specimens from living individuals that are individually identifiable to the investigator(s), including specimens obtained for routine patient care that would have been discarded if not used for research;

- Private information, such as medical information, about living individuals that is individually identifiable to the investigator(s), even if the information was not specifically collected for the study in question. This includes research on genetic information that can be readily associated by the investigator(s) with identifiable living individuals.

Research that involves only *coded* private information/data or *coded* human biological specimens may not constitute human subjects research under the DHHS human subjects regulations (45 CFR Part 46) if:

- the specimens and/or private information were not collected specifically for the currently proposed research project through an interaction/intervention with living individuals AND

- the investigator(s) (including collaborators) on the proposed research cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain (e.g., the researcher's access to subject identities is prohibited by written repository procedures and policies and/or through a written agreement signed by the investigator and the repository providing the specimens and/or data).

See definition of *coded* in Part III.3 under Human Subjects definitions, and the following guidance from the Office for Human Research Protections (OHRP) for additional information and examples: http://www.hhs.gov/ohrp/policy/cdebiol.html.

Individuals who provide *coded* information or specimens for proposed research and who also collaborate on the research involving such information or specimens are considered to be involved in the conduct of human subjects research as investigators (see definition of human subjects).

Additional information is available at:

- OHRP Decision Charts: http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html

- OHRP Guidance on Repositories: http://www.hhs.gov/ohrp/policy/reposit.html; http://www.hhs.gov/ohrp/policy/engage08.html

- OHRP Memo on Engagement: http://www.hhs.gov/ohrp/policy/engage08.html

- NIH Office of Extramural Research Human Subjects website: http://grants.nih.gov/grants/policy/hs/index.htm.

Item 9a. Exemptions from Department of Health and Human Services (DHHS) Human Subjects Regulations

Check "Yes" if the activities proposed are exempt from the regulations at 45 CFR Part 46. Insert the exemption number(s) corresponding to one or more of the six exemption categories listed in Part III under Human Subjects Research Definitions and Terms.

OHRP guidance states that appropriate use of Exemptions described in 45 CFR 46 should be determined by an authority independent from the investigators (http://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 the time of application, the exemptions designated in item 9a often represent the opinion of the PD/PI, and the justification provided for the exemption by the PD/PI is evaluated during peer review.

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

Check "No" if the planned activities involving human subjects are not exempt, and complete the remaining parts of Item 9.

Item 9b. Federalwide Assurance Number

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

Enter "None" in Item 9b if the applicant organization does not have an approved FWA on file with OHRP. In this case, the signature on the Face Page is a declaration that the applicant organization will comply with 45 CFR Part 46 and proceed to obtain a FWA (see http://www.hss.gov/ohrp).

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

Item 9c. Clinical Trial

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

Item 9d. NIH-Defined Phase III Clinical Trial

Check "Yes" or "No" to indicate whether the project is an NIH-Defined Phase III Clinical Trial. Refer to the definition of "NIH-Defined Phase III Clinical Trial" in Part III.3, under Human Subjects Research Definitions and Terms.

Item 10. Vertebrate Animals

Check "No" if activities involving vertebrate animals are not planned at any time during the proposed project period, and leave item 10a blank. Note that generation of custom antibodies constitutes an activity involving vertebrate animals.

Check "Yes" if activities involving vertebrate animals are anticipated or planned at any time during the proposed project period, either at the applicant organization or at any other Project/Performance Site or collaborating institution. If animal involvement is anticipated within the period of award but plans are indefinite and it is not possible to describe the use of animals, check "Yes" and in the Research Training Plan, Item 15, provide an explanation and indicate when it is anticipated that animals will be used. Before activities with animals begin, the applicant must provide all of the information required by the, Research Training Plan, Item 15, Vertebrate Animals, with verification of current IACUC approval,

to the awarding component for prior approval. IACUC approval must have occurred within the past three years to be considered current.

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

Item 10a. Animal Welfare Assurance

If the applicant organization has a current approved Animal Welfare Assurance on file with the Office of Laboratory Animal Welfare (OLAW), enter the Assurance number of the applicant organization in Item 10a. To determine whether the organization holds an Animal Welfare Assurance, contact the IACUC or see http://grants.nih.gov/grants/olaw/olaw.htm#assur.

Enter "None" in Item 10a if the applicant organization does not have an Animal Welfare Assurance on file with OLAW. **Do not enter the Animal Welfare Assurance number of any Project/Performance Site or collaborating institution.** The signature on the Face Page constitutes declaration that the applicant organization will comply with PHS Policy on Humane Care and Use of Laboratory Animals by submitting an Animal Welfare Assurance when requested by OLAW and providing verification of IACUC approval when requested by the PHS awarding component.

Item 11, Sponsoring Institution

Name the one institution that will be legally responsible for committing facilities for the applicant and financially responsible for the use and disposition of any funds awarded based on this application. The address should include the street, city, state, and zip code.

Item 12a&b, Entity Identification Number and Dun & Bradstreet Number (DUNS)

The Entity Identification Number (EIN) should be checked or supplied by the business official of the sponsoring institution. The EIN is used by DHHS for payment and accounting purposes. If a number has not yet been assigned by DHHS, enter the institution's Internal Revenue Service (IRS) employer identification number (nine digits). This number will identify the organization to which funds will be disbursed.

A Dun & Bradstreet (D&B) Data Universal Numbering System (DUNS) number for the sponsoring institution must be entered. The DUNS number is a nine-digit identification code assigned by Dun & Bradstreet. For additional information on this requirement see NIH Guide Notice OD-03-055 (http://grants.nih.gov/grants/ guide/notice-files/NOT-OD-03-055.html). The EIN and DUNS numbers are not applicable for fellows at Federal laboratories.

Item 13, Official Signing for Sponsoring Institution

Name the sponsoring 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.

This information is to be supplied for the business official of the sponsoring institution, including Federal laboratories.

Item 14, Applicant Organization Certification and Acceptance

An original signature, in ink, is required. Only an institutional official with formal designated or delegated authority to sign on behalf of the organization may sign the form. The signature must be dated. *In signing the application Face Page, the 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

Research on Transplantation of Human Fetal Tissue

Research Using Human Embryonic Stem Cells

Women and Minority Inclusion Policy

Inclusion of Children Policy

ClinicalTrials.gov Requirements

Vertebrate Animals

Debarment and Suspension

Drug-Free Workplace

Lobbying

Non-Delinquency on Federal Debt

Research Misconduct

Civil Rights

Handicapped Individuals

Sex Discrimination

Age Discrimination

Recombinant DNA, including Human Gene Transfer Research

Financial Conflict of Interest

Smoke-Free Workplace

Prohibited Research

Select Agent Research

Fellow and Sponsor Assurance

Impact of Grant Activities on the Environment and Historic Properties

4.2 Form Page 2

4.2.1 Sponsor and Co-Sponsor Contact Information

Items 15 and 16. These sections are to be completed in consultation with your sponsor and co-sponsor (if any).

Include complete contact information. If applicable, identify the co-sponsor in the section (labeled co-sponsor) below and provide contact information. A biographical sketch is required for the sponsor and any co-sponsor. See other required information as specified in Section 5.8.

4.2.2 Department, Service, Laboratory, or Equivalent

Indicate the sponsor's organizational affiliation at the sponsoring institution, e.g., Department of Medicine, Materials Research Laboratory, or Social Science Institution. If the department, etc. is part of a larger component, indicate both, e.g., Section on Anesthesiology, Department of Surgery, or Division of Laboratory Medicine, Department of Medicine.

4.2.3 Major Subdivision

The component named in Item 15c is a part of the Major Subdivision.

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

4.2.4 Co-Sponsor

If the research training proposed involves a co-sponsor, complete this section. Otherwise leave blank.

4.2.5 Research Proposal Description: Project Summary and Relevance

Item 17. 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 NIH IC or AHRQ*). 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.

4.3 Form Page 3

4.3.1 Career and Training Goals

Item 18. Describe your overall career goals and explain how the training proposed here will enable you to reach these goals. Identify the skills, theories, conceptual approaches, etc. to be learned or enhanced during the award. You may use a continuation page if necessary.

4.3.2 Activities Planned Under This Award

Item 19. Using the chart provided, specify by year the activities (research, course work, etc.) you will be involved in under the proposed award and estimate the percentage of time to be devoted to each activity. The percentages should total 100 for each year. Base the percentage figures on a normal working day for a full-time fellow as defined by the sponsoring institution. Also, briefly explain activities other than research and relate them to the proposed research training.

For postdoctoral fellowships, do not exceed three years. Predoctoral fellowships may reflect up to five years. MD/Ph.D. applicants may request up to six years if this limit is stated in the program announcement.

4.3.3 Training Site(s)

Item 20. Is the Primary Training Site the same as the Sponsoring Institution (check Yes or No)? If No, provide the detailed information for the Primary Training Site Location.

If there is more than one Training (Project/Performance) Site, list all the sites, including Department of Veterans Affairs (V.A.) facilities and foreign sites, as required by the Federal Financial Accountability and Transparency Act (FFATA), and provide an explanation. One of the sites indicated must be the

sponsoring organization. Provide the explanation under the Research Training Plan, Item 20, Selection of Sponsor and Institution.

If a Training (Project/Performance) Site is engaged in research involving human subjects, the applicant organization is responsible for ensuring that the Project/Performance Site operates under an appropriate Federalwide 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 416-1 and GPS.

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

4.3.4 Human Embryonic Stem Cells

Item 21. 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/research/registry/defaultpage.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. See http://stemcells.nih.gov/research/registry/eligibilityCriteria.asp for additional information on stem cells, and http://stemcells.nih.gov/policy/guidelines.asp for Federal policy statements and guidelines on federally funded stem cell research.

4.4 Table of Contents (Form Page 4)

Self-explanatory.

4.5 Applicant/Fellow Biographical Sketch

The Applicant/Fellow Biographical Sketch Format Page is available only in MS Word format.

The biographical sketch for you, the applicant/fellow, is very similar to the traditional biographical sketch format used by your sponsor. However, there are notable differences so follow these special instructions and use the special sample format provided. If you are applying for a predoctoral or postdoctoral fellowship, use this custom biographical sketch format page. If you are applying for a Senior Fellowship, use the traditional PHS 398 Biographical Sketch Format Page.

All individuals who have the PD/PI role **must** be registered in the eRA Commons, and **must** include the assigned Commons User Name. This information is required. For information on the eRA Commons, see https://commons.era.nih.gov/commons/index.jsp.

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

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

The Biographical Sketch for you the Applicant/Fellow may not exceed four pages. This page limit includes the information requested in the boxes, tables and charts on the form. See **Sample Biographical Sketch**.

Education/Training.

List all degree programs beginning with baccalaureate or other initial professional education and licensure, such as nursing (RN). Include all dates (month (mm) and year (yyyy)) of degrees received or expected, in addition to other information requested.

A. Positions and Honors

List in chronological order all non-degree training, including postdoctoral research training, all employment after college, and any military service. Clinicians should include information on internship, residency and specialty board certification (actual and anticipated with dates) in addition to other information requested. This information is used in reviewing the application and in determining the stipend level for Postdoctoral Fellowships. State the Activity/Occupation and include beginning/end dates, field, name of institution/company, and the name of your supervisor/employer.

List any academic and professional honors that would reflect upon your potential for a research career and qualifications for an Individual Fellowship. Include all scholarships, traineeships, fellowships, and development awards other than Kirschstein-NRSA. Indicates sources of awards, dates, and grant or award numbers. List current memberships in professional societies, if applicable.

B. Publications

List your entire bibliography, separating research papers, abstracts, book chapters, and reviews. Within each subsection the list should be chronological. For each publication, list the authors in published sequence, full title of article, journal, volume number, page numbers, and year of publication. Indicate if you previously used another name that is reflected in any of the citations. Manuscripts listed as “pending publication” or “in preparation” should be included and identified.

When citing articles that fall under the Public Access Policy, were authored or co-authored by the applicant and arose from NIH support, provide the NIH Manuscript Submission reference number (e.g., NIHMS97531) or the PubMed Central (PMC) reference number (e.g., PMCID234567) for each article. If the PMCID is not yet available because the Journal submits articles directly to PMC on behalf of their authors, indicate "PMC Journal - In Process." A list of these Journals is posted at: http://publicaccess.nih.gov/submit_process_journals.htm. Citations that are not covered by the Public Access Policy, but are publicly available in a free, online format may include URLs or PMCID numbers along with the full reference (note that copies of these publications are not accepted as appendix material, see Section 5.7).

C. Scholastic Performance

Predoctoral applicants: Using the chart provided, list by institution and year all undergraduate and graduate courses with grades.

In addition, in the space following the chart, explain any marking system if other than 1-100, A, B, C, D, F, or 0-4.0 if applicable. Show levels required for a passing grade. Predoctoral applicants must also provide scores for the Graduate Record Examination (GRE), if available. MD/PhD applicants should provide MCAT scores, if available.

Postdoctoral applicants: Using the chart provided, list by institution and year all undergraduate courses and graduate scientific and/or professional courses germane to the training sought under this award with grades. In the space following the chart, explain any marking system if other than 1-100, A, B, C, D, F, or 0-4.0 if applicable. Show levels required for a passing grade.

Predoctoral and postdoctoral candidates may be asked to send transcripts prior to award. Unless specified in a particular announcement (RFA/PA), do not include transcripts with the application.

4.6 Previous Research Experience (Form Page 5)

4.6.1 Prior and Current Kirschstein-NRSA Support (Individual or Institutional)

Item 22. Follow the instructions on the form. An individual cannot receive more than 5 years cumulative predoctoral Kirschstein-NRSA support and 3 years cumulative postdoctoral Kirschstein-NRSA support (the total of Institutional Grants and Individual Fellowships) without a waiver from the NIH IC or AHRQ. The NIH ICs have different policies on waiving the statutory limits on support. Therefore, you must request a waiver from the probable funding IC or AHRQ before requesting a period of support that would exceed these limits.

Promptly report to the NIH IC to which this application is assigned or to AHRQ any additional NRSA support received while this application is pending.

4.6.2 Application(s) for Concurrent Support

Item 23. Check the appropriate box. If the candidate has applied or will be applying for other support that would run concurrently with the period covered by this application check “Yes” and include the type, dates, source(s) and amount. The candidate must promptly report to the NIH IC to which this application is assigned any support resulting from other such applications.

4.6.3 Title(s) of Thesis/Dissertation(s)

Item 24a. Self-explanatory. Applications for Predoctoral and Senior Fellowships should omit this item.

4.6.4 Dissertation Advisor or Chief of Service

Item 24b. Include name, title, department, and institution of this individual. If this individual is not submitting a reference, explain why not. Applications for Predoctoral and Senior Fellowships should omit this item.

4.6.5 Doctoral Dissertation and Other Research Experience

Item 25. Summarize in chronological order your research experience, including the areas studied and conclusions. Specify which areas were part of your thesis or dissertation and which were part of a previous postdoc project, if any. If you have no research experience, list other scientific experience. Do not list academic courses here. Do not exceed two pages.

Unless otherwise instructed in a specific Funding Opportunity Announcement, applicants for early (pre-dissertation) Predoctoral and Senior Fellowships should omit their doctoral dissertation, but should include any other research experience, if applicable. Advanced graduate students (ONLY) must also include a narrative of their doctoral dissertation (may be preliminary) and any other research experience. The information is required of advanced graduate students who have successfully completed their comprehensive examinations or the equivalent by the time of award and will be performing dissertation research.

4.7 Personal Data

Follow the instructions on the form. Place the form at the end of the signed original application after the Checklist. *Do not copy*. The Personal Data page applies only to the fellow.

5. Preparing the Research Training Plan

5.1 (Reserved)

5.2 (Reserved)

5.3 (Reserved)

5.4 Research Training Plan Format and Notice of Proprietary Information

5.4.1 Research Training Plan Format

No Specific Form Page - Use Continuation Page

The Research Training Plan consists of Items 1-21, as applicable. It should be self-contained and include sufficient information to evaluate the project, independent of any other document (e.g., previous application). Be specific and informative, and avoid redundancies. For grant writing tips, see http://grants.nih.gov/grants/grant_tips.htm.

This section should be well-formulated and presented in sufficient detail that it can be evaluated for both its research training potential and scientific merit. It is important that it be developed *in collaboration with your sponsor*, but it should be *written by you the applicant*.

Page Limitations

The Research Training Plan includes multiple subsections, some of which have page limits. Sections 2 through 5 of this section must not exceed 10 pages, including all tables, graphs, figures, diagrams, and charts. Follow the format provided below.

Use of URLs

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

Other Materials

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

PDF images of material such as electron micrographs or gels may be included in the Appendix; however, a photocopy of each must also be included within the page limitations of the Research Training Plan.

Reference Letters for Resubmission Application.

Applicants must resubmit three sealed reference letters with the application. See Reference Letter instructions for additional details.

5.4.2 Notice of Proprietary Information

Applicants are discouraged from submitting information considered proprietary unless it is deemed essential for proper evaluation of the application. However, when the application contains information that constitutes trade secrets, or information that is commercial or financial, or information that is confidential or privileged, identify the pages in the application that contain this information by marking those paragraphs or lines with an asterisk (*) in the left-hand margin and providing the page numbers before Item 2. Specific Aims, in the Research Training Plan.

When information in the application constitutes trade secrets, 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 such information shall be used or disclosed only for evaluation of this application. If an award is issued as a result of or in connection with the submission of this application, the Government shall have the right to use or disclose the information to the extent authorized by law. This restriction does not limit the Government's right to use the information if it is obtained without restriction from another source.

5.5 Contents of Research Training Plan

1. Introduction (Resubmission Applications Only)

All resubmission applications must include an Introduction of no more than one page that summarizes the substantial additions, deletions, and changes. The Introduction must also include responses to criticisms and issues raised in the summary statement for the previous application. Insert the Introduction just before the very beginning of the Research Training Plan.

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

2. 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.

3. 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 broad, long-term objectives and to the **mission of the NIH IC or AHRQ**.

4. Preliminary Studies/Progress Report

(a) Preliminary Studies. Use this section to provide an account of preliminary studies, if any, that are pertinent to this application. This information will help reviewers and NIH staff evaluate your experience and determine your competence to pursue the proposed project. It will also help demonstrate the utility of the proposed project as a training experience.

When applicable, provide a succinct account of published and unpublished results, indicating progress toward their achievement.

(b) Progress Report for Competing Continuation Applications. Competing Continuation applications for individual fellowships are rare. You should consult with your program official before preparing such an application. If you are submitting a Competing Continuation, a Progress Report must be provided. 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. Include the complete references to appropriate publications and manuscripts accepted for publication (not part of the page limitations).

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

See Part II, Section 4.3 for more detailed instructions on which Target and Enrollment Report or Table to use.

5. 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. Include how the data will be collected, analyzed, and interpreted. 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.

For Postdoctoral and Senior Fellowship applications, include any courses that you plan to take to support the research training experience.

6. Inclusion Enrollment Report (for RENEWAL applications only)

In the rare instance that you are submitting a renewal application, and it involves clinical research, then you must report on the enrollment of research subjects and their distribution by ethnicity/race and sex/gender using the inclusion Enrollment Report of each protocol. (Not part of the page limitations of the Research Training Plan.)

7. Progress Report Publication List (for RENEWAL applications only)

In the rare instance when you are submitting a renewal application, list the title and complete references to all appropriate publications, manuscripts accepted for publication, patents, and other printed materials that have resulted from the project since it was last reviewed competitively. (Not part of the page limitations of the Research Training Plan.)

8. Human Subjects Research

If you have marked Item 9 on the face page of the application as "Yes" consult with your *sponsor* before completing this section and refer to Part II of the PHS 416-1, Supplemental Instructions for Preparing the Human Subjects Section of the Research Training Plan. Human subjects requirements may apply even if you are obtaining specimens/data from collaborators or if you are subcontracting the human research to another organization. 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. 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 Fellowship application is identical to information that you will be required to provide for IRB review at your own institution.

9. *Clinical* Trial

If you have checked "yes" to item 9c.and this project involves a clinical trial refer to Part II of the 416-1 Part II, Supplemental Instructions for Preparing the Human Subjects Section of the Research Training Plan for further details.

10. Agency-Defined Phase III Clinical Trial

If you have checked "yes" to item 9d.and this project involves a agency-defined phase III clinical trial refer to Part II of the 416-1 Part II, Supplemental Instructions for Preparing the Human Subjects Section of the Research Training Plan for further details.

11. Protection of Human Subjects

Refer to Part II of the PHS 416-1 Part II, Supplemental Instructions for Preparing the Human Subjects Section of the Research Training Plan if the proposed research will involve human subjects.

12. Inclusion of Women and Minorities

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

13. Targeted/Planned Enrollment Table

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

14. Inclusion of Children

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

15. Vertebrate Animals

If vertebrate animals are involved in the project, address each of the five points below.

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

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

The five points are as follows:

1. Provide a detailed description of the proposed use of the animals for the work outlined in the Research 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 reason(s) for its selection. State whether this method is consistent with the recommendations of the American Veterinary Medical Association (AVMA) Guidelines on Euthanasia. If not, include a scientific justification for not following the recommendations.

If the involvement of animals is **indefinite**, provide an explanation and indicate when it is anticipated that animals will be used.

16. Select Agent Research

Select Agents are hazardous biological agents and toxins that have been identified by DHHS or USDA as having the potential to pose a severe threat to public health and safety, to animal and plant health, or to animal and plant products. CDC maintains a list of these agents; see http://www.cdc.gov/od/sap/docs/salist.pdf.

If the activities proposed in the application involve only the use of a strain(s) of Select Agents which has been excluded from the list of select agents and toxins as per 42 CFR 73.4(f)(5), the Select Agent requirements do not apply. Use this section to identify the strain(s) of the Select Agent that will be used and note that it has been excluded from this list. The CDC maintains a list of exclusions at http://www.cdc.gov/od/sap/sap/exclusion.htm.

If the strain(s) is not currently excluded from the list of select agents and toxins but you have applied or intend to apply to DHHS for an exclusion from the list, use this section to indicate the status of the request or the intent to apply for an exclusion and provide a brief justification for the exclusion.

If any of the activities proposed in the application involve the use of Select Agents at any time during the proposed project period, either at the applicant organization or at any other Project/Performance Site, address the following three points for each site at which Select Agent research will take place. Although no specific page limitation applies to this section, be succinct.

1. Identify the Select Agent(s) to be used in the proposed research.
2. Provide the registration status of all entities* where Select Agent(s) will be used.

    - If the Project/Performance Site(s) is a foreign institution, provide the name(s) of the country or countries where Select Agent research will be performed.

    *An "entity" is defined in 42 CFR 73.1 as "any government agency (Federal, State, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity."

3. Provide a description of all facilities where the Select Agent(s) will be used.

    - Describe the procedures that will be used to monitor possession, use and transfer of Select Agent(s).

    - Describe plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

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

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

17. Bibliography and References Cited (formerly Literature Cited)

Provide a bibliography of any references cited in the description of the Project Summary and Relevance (Form Page 2). Each reference must include names of all authors (in the same sequence in which they appear in the publication), the article and journal title, book title, volume number, page numbers, and year of publication. Include only bibliographic citations. Follow scholarly practices in providing citations for source materials relied upon in preparing any section of the application.

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

18. Resource Sharing

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

(a) *Data Sharing Plan*: Investigators seeking $500,000 or more in direct costs in any year are expected to include a brief 1-paragraph description of how final research data will be shared, or

explain why data-sharing is not possible. Specific FOAs may require that all applications include this information regardless of the dollar level. Applicants are encouraged to read the specific opportunity carefully and discuss data-sharing plans with their program contact at the time they negotiate an agreement with the Institute/Center (IC) staff to accept assignment of their application. See Data-Sharing Policy or http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html.

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

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

19. Respective Contributions

Describe the collaborative process between you and your sponsor/co-sponsor in the development, review, and editing of this research training plan. Do not include the respective roles in accomplishing the proposed research (limit to one page).

20. Selection of Sponsor and Institution

1. Explain why the sponsor, co-sponsor (if any), and institution were selected to accomplish the research training goals. If the proposed research training is to take place at a site other than the sponsoring organization, provide an explanation here.
2. Doctorate or Current Institution. Since research training is expected to broaden a fellow's perspective, postdoctoral applicants requesting training at either their doctorate institution or at the institution where they have been training for more than a year must explain why further training at that institution would be valuable. Individuals applying for Senior Fellowships who are requesting training at the institution at which they are employed should provide a similar explanation. Ordinarily, the new training value of an environment diminishes as your association there lengthens. If you are staying at the same institution, explain briefly.
3. Foreign Institution. If you are proposing a research training experience at a foreign institution, show that the foreign institution and sponsor offer special opportunities for training that are not currently available in the United States. Key factors in the selection of a foreign institution should be described. If applicable, the need for and level of proficiency in reading, speaking, and comprehending the foreign language should be addressed.

21. Responsible Conduct of Research

Note: No award will be made if an application lacks this component.

Every fellow must receive instruction in the responsible conduct of research (http://grants.nih.gov/grants/guide/notice-files/not92-236.html). Applications must include the sponsoring institution's plans to provide and the candidate's plans for obtaining instruction in the responsible conduct of research, including the rationale, subject matter, appropriateness, format, frequency and duration of instruction. The amount and nature of faculty participation must be

described. The plan will be discussed after the overall determination of merit, so that the review panel's evaluation of the plan will not be a factor in the determination of the priority score. The plan will be judged as acceptable or unacceptable. The acceptability of the plan will be described in an administrative note of the summary statement. Regardless of the priority score, an application with an unacceptable plan will not be funded until the applicant provides a revised acceptable plan. Staff in the NIH awarding component will judge the acceptability of the revised plan.

In most cases, the applicant's plan for Responsible Conduct of Research will include participation in an established course or seminar series, as either an instructor or a student (for-credit or non-credit). If the institution does not offer a course or seminar series that fulfills the Responsible Conduct of Research requirement, the applicant may lead or participate in a discussion group in lieu of a formal activity. If neither option is possible, the applicant may obtain on-line instruction in Responsible Conduct of Research. Suggested topics for courses, seminars, and discussion groups include conflict of interest, responsible authorship, policies for handling misconduct, data management, data sharing, policies regarding the use of animals and/or human subjects, and institutional vs. individual responsibilities for scientific integrity. Courses, seminars, and discussion groups taken to fulfill the Responsible Conduct of Research requirement need not cover all of these topics but should include a majority of them.

Attach a description, limited to no more than one page, of plans for obtaining instruction in the responsible conduct of research. This must include the rationale, subject matter, appropriateness, format, frequency and duration of instruction. The amount and nature of faculty participation must be described.

5.6 Checklist

A. Type of Application

Check applicable.

B. Assurances/Certifications

Each application to the PHS requires that the policies, assurances, and certifications provided in Part III and listed in Part I, under Item 14 of the Face Page, be verified by the signature of the official signing for the applicant organization on the Face Page of the application. If unable to certify compliance, where applicable, provide an explanation.

C. Kirschstein-NRSA Senior Fellowship Applicants

Section to be completed only by Senior Fellowships applicants, providing requested salary/stipend budgetary information. Predoctoral and postdoctoral applicants should leave this section blank.

D. Tuition and Fees

Sections to be completed by pre- and postdoctoral applicants, providing requested budgetary information as applicable. Senior Fellowship applicants should leave this section blank.

5.7 Appendix

Do not use the appendix to circumvent the page limitations of the Research Training Plan. Graphs, diagrams, tables, and charts should be included in the body of the Research Training Plan unless a

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

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

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

- Label each disk with the Applicant Fellow name and application title.

- If burning CD-ROM disks on a Mac, select the ISO 9660 format.

- Do not use compression techniques for the electronic files.

- Do not use password protection, encryption, digital signature and/or digital certification in the PDF files.

The following materials may be included in the appendix to New, Revision, Renewal and Resubmission applications:

- Up to 3 publications of the following types. In each case include the entire document:

    - Manuscripts and/or abstracts accepted for publication but not yet published.

    - Published manuscripts and/or abstracts where a free, online, publicly available journal link is not available.

    - Patents directly relevant to the project.

  Do not include unpublished theses or abstracts/manuscripts submitted, but not yet accepted, for publication.

- Surveys, questionnaires, and other data collection instruments, clinical protocols, and informed consent documents.

- Color images of gels, micrographs, etc., provided that a photocopy (may be reduced in size) is also included within the 10-page limit of Items A-D of the Research Training Plan. No images may be included in the appendix that are not also represented within the Research Training Plan.

- For materials that cannot be submitted on CD (e.g., medical devices, prototypes), applicants should contact the Scientific Review Officer for instructions following notification of assignment of the application to a study section. Applicants are encouraged to be as concise as possible and submit only information essential for the review of the application.

Publications that are publicly accessible must not be included in the appendix. For such publications, the URL or PMC submission identification numbers along with the full reference should be included as appropriate in the Bibliography and References Cited/Progress Report Publication List section of the Research Training Plan, and/or in the Biographical Sketch.

5.8 Sponsor and Co-Sponsor Information (Application Section II)

All the information in this section is to be completed by the sponsor and any co-sponsor (if any).

Sponsor's and Co-Sponsor's Biographical Sketch Format Page

See Sponsor's and Co-Sponsor's Biographical Sketch Sample.

The Biographical Sketch format used by the Sponsor and Co-Sponsor (if any) is identical to the Biographical Sketch Format Page in the Application for Public Health Service Grant (PHS 398). Therefore the PHS 398 Format Page may be used in lieu of the Format Page provided in the 416-1. If the PHS 398 page is used, place the name of the fellowship applicant in the upper right corner in lieu of the Principal Investigator/Program Director. *The Biographical Sketch for the Sponsor and Co-Sponsor (if any) may not exceed four pages for each person. This 4-page limit includes the table at the top of the first page.*

If this application involves a co-sponsor who has a substantial involvement and/or critical role in the Research Training Proposal, include their Biographical Sketch; a letter of commitment from that individual; and required information for the items addressed below.

Sponsor's and Co-Sponsor's Information

No Specific Form Page - Use Continuation Page

Create a heading at the top of the first page titled "Section II--Sponsor and Co-Sponsor Information".

Complete these items as comprehensively as possible so that a meaningful evaluation of the training environment can be made by the reviewers. Use continuation pages as needed.

1. Research Support Available

In a table, list all current and pending research and research training support specifically available to the applicant for this particular training experience. Include funding source, complete identifying number, title of the research or training program, and name of the principal investigator, dates, and amount of the award. Include this information for any co-sponsor as well.

2. Sponsor's/Co-Sponsor's Previous Fellows/Trainees

Give the total number of predoctoral and postdoctoral individuals previously sponsored. Select five that are representative and, for those five, provide their present employing organizations and position titles or occupations. Include this information for any co-sponsor as well.

3. Training Plan, Environment, Research Facilities

Describe the research training plan that you have developed specifically for the applicant/fellow. Include items such as classes, seminars, and opportunities for interaction with other groups and

scientists. Describe the research environment and available research facilities and equipment. Indicate the relationship of the proposed research training to the applicant's career goals. Describe the skills and techniques that the applicant will learn. Relate these to the applicant's career goals.

4. Number of Fellows/Trainees to be Supervised During the Fellowship

Indicate whether pre- or postdoctoral. Include this information for any co-sponsor as well.

5. Applicant's Qualifications and Potential for a Research Career

Self-explanatory.

5.9 Letters of Reference (Application Section III)

At least three completed, sealed letters of reference must be submitted with the application. Referees should use the reference letter format and return the letter of reference in a sealed envelope to you as soon as possible. Remind them that reference reports should be provided in the letters of reference and any continuation pages. You are asked not to open the reference envelopes to ensure the confidentiality of such information. The sealed envelopes must be attached to the original application. If you are *submitting a resubmission application or a competing continuation application, you also must submit three sealed reference letters*.

Your references should be carefully selected. Only those individuals who can make the most meaningful comments about your qualifications for a research career should be used. The sponsor and co-sponsor of this application cannot be counted as references. The sponsor's/co-sponsor's recommendation is included as part of the application (see Sponsor*/Co-Sponsor Information).* Whenever possible, select at least one referee who is not in your current department. If not submitting a reference from the dissertation advisor or chief of service, provide an explanation in Item 24b on Form Page 5. For postdoctoral applications, references from graduate or medical school are preferred over those from undergraduate school.

Request reference reports only from individuals who will be able to return them in time for submission of the application. Consider any factor (e.g., illness or extended vacation) that might cause an inordinate delay. Give these reference letter formats to the referees well in advance of the application submission date.

Failure to provide references may delay processing of your application or may result in the application being returned to you without review.

6. The Peer Review Process

A description of what happens to your individual fellowship application after it is received for peer review can be found at the following location: http://grants.nih.gov/grants/peer_review_process.htm. Most applications submitted to the NIH or AHRQ will be reviewed through a two-tier system. The first level of review will be performed by a Scientific Review Group (SRG), 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://cms.csr.nih.gov/. The complete listing of Rosters for NIH Scientific Review Groups (SRGs) is available at http://era.nih.gov/roster/index.cfm.

SRG members will be instructed to evaluate research applications by addressing four review criteria (see below) and assigning a single, global score for each application. *Requests for Applications (RFAs) and other types of grants may have different and/or additional review criteria.*

As part of the initial merit review, all applicants will receive a written critique, called a Summary Statement. Predoctoral fellowship Summary Statements represent a combination of the reviewers' written comments, the Scientific Review Officer's resume/summary of discussion, the recommendations of the study section, and administrative notes of special considerations.

Staff members within the assigned NIH IC or ARHQ provide a second level of review.

6.1 Individual Fellowship Application Review Criteria

The criteria for reviewing Individual Fellowship applications focus on four main components: the candidate, the sponsor/training environment, the research proposal, and the training potential. Since each application is considered on an individual basis, these four areas do not necessarily receive equal weight in the SRG's consideration, as reflected by the priority score. Within each of the four main areas, the following is given consideration:

Candidate: The candidate's previous academic and research performance and the potential to become an important contributor to biomedical, behavioral, or clinical science.

Sponsor and Training Environment: The quality of the training environment and the qualifications of the sponsor as a mentor within the proposed research training experience.

Research Proposal: The merit of the scientific proposal and its relationship to the candidate's career plans.

Training Potential: The value of the proposed fellowship experience as it relates to the candidate's needs in preparation for a career as an independent researcher.

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

Protection of Human Subjects: 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 training plan according to the following five review criteria: (1) Risk to subjects, (2) Adequacy of protection against risks (3) Potential

benefits of the proposed research to the subjects and others; (4) Importance of the knowledge to be gained; and (5) Data and safety monitoring for clinical trials.

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) Characteristics of the population, and (2) Sources of Materials.

Inclusion of Women, Minorities, and Children: 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 the Research Proposal.

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 the Research Proposal and Sponsor 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.

Consideration Outside of the Priority Score

Responsible Conduct of Research: While not a factor in the scientific merit or priority score, reviewers will also access the adequacy of the research training plan in Responsible Conduct of Research.

7. Fields of Training

1000 I. PREDOMINANTLY NON-CLINICAL OR LAB-BASED RESEARCH TRAINING

1100 BIOCHEMISTRY
1110 Biological Chemistry
1120 Bioenergetics
1130 Enzymology
1140 Metabolism

1200 BIOENGINEERING
1210 Bioelectric/Biomagnetic
1220 Biomaterials
1230 Biomechanical Engineering
1240 Imaging
1250 Instrumentation and Devices
1260 Mathematical Modeling
1270 Medical Implant Science
1280 Nanotechnology
1290 Rehabilitation Engineering
1310 Tissue Engineering

1400 BIOPHYSICS
1410 Kinetics
1420 Spectroscopy
1430 Structural Biology
1440 Theoretical Biophysics

1500 BIOTECHNOLOGY
1510 Applied Molecular Biology
1520 Bioprocessing and Fermentation
1530 Metabolic Engineering

1600 CELL AND DEVELOPMENTAL BIOLOGY
1610 Cell Biology
1620 Developmental Biology

1700 CHEMISTRY
1710 Analytical Chemistry
1720 Bioinorganic Chemistry
1730 Bioorganic Chemistry
1740 Biophysical Chemistry
1750 Medicinal Chemistry
1760 Physical Chemistry
1770 Synthetic Chemistry

1900 ENVIRONMENTAL SCIENCES

2000 GENETICS
2010 Behavioral Genetics
2020 Developmental Genetics
2030 Genetic Epidemiology
2040 Genetics of Aging
2050 Genomics
2060 Human Genetics
2070 Molecular Genetics
2080 Population Genetics

2200 IMMUNOLOGY
2210 Asthma and Allergic Mechanisms
2220 Autoimmunity
2230 Immunodeficiency
2240 Immunogenetics
2250 Immunopathology
2260 Immunoregulation
2270 Inflammation
2280 Structural Immunology
2290 Transplantation Biology
2310 Vaccine Development

2400 MICROBIOLOGY AND INFECTIOUS DISEASES
2410 Bacteriology
2420 Etiology
2430 HIV/AIDS
2440 Mycology
2450 Parasitology
2460 Pathogenesis of Infectious Diseases
2470 Virology

2600 MOLECULAR BIOLOGY

2800 NEUROSCIENCE
2810 Behavioral Neuroscience
2820 Cellular neuroscience
2830 Cognitive neuroscience
2840 Communication Neuroscience
2850 Computational Neuroscience
2860 Developmental Neuroscience
2870 Molecular Neuroscience
2880 Neurochemistry
2890 Neurodegeneration
2910 Neuropharmacology
2920 Systems/Integrative Neuroscience

3100 NUTRITIONAL SCIENCES

3200 PHARMACOLOGY
3210 Molecular Pharmacology
3220 Pharmacodynamics
3230 Pharmacogenetics
3240 Toxicology

3300 PHYSIOLOGY
3310 Aging
3320 Anesthesiology (basic science)
3330 Endocrinology (basic science)
3340 Exercise Physiology (basic science)
3350 Integrative Biology
3360 Molecular Medicine
3370 Physiological Optics
3380 Reproductive Physiology

3500 PLANT BIOLOGY

3600 PSYCHOLOGY, NON-CLINICAL
3610 Behavioral Communication Sciences
3620 Behavioral Medicine (non-clinical)
3630 Cognitive Psychology
3640 Developmental and Child Psychology
3650 Experimental & General Psychology
3660 Mind-Body Studies
3680 Neuropsychology
3690 Personality and Emotion
3710 Physiological Psychology & Psychobiology
3720 Psychology of Aging
3730 Psychometrics
3740 Psychophysics
3750 Social Psychology

3900 PUBLIC HEALTH
3910 Disease Prevention and Control
3920 Epidemiology
3930 Health Economics
3940 Health Education
3950 Health Policy Research
3960 Health Services Research
3970 Occupational and Environmental Health

4100 RADIATION, NON-CLINICAL
4110 Nuclear Chemistry
4120 Radiation Physics
4130 Radiobiology

4200 SOCIAL SCIENCES
4210 Anthropology
4220 Bioethics
4230 Demography & Population Studies
4240 Economics
4250 Education
4260 Language and Linguistics
4270 Sociology

4400 STATISTICS AND/OR RESEARCH METHODS AND/OR INFORMATICS
4410 Biostatistics and/or Biometry
4420 Bioinformatics
4430 Computational Science
4440 Information Science
4450 Clinical Trials Methodology

4600 TRAUMA, NON CLINICAL

5000 OTHER, Predominantly Non-Clinical or Lab-Based Research Training

6000 II. PREDOMINANTLY CLINICAL RESEARCH TRAINING (can include any degree):

6100 ALLIED HEALTH
6110 Audiology
6120 Community Psychology
6130 Exercise Physiology (clinical)
6140 Medical Genetics
6150 Occupational Health
6160 Palliative Care
6170 Physical Therapy
6180 Pharmacy
6190 Social Work
6210 Speech-language Pathology
6211 Rehabilitation

6400 DENTISTRY

6500 CLINICAL DISCIPLINES
6510 Allergy
6520 Anesthesiology
6530 Behavioral Medicine (clinical)
6540 Cardiovascular Diseases
6550 Clinical Laboratory Medicine
6560 Clinical Nutrition
6570 Clinical Pharmacology
6580 Complementary and Alternative Medicine
6590 Clinical Psychology
6610 Connective Tissue Diseases
6620 Dermatology
6630 Diabetes
6640 Gastroenterology
6650 Endocrinology
6660 Immunology

6670 Gene Therapy (clinical)
6680 Geriatrics
6690 Hematology
6710 HIV/AIDS
6820 Infectious Diseases
6830 Liver Diseases
6840 Metabolic Diseases
6850 Nephrology
6860 Neurology
6870 Ophthalmology
6880 Nuclear Medicine
6890 OB-GYN
6910 Oncology
6920 Orthopedics
6930 Otorhinolarynology
6940 Preventive Medicine
6950 Radiation, Interventional
6960 Pulmonary Diseases
6970 Radiology, Diagnostic
6980 Rehabilitation Medicine
6990 Psychiatry
7110 Surgery
7120 Trauma
7130 Urology

7300 PEDIATRIC DISCIPLINES
7310 Pediatric Endocrinology
7320 Pediatric Hematology
7330 Pediatric Oncology
7340 Pediatric, Prematurity & Newborn

7500 NURSING

7700 VETERINARY MEDICINE

8000 OTHER, Predominantly Clinical Research Training

8. KIRSCHSTEIN-NRSA Payback Assurance

Section 487 of the Public Health Service Act, as, amended (42 USC 288), and implementing regulations (42 CFR Part 66) require satisfactory assurance from a prospective recipient of a Kirschstein-NRSA Individual Fellowship that, in the first 12 months of Kirschstein-NRSA postdoctoral support, he or she will meet the following service requirement. Kirschstein-NRSA predoctoral fellows or other fellows who have already had 12 months of Kirschstein-NRSA postdoctoral support do not incur a service payback obligation.

Kirschstein-NRSA Individual Fellowships will be governed by the service payback requirements articulated in the National Research Service Award Guidelines for Individual Awards and Institutional Grants. These guidelines can be found in the NRSA portion of the most recent version of the NIH Grants Policy Statement found at: http://grants.nih.gov/grants/policy/policy.htm#gps. Applicants accepting an approved Kirschstein-NRSA Individual Fellowship agree to the following assurance:

I. Service Requirement - In accepting a Ruth L. Kirschstein National Research Service Award to support my postdoctoral research training, I understand that my first 12 months of Kirschstein-NRSA Individual Fellowship support for postdoctoral research training carry with it a payback obligation. I hereby agree to engage in a month of health-related research, health-related research training, health-related teaching, and/or health-related activities for each month I receive a Kirschstein-NRSA Individual Fellowship for postdoctoral research training up to and including 12 months. If I receive a Kirschstein-NRSA Individual Fellowship for postdoctoral research training for more than 12 months, I agree that the 13th month and each subsequent month of Kirschstein-NRSA-supported postdoctoral research training will satisfy a month of my payback obligation incurred in the first 12 months. This service shall be initiated within 2 years after the end of Kirschstein-NRSA support. The health-related research, teaching, and/or activities shall be on a continuous basis and shall average more than 20 hours per week of a full work year.

II. Financial Payback Provisions - I understand that if I fail to undertake or perform such service in accordance with Section I above, the United States will be entitled to recover from me an amount determined in accordance with the following formula:

$$A = F [(t-s)/t]$$

where "A" is the amount the United States is entitled to recover; "F" is the sum of the total amount paid to me under the initial 12 months of my postdoctoral Ruth L. Kirschstein National Research Service Award support; "t" is the total number of months in my service obligation; and "s" is the number of months of such obligation served.

Except as provided in Section III below, any amount the United States is entitled to recover from me shall be paid within the 3-year period beginning on the date the United States becomes entitled to recover such amount. The United States becomes entitled to recover such amount 2 years after termination of my Ruth L. Kirschstein National Research Service Award support if I do not engage in acceptable service payback activities in accordance with Section I. If I elect to engage in financial repayment before the end of the 2-year period, the United States becomes entitled to recover such amount on the date of my election. Interest on the amount begins on the date the United States becomes entitled to recover such amount and is at the rate fixed by the Secretary of the Treasury after taking into consideration private consumer rates prevailing on that date. I understand that I will be allowed an initial 30-day interest-free period in which to fully pay such amount, and that I may prepay any outstanding balance after that period to avoid additional interest. I further understand that I

will be subject to authorized debt collection action(s) (including any accrued interest and late fees) should I fail to comply with the payback provisions of this Section II.

III. Conditions for Break in Service, Waiver, and Cancellation - I hereby understand that the Secretary of Health and Human Services:

A. May extend the period for undertaking service, permit breaks in service, or extend the period for repayment, if it is determined that:

1. Such an extension or break in service is necessary to complete my clinical training or to participate in a NIH Loan Repayment Program;
2. Completion would be impossible because of temporary disability; or
3. Completion would involve a substantial hardship and failure to extend such period would be against equity and good conscience;

B. May waive my obligation, in whole or in part, if it is determined that:

1. Fulfillment would be impossible because I have been permanently or totally disabled; or
2. Fulfillment would involve a substantial hardship and the enforcement of such obligation would be against equity and good conscience;

C. Will, in the event of my death, cancel any obligation incurred under this payback agreement.

IV. Termination Notice-Annual Report of Employment-Change of Address and/or Name - I agree to complete and submit a termination notice immediately upon completion of support. Thereafter, on an annual basis I agree to complete and submit all Payback Activities Certification forms sent to me by the National Institutes of Health or the Agency for Healthcare Research and Quality concerning post-award activities, and agree to keep those agencies advised of any change of address and/or name until such time as my total obligation is fulfilled.

V. Program Evaluation - I understand that I also may be contacted from time to time, but no more frequently than once every 2 years, after the end of this award to determine how the training obtained has influenced my career. Any information thus obtained would be used only for statistical purposes and would not identify me individually.

VI. Certification - By signing the certification block on the application form, I certify that I have read and understood the requirements and provisions of this assurance and that I will abide by them if an award is made.