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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 Form PHS 416-1

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**********IMPORTANT CHANGES AND REMINDERS**********

IMPORTANT CHANGES

CHANGES TO THE PHS 416-1 FORM AND INSTRUCTIONS

Electronic Format

PHS 416-1 is available in electronic format only. PHS 416-1 has been modified to enable the fields to be completed (filled) using Adobe Acrobat Reader software. In addition, the PHS 416-1 may be completed using any word processing software that can read Microsoft Word (MS Word) files. **Note: Documents can be saved only if you have obtained Adobe Acrobat.**

At this time, NIH is not accepting Ruth L. Kirschstein National Research Service Award Individual Fellowship applications electronically. Applications must be submitted in hard-copy form.

The Table of Contents includes direct links to specific sections of the form. Moreover, the revised instructions include dynamic website links and cross-references, which enable users to easily navigate through the various sections of this document.

Human Subjects Research

Specific instructions are provided for the use of human subjects in research, including new format pages for Women and Minority Inclusion enrollment. See Section I.C, Item 30b of these instructions.

Responsible Conduct of Research

Language in this section has been revised on April 14, 2003. See Section I.C, Item 30e of these instructions.

Application Receipt Dates

The Application Receipt Date for the Minority and Disability Programs has been corrected to May 1. See Section II.A.3 of these instructions.

Vertebrate Animals

Institutional Animal Care and Use Committee (IACUC) approval of proposed research involving vertebrate animals is no longer required before an application will be accepted for peer review. As part of the peer review process, the peer review group will continue to address the adequacy of animal usage and protections in applications; however, IACUC approval is required only on a just-in-time" basis before an award can be made.

See http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-064.html

CHANGES IN THE APPLICATION FORM PAGES

Changed Format Pages

Face Page: Form Page 1

Human Subjects fields have been modified as follows:

9a: No/Yes — check applicable box for "Research Exempt."

9b: If 9a is checked "No," provide Human Subjects Assurance Number.

9c: check applicable box for NIH-Defined Phase III Clinical Trial.

Vertebrate Animals fields have been modified as follows:

10a: No/Yes — check the applicable box concerning involvement of vertebrate animals.

10b: If 10a is marked "Yes," provide Animal Welfare Assurance Number or indicate "None."

Personal Data Page

The Personal Data on Kirschstein-NRSA Individual Fellowship Applicant Page has been modified to reflect updated Ethnicity and Race categories.

New Format Pages

Targeted/Planned Enrollment Table and Inclusion Enrollment Report.

REMINDER

Type size, character limitations, and format specifications must be followed; if not, application processing may be delayed or it may be returned to the applicant without review.

FOREWORD

The PHS 416-1 instructions contain information for preparing applications for Ruth L. Kirschstein National Research Service Award (NRSA) Individual Fellowships available from the National Institutes of Health (NIH) and the Agency for Healthcare Research and Quality (AHRQ). Kirschstein-NRSA Individual Fellowships are available at the predoctoral, postdoctoral, and senior fellowship levels. Not all of the Individual Fellowship levels are supported by each NIH Institute and Center (IC) and AHRQ. Prospective applicants should contact the probable funding NIH IC or AHRQ before preparing an application. Contact information can be found in the program announcement or request for applications and Section II.C on pages 31-32 of these instructions.

Within these instructions, the specific instructions for completing the application appear first, followed by general information on submitting the application. The last section of the instructions contains policies, certifications, assurances, a glossary, and other relevant information. The form pages are included after the instructions.

The PHS 416-1 form pages are available in electronic PDF and MS Word format. Form pages are available separately on the NIH Web Site http://grants1.nih.gov/grants/forms.htm**. Sponsors and sponsoring institutions are encouraged to bookmark this site for future submissions.**

These instructions and application forms (06/02 version) supersede all previous editions. Applicants should give careful attention to the instructions. An application that fails to meet the stated requirements may be returned without review. A properly prepared application will facilitate the administrative processing and peer review that must occur before an award can be made.

GRANTS INFORMATION

The Division of Extramural Outreach and Information Resources (DEOIR), Office of Extramural Research, NIH is the central source for general information about NIH extramural research and research training programs, funding mechanisms, the peer review system, and application procedures. The NIH Grants Information Web site (http://grants.nih.gov/grants/oer.htm) provides a repository of helpful information. Additional information can be obtained by e-mailing GrantsInfo@nih.gov or by calling (301) 435-0714.

GRANTS POLICY STATEMENTS

The *NIH Grants Policy Statement* serves as the terms and conditions of NIH grant awards. It also is a compilation of other salient information regarding the award and administration of NIH grants. This document may be found on the NIH Web site at http://grants.nih.gov/grants/oer.htm. AHRQ uses the *PHS Grants Policy Statement* in administering its grant awards. This publication may be available in institutional offices of sponsored research. Otherwise, the *PHS Grants Policy Statement* may be obtained from the NIH Web site at http://grants.nih.gov/grants/oer.htm).

NIH GUIDE FOR GRANTS AND CONTRACTS

The *NIH Guide for Grants and Contracts*, a weekly electronic publication, contains all NIH requests for applications (RFAs) and program announcements (PAs) and information about NIH policies and procedures. It also may include RFAs and PAs from other agencies, such as AHRQ. The NIH Guide is available on the NIH Web site at http://grants.nih.gov/grants/guide or via LISTSERV e-mail. For instructions to subscribe, visit http://grants.nih.gov/grants/guide/listserv.htm.

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 (0925-0002). **Do not send applications to this address.**

SECTION I.
PREPARING THE APPLICATION

A. INTRODUCTION

Read all of the instructions thoroughly before preparing an application.

Use this application to apply for new and competing continuation (renewal) Kirschstein-NRSA Individual Fellowships from NIH or AHRQ. Applications for Kirschstein-NRSA 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.

1. Program Announcements and Requests for Applications

An NIH IC or AHRQ may issue 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, application receipt date, award provisions, and service payback provisions.

2. 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.

B. GENERAL INSTRUCTIONS

Read and follow these instructions carefully to avoid delays, misunderstandings, and possible return of applications. In preparing the application, stay within the margin limitations indicated in the instructions and on the form and format pages. The print must be clear and legible. Use standard size, black letters that can be clearly copied.

In preparing the application, use English and avoid jargon. If terms are not universally known, spell out the term the first time it is used, with the appropriate abbreviation in parentheses. The abbreviation may be used thereafter.

1. Format Specifications

Observe type size and format specifications throughout the application or processing and review of the application. See frequently asked questions (FAQs) (http://www.format.nih.gov/FAQ/FAQ.htm) for additional information related to format requirements. The application must be clear, readily legible, and conform to the following requirements:

1. The height of the letters must not be smaller than 10 point; Helvetica or Arial 12 point is the suggested font.
2. Type density, including characters and spaces, must be no more than 15 characters per inch (cpi). For proportional spacing, the average for any representative section of text must not exceed 15 cpi;
3. No more than 6 lines of type within a vertical inch;
4. Margins, in all directions, must be at least ½ inch.

Applicants should check the type size using a standard device for measuring type size rather than relying on the font selected for a particular word processing/printer combination. Figures, charts, tables, figure legends, and footnotes may be smaller in size but must be readily legible. The type size and format used throughout the application must conform to all four requirements. **Small type size makes it difficult for reviewers to read the application; consequently, the application may be**

returned and further processing delayed until the application is conformed. Adherence to type size and line spacing requirements also is necessary so that no applicant will have an unfair advantage, by using small type, or providing more text in their applications.

Do not use photo reduction. Prepare all graphs, diagrams, tables, and charts in black ink. The application must contain only material that can be photocopied. Glossy photographs or other materials that cannot be photocopied must be submitted in three collated sets as appendices (see Section II.A.I.(4))

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. If additional space is needed to complete any of the items, use continuation pages. Blank continuation pages are provided with the form pages for both the applicant and the sponsor. Identify the application item number and title. Insert continuation pages immediately after the printed page it supports; then number the entire application consecutively. Do not use suffixes, such as 6a or 6b.

2. 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.

The Division of Receipt and Referral, Center for Scientific Review (CSR), is responsible for the final determination of legibility and has the authority to return applications. Questions should be directed to the Division of Receipt and Referral, CSR (301) 435-0715.

Page Limitations and Content Requirements		
SECTION	**PAGE LIMIT**	**CONTENT**
APPLICANT		
Research Proposal—Description (Form Page 2, Item 22)	Limited to space provided on form	Succinct and accurate description of proposed work when separated from application
Research Experience (Form Page 6, Item 28) Item 28a Item 28b Item 28c (if applicable) Item 29 (if applicable)	 1 1 2 1 (Introduction)	See Instructions
Research Training Proposal (Form Page 6, Item 30b, subsections (1)-(3)	10	Text plus all figures and tables
Literature Cited (Form Page 6, Item 30.b, subsection (4)	None (**not** part of the 10-page limit for the research training proposal)	Complete citations, including titles and all authors
Human Subjects Research Women and Minority Inclusion in Clinical Research Data and Safety Monitoring Plan (Form Page 6, Item 30b, subsection (5))	None None None	See Instructions See Instructions See Instructions
Vertebrate Animals (Form Page 6, Item 30b, subsection (6)	None	See Instructions
SPONSOR		
Biographical Sketch (Form Page 7) Items A (Positions and Honors) + B (Selected peer-reviewed publications)	4 2 of the 4	May use Biographical Sketch in PHS-398 in lieu of Form Page 7
Facilities and Commitment (Form Page 8, Item 37) Human Subjects Vertebrate Animals	 None None	 See Instructions See Instructions

Note: Failure to comply with the type size specifications, other specified formatting requirements, and page limitations may result in a delay in processing the application, return of the application, or deferral of peer review.

C. Specific Instructions for Applicant (Part I)

The Kirschstein-NRSA Individual Fellowship application consists of two parts:

Part I: To be completed by the Applicant

- Face Page (Form Page 1),
- Form Pages 2-6,
- Section I on the Checklist (Form Page 9), and
- Personal Data on Kirschstein-NRSA Individual Fellowship Applicant Page .

Part II: To be completed by the Sponsor and Sponsoring Institution Officials

- Items 9-14 on the Face Page (Form Page 1),
- Items 19, 20, and 21 on Form Page 2,
- Form Pages 7 and 8, and
- Section II on the Checklist (Form Page 9).

Both parts 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 Applicants for Kirschstein-NRSA Predoctoral and Senior Fellowships	
Predoctoral Fellowships	
Item 2, Level of Fellowship, Face Page	Special Instructions
Item 23, Scholastic Performance, Form Page 4	Special Instructions
Section I.C, Checklist, Form Page 9	Omit
Section I.D, Checklist, Form Page 9	Special Instructions
References	Special Instructions
Kirschstein-NRSA Assurance	Special Instructions
Senior Fellowships	
Item 2, Level of Fellowship, Face Page	Special Instructions
Item 17, Applicant's Training/Employment, Form Page 2	Special Instructions
Item 23, Scholastic Performance, Form Page 4	Omit
Item 25b, Title(s) of Thesis/Dissertation(s), Form Page 5	Omit
Item 28b, Doctoral Dissertation, Form Page 6	Omit
Item 30d(2), Selection of Sponsor and Institution, Form Page 6	Special Instructions
Section I.C, Checklist, Form Page 9	Special Instructions
Section I D, Checklist, Form Page 9	Omit

After the applicant completes Part I (Form Pages 1-6 and 9), including Section I on the Checklist and the Personal Data Page, the application should 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** (see page 22 of these instructions). The sponsor and sponsoring institution should review the specific instructions for and complete Part II, including Section II on the Checklist. 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 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_2001/.

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, Form Page 9, 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.

1. Face Page (Form Page 1)

Note: The electronic formatting enforces established limits on the number of characters that may be included in each field on the Face Page. These limits cannot be exceeded. For example, the title of the research training proposal may not exceed 56 characters, including the spaces between words and punctuation.

Item 1, Title of Research Training Proposal

Choose a title that is specifically descriptive rather than general. The title should not be worded in a way that could easily be misconstrued if quoted out of context.

Item 2, Level of Fellowship

Indicate the level of fellowship requested in the Kirschstein-NRSA Individual Fellowship application (predoctoral, postdoctoral, senior). Postdoctoral fellowships are provided by the NIH ICs and AHRQ. Predoctoral and senior fellowships are provided by a limited number of NIH ICs. Therefore, individuals interested in these types of awards should consult with the appropriate IC before submitting an application.

Note that 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

Provide the PA/RFA number if the application is submitted in response to a published PA/RFA. For responses to RFAs, attach the RFA label or a facsimile 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. If the application is not submitted in response to a PA/RFA, leave Item 3 blank.

Item 4a, Name of Applicant

Provide last name followed by a comma, first name, and middle name.

Item 4b, E-mail

Provide the applicant's e-mail address.

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 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 address where the applicant/fellow can always be contacted. Changes should be reported promptly in writing. If the same as 4d, so indicate.

Items 4f to 4i

Self-explanatory.

Item 4j, Citizenship

Check the appropriate box. Applicants that have been lawfully admitted for permanent residence, i.e., are in possession of an Alien Registration Receipt Card or other legal verification of such status, should check the "Permanent Resident of U.S." box. Applicants that have applied for and have not yet been granted admission as a permanent resident should check the same box, but should insert the word "Pending." To be eligible for a Kirschstein-NRSA Individual Fellowship, an individual 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. A permanent resident must submit a notarized statement before the award is issued that a notary has seen the applicant's Alien Registration Receipt Card or some other verification from the U.S. Immigration and Naturalization Service of legal admission to the U.S. as a permanent resident.

Item 5, Training Under Proposed Award

List the proposed area of research training according to the Kirschstein-NRSA Fields of Training in Section IV (page 42) of these instructions. The Kirschstein-NRSA 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 Kirschstein-NRSA Fields of Training listing does not provide a good descriptor, use the closest subcategory from the list.

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

If "Yes," refer to Item 24 (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 on page 30 of these instructions, "Receipt, Review, and Award Schedule."

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 (Completed by the Sponsor)

The instructions for these items are in Specific Instructions for Sponsors (Part II), beginning on page 23.

Item 15, Applicant Certification and Acceptance

Read the assurance and certification language carefully. Review the assurances and certifications referenced on the Checklist in Section I.B as well as the Kirschstein-NRSA Assurance (page 44 of these instructions). By signing the application Face Page, the applicant certifies compliance with the assurances and certifications identified in the Applicant Section on the Checklist. Deliberate withholding, falsification, or misrepresentation of information could result in an administrative action(s), such as withdrawal of an application, suspension and/or termination of an award, or debarment of an individual, as well as possible criminal penalties. Failure to sign the certification precludes the possibility of an award.

2. Form Page 2

Item 16, Applicant's Education

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.

Item 17, Applicant's Training/Employment

List in chronological order all non-degree training, including postdoctoral research training, all employment after college, and 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 Kirschstein-NRSA Postdoctoral Fellowships.

Since their stipend is determined on a different basis, Kirschstein-NRSA Senior Fellowship applicants should list only employment after completion of the doctoral degree. Senior applicants should include education and other training, as appropriate.

Item 18, Goals for Kirschstein-NRSA Individual Fellowship Training and Career

Explain training goals under the proposed Kirschstein-NRSA Individual Fellowship and their relevance to the applicant's career goals. Identify the skills, theories, conceptual approaches, etc. to be learned or enhanced during the award. Describe how the proposed activities, including any research, will contribute to the achievement of these career goals. You may use a continuation page if necessary.

Items 19, 20, and 21, Sponsor

To be completed by the sponsor.

Item 22, Research Proposal--Description

State the broad, long-term objectives and specific aims of the research proposal, referring to the health relatedness of the project. Describe concisely the research design and methods for achieving these goals. Do not summarize past accomplishments and avoid the use of the first person. **The description must be limited to the field provided on Form Page 2**. This should serve as a succinct and accurate description of the proposed work when separated from the application. If the application is funded, this description will be entered into an NIH database (CRISP) and will become public information. Therefore, do not include proprietary or confidential information.

3. Table of Contents (Form Page 3)

Self-explanatory.

4. Scholastic Performance (Form Page 4)

Item 23, Scholastic Performance

Listing scholastic performance facilitates the review process. Predoctoral and postdoctoral applicants must complete this item as provided on Form Page 4. In addition, predoctoral applicants must provide scores for the Graduate Record Examination (GRE), if available. Predoctoral and postdoctoral candidates may be asked to send transcripts prior to award. Do not include transcripts with the application. Applicants for Kirschstein-NRSA Senior Fellowships should omit this item.

5. Background (Form Page 5)

Item 24, Prior and/or Current Kirschstein-NRSA Support (Individual or Institutional)

Follow the instructions on the form. Promptly report to the NIH IC to which this application is assigned or to AHRQ any additional Kirschstein-NRSA support received while this application is pending. An individual cannot receive more than 5 years cumulative Kirschstein-NRSA support (the total of all support under Kirschstein-NRSA Institutional Grants and/or Individual Fellowships) at the predoctoral level and 3 years cumulative Kirschstein-NRSA support at the postdoctoral level unless a waiver has been obtained from the NIH IC or AHRQ. The NIH ICs have different policies on waiver of the statutory limits on Kirschstein-NRSA support. Before requesting a period of support that will exceed these limits, contact the probable funding IC.

Item 25a, Academic and Professional Honors

List any honors that would reflect upon the applicant's potential for a research career and qualifications for a Kirschstein-NRSA Individual Fellowship. Include current memberships in professional societies.

Item 25b, Title(s) of Thesis/Dissertation(s)

Self-explanatory. Applicants for Kirschstein-NRSA Senior Fellowships should omit this item.

Item 26, Dissertation Advisor or Chief of Service

Include name, title, department, and institution of this individual. If not submitting a reference from this person, explain why not.

Item 27, Application for Concurrent Support

Check the appropriate box. If the applicant has applied or will be applying for other support that would run concurrently with the period covered by this application, include the type, dates, source, and amount.

6. Research (Form Page 6)

Item 28, Research Experience

Item 28a, Summary

Summarize in chronological order the applicant's research experience, including the problems studied and conclusions. Specify which problems were part of a thesis or dissertation. If the applicant has no research experience, list other scientific experience. Do not list academic courses here. Do not exceed one page.

Item 28b, Doctoral Dissertation

Summarize, not exceeding one page. Applicants for Kirschstein-NRSA Senior Fellowships should omit this item.

Item 28c, Publications

In chronological order, list the applicant's entire bibliography, separating abstracts, book chapters, reviews, and research papers. **If the list of publications cannot be accommodated within two pages, select only the most pertinent publications.** For each publication, give the authors in published sequence, full title, journal, volume number, page numbers, and year of publication. Indicate if another name was previously used. Manuscripts pending publication or in preparation should be included and identified.

Submit three collated sets of the three most significant publications (two publications for predoctoral applicants). For competing continuation applications, submit three collated sets of all publications resulting from the current Kirschstein-NRSA period of support.

Item 29, Revised Application

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

Note: NIH policy limits the number of revised (amended) versions of an application to two, which must be submitted within 2 years of the submission date of the original version of the application.

All revised (amended) applications must include an Introduction of no more than one page. In the Introduction, specify significant changes that have been made, including additions, deletions, revisions, and any responses to criticisms in the summary statement for the previous application**. All changes should be highlighted by appropriate bracketing, indenting, or change of typography, unless the changes are so extensive as to include most of the text.** A revised application will be returned without review if no substantive revisions have been made. **Sealed reference letters** **must be submitted with the revised application as directed on page 22 of these instructions.** Acceptance of a revised application automatically withdraws the prior version since two versions of the same application cannot be pending simultaneously.

Item 30, Research Training Plan

Item 30a, Activities Under Award

By year, specify the activities (research, course work, etc.) the applicant will be involved in under the proposed award and the percentage of time to be devoted to each activity. The percentages

should add to 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.

Item 30b, Research Training Proposal

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 the sponsor, but it is to be **written by the applicant.**

Include sufficient information to permit an effective review without reviewers having to refer to the literature or any previous application. Brevity and clarity in the presentation will be considered indicative of an applicant's approach and ability to conduct a superior project. Subsections (1) through (3) of this item are not to exceed 10 pages, including all tables and figures. Follow the format below:

(1) Specific Aims.

State the specific purposes of the research proposal and the hypotheses to be tested.

(2) Background and Significance.

Sketch briefly the background to the proposal. State concisely the importance of the research described in this application by relating the specific aims to broad, long-term objectives. Use this section to provide an account of any preliminary studies that might demonstrate the utility of the proposed project as a training experience. **For competing continuation applications, be sure to summarize progress under your current award.**

(3) Research Design and Methods.

Provide an outline of:

- Research design and the procedures to be used to accomplish the specific aims;
- Tentative sequence for the investigation;
- Statistical procedures by which the data will be analyzed;
- Any procedures, situations, or materials that may be hazardous to personnel and the precautions to be exercised; and
- Any courses planned which support the research training experience.

Potential experimental difficulties should be discussed together with alternative approaches that could achieve the desired aims.

Notice of Proprietary Information

Applicants are discouraged from submitting information considered proprietary unless it is deemed essential for proper evaluation of the application. However, if the application contains information that is considered to be trade secrets, information that is commercial or financial, or information that is confidential or privileged, identify the pages in the application which contain such information by marking those paragraphs or lines using bold or italicized type and providing the page numbers before "(1) Specific Aims."

When information in the application constitutes trade secrets, information that is commercial or financial, or 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 herein 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.

Note: Proprietary information and trade secrets should NOT be included in the research proposal description located on Form Page 2 . If the application is funded, the project description will be entered into an NIH database (CRISP) and will become public information.

(4) Literature Cited.

List all literature references. Each reference must include the title, names of all authors, book or journal, volume number, page numbers, and year of publication. **The reference should be**

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

(5) Human Subjects Research.

Applicants are encouraged to use the decision charts on the Office for Human Research Protections' (OHRP) website (http://ohrp.osophs.dhhs.gov/humansubjects/guidance/decisioncharts.htm) for guidance in determining whether the proposed research involves human subjects research. If Item 9 on the Face Page of the application is marked "Yes," create a subsection heading entitled **"Human Subjects Research"** immediately following the last entry in the **"Literature Cited"** section. (Instructions for completing Item 9 are on pages 23-24.)

As part of this subsection, address those considerations specified under the headings entitled **"Women and Minority Inclusion in Clinical Research"** (page 15), **"Inclusion of Children"** (page 19), and **"Data and Safety Monitoring Plan"** (page 20)**.**

All applications involving Human Subjects Research **(exempt or non-exempt)** are subject to HHS regulations at 45 CFR 46.120 (http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm). See also "Human Subjects" in Section III.B, "Policies, Assurances, and Certifications" (page 33).

Although no specific page limitation applies to this section of the application, be succinct.

In the "Human Subjects Research" subsection, applicants must (1) address the involvement of human subjects and protections from research risk relating to their participation in the proposed research plan, or (2) provide sufficient information on the research subjects to allow a determination by peer reviewers and NIH or AHRQ staff that a designated exemption is appropriate. Applications that fail to comply with this requirement will be considered incomplete and will be returned without peer review.

The following table is intended to provide guidance on what must be included in the "Human Subjects Research" section. See "Human Subjects" in Section III. B, Policies, Assurances, and Certifications, for definitions of clinical research, clinical trial, and NIH-defined Phase III clinical trial (pages 35-36).

Guidance for Preparing the Human Subjects Research Section

SCENARIO	HUMAN SUBJECTS	EXEMPT	CLINICAL RESEARCH	CLINICAL TRIAL	REQUIREMENTS
A	No	N/A	N/A	N/A	Indicate "No Human Subjects Research"
B	Yes	No	Yes	No	Address Protection of Human Subjects Address Inclusion of Women and Minorities in Clinical Research Address Inclusion of Children Ethnic/racial "Targeted/Planned Enrollment Table Format Page" (New applications and Competing Continuation applications) Ethnic/racial "Inclusion Enrollment Report Table Format Page" (Competing Continuation applications and annual Progress Reports)
C	Yes	No	Yes	Yes	All requirements in Scenario B Data and Safety Monitoring Plan Note: Phase III trials require a Data and Safety Monitoring Board
D	Yes	Yes	No	N/A	Indicate Exemption Number Justification that the designated exemption is appropriate Address Inclusion of Women and Minorities in Clinical Research Address Inclusion of Children

Special Populations

Investigators who conduct research involving fetuses, pregnant women, neonates, prisoners, or children must follow the regulatory provisions in Subparts B, C, and D of 45 CFR 46, respectively, which describe the additional protections required for these populations. Relevant information may be obtained at the OHRP website at http://ohrp.osophs.dhhs.gov/polasur.htm.

Exemptions 1-6 below do not apply to research involving prisoners, fetuses, pregnant women, or neonates (see Subparts B and C of the regulations). Further, Exemption 2 below, for research involving survey or interview procedures or observation of public behavior, does not apply to research with children (see Subpart D), except for research involving observations of public behavior when the investigator(s) does not participate in the activities being observed.

Exempt Human Subjects Research

If Item 9a on the Face Page is marked "Yes" and an exemption from the human subjects regulations is claimed, create a subsection entitled, "**Exempt Human Subjects Research,"** and then identify which one (or more) of the exemptions identified below applies. Provide a justification with sufficient information about the involvement of human subjects (Population Sample and Sources) in the proposed research to allow a determination by peer reviewers and NIH and AHRQ staff that the designated exemption is appropriate. See page 23 of these instructions for the effect of not providing the required information.

Population Sample

Describe the characteristics of the subject population, including their anticipated number, age range, and health status. Identify the criteria for inclusion or exclusion of any subpopulation. Explain the rationale for the involvement of special classes of subjects, such as children, prisoners, institutionalized individuals, or others who may be considered vulnerable populations.

Sources

Applicants should identify the source of the research material obtained from living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether existing specimens, records, or data will be used.

For additional information, see 45 CFR 46.120 (http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm).

Exemption Categories

The six categories of research that qualify for exemption from coverage by 45 CFR Part 46 include activities in which the only involvement of human subjects will be in one or more of the following categories:

Exemption 1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special education instructional strategies, or (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Exemption 2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, unless (a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects, and (b) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

Exemption 3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under exemption (2)(b) above, if (a) the human subjects are elected or appointed public officials or candidates for public office, or (b) a Federal statute(s) requires without exception that the confidentiality of the

personally identifiable information will be maintained throughout the research and thereafter.

Exemption 4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

Exemption 5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine (a) public benefit or service programs, (b) procedures for obtaining benefits or services under those programs, (c) possible changes in or alternatives to those programs or procedures, or (d) possible changes in methods or levels of payment for benefits or services under those programs.

Exemption 6. Taste and food quality evaluation and consumer acceptance studies, if:\ (a) wholesome foods without additives are consumed, or (b) a food is consumed that contains a food ingredient at or below the level and use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration (FDA) or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Note: If the proposed research does not meet one or more of the above exemptions, then it is not exempt from the human subjects regulations and the instructions in the "Non-Exempt Human Subjects Research" subsection must be followed.

Note: Even if the proposed research is exempt from these regulations, applicants must address the inclusion of women and members of minority groups, and their subpopulations, and the inclusion of children in developing the research design (see instructions below for "Women and Minority Inclusion in Clinical Research" as well as the "Inclusion of Children").

Non-Exempt Human Subjects Research

Protection of Human Subjects

If Item 9 on the Face Page is marked "Yes," and no exemption(s) from the regulations is claimed, create a subsection entitled **"Protection of Human Subjects."** In this section, the information provided **must address all** of the following four criteria as they apply to the proposed research.

Failure to address the following human subjects protection criteria will result in the application being designated as incomplete, and it will be returned without peer review.

Under each criterion, indicate whether the information relates to the primary research site, or to a collaborating performance site(s), or to all sites.

1. RISKS TO THE SUBJECTS

Human Subjects Involvement and Characteristics: Describe the proposed involvement of human subjects in the work outlined in the "Research Design and Methods" section. Describe the characteristics of the subject population, including their anticipated number, age range, and health status. Identify the criteria for inclusion or exclusion of any subpopulation. Explain the rationale for the involvement of special classes of subjects, such as fetuses, neonates, pregnant women, children, prisoners, institutionalized individuals, or others who may be considered vulnerable populations.

Sources of Materials: Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data.

Potential Risks: Describe the potential risks to subjects (physical, psychological, social, legal, or other) and assess their likelihood and seriousness to the subjects. Where appropriate, describe alternative treatments and procedures, including the risks and benefits of the alternative treatments and procedures to participants in the proposed research.

2. ADEQUACY OF PROTECTION AGAINST RISKS

Recruitment and Informed Consent: Describe plans for the recruitment of subjects and the process for obtaining informed consent. Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. The informed consent document need not be submitted to NIH or AHRQ unless requested.

Protection Against Risk: Describe the planned procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness. Where appropriate, discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects. In studies that involve clinical trials (biomedical and behavioral intervention studies), describe the plan for data and safety monitoring of the research to ensure the safety of subjects.

3. POTENTIAL BENEFITS OF THE PROPOSED RESEARCH TO THE SUBJECTS AND OTHERS

Discuss the potential benefits of the research to the subjects and others. Discuss why the risks are reasonable in relation to the anticipated benefits to subjects and others.

4. IMPORTANCE OF THE KNOWLEDGE TO BE GAINED

Discuss the importance of the knowledge gained or to be gained as a result of the proposed research. Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that reasonably may be expected to result.

Note: If a test article (investigational new drug, device, or biologic) is involved, name the test article and state whether the 30-day interval between submission of applicant certification to FDA and its response has elapsed or has been waived and/or whether use of the test article has been withheld or restricted by FDA.

Collaborating Site(s)

When research involving human subjects will take place at collaborating site(s) or other performance site(s), provide in this section of the application a list of the collaborating sites and their assurance numbers. Further, obtain in writing, and keep on file, an assurance from each site that the criteria above have been adequately addressed at a level of attention that is at least as high as that documented at the sponsoring organization. Site(s) added after an award is made also must adhere to these requirements.

Women and Minority Inclusion in Clinical Research

If you plan to conduct clinical research (see definition in Section III.B. on page 35), create a subsection heading entitled **"Inclusion of Women"** and a separate subsection heading entitled **"Inclusion of Minorities**." Place these subsections immediately after the "**Human Subjects Research"** section in the application. Address each of the items identified below with respect to plans for the inclusion of women and the inclusion of minorities (and their subpopulations) as they relate to the proposed research. Although no specific page limitation applies to these subsections of the application, be succinct.

NIH policy (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-048.html) requires that women and members of minority groups and their subpopulations be included in all NIH-supported biomedical and behavioral clinical research projects involving human subjects. Their inclusion must be addressed in developing a research design appropriate to the scientific objectives of the study. **Inclusion is required unless a clear and compelling rationale shows that inclusion is inappropriate with respect to the health of the subjects or that inclusion is inappropriate for the purpose of the study.** Exclusion under other circumstances may be appropriate based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research. This policy applies to research subjects of all ages.

Applications that fail to address "Women and Minority Inclusion in Clinical Research" will be considered incomplete and will be returned without peer review.

INFORMATION TO BE PROVIDED FOR ALL CLINICAL RESEARCH STUDIES (see definition in Section III.B on page 35)

Provide information on the composition of the proposed study population in terms of sex/gender and racial/ethnic group and provide a rationale for selection of such subjects in terms of the scientific objectives and proposed study design. The description may include (but is not limited to) information on the population characteristics of the disease or condition under study, national and local demography, knowledge of the racial/ethnic/cultural characteristics of the population, prior experience and collaborations in recruitment and retention of the populations and subpopulations to be studied, and the plans, arrangements and letters of commitment from relevant community groups and organizations for the planned study.

The research plan must include the following information:

- A description of the subject selection criteria and rationale for selection in terms of the scientific objectives and proposed study design.
- The proposed dates of enrollment (beginning and end).
- A description of proposed outreach programs for recruiting women and minorities as subjects in clinical research.
- A compelling rationale for proposed exclusion of any sex/gender or racial/ethnic group.
- The proposed sample composition using the "Targeted/Planned Enrollment Table" and/or the "Inclusion Enrollment Report" format pages.

OFFICE OF MANAGEMENT AND BUDGET (OMB) STANDARDS FOR COLLECTING AND REPORTING DATA ON RACE AND EHTNICITY:

OMB Directive No. 15 (www.whitehouse.gov/OMB/fedreg/ombdir15.html) defines minimum standards for maintaining, collecting and presenting data on race and ethnicity for all Federal reporting (including NIH and AHRQ). The categories in this classification are social-political constructs and should not be interpreted as being scientific or anthropological in nature. The standards were revised in 1997 and now include five racial categories: American Indian or Alaska Native, Asian; Black or African American, Native Hawaiian or Other Pacific Islander, and White. There are two categories for ethnicity: "Hispanic or Latino," and "Not Hispanic or Latino." Reports of data on race and ethnicity shall use these categories. NIH and AHRQ are required to use these definitions to allow comparisons to other Federal databases, especially the census and national health databases. The following definitions apply for the ethnic and racial categories (OMB Directive 15).

ETHNIC CATEGORIES:

Hispanic or Latino: A person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race. The term, "Spanish origin" can be used in addition to "Hispanic or Latino."

Not Hispanic or Latino

RACIAL CATEGORIES:

American Indian or Alaska Native: A person having origins in any of the original peoples of North, Central, or South America, and who maintains tribal affiliation or community attachment.

Asian: A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam. (Note: Individuals from the Philippine Islands have been recorded as Pacific Islanders in previous data collection strategies.)

Black or African American: A person having origins in any of the black racial groups of Africa. Terms such as "Haitian" or "Negro" can be used in addition to "Black or African American."

Native Hawaiian or Other Pacific Islander: A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.

White: A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.

***Standards for Collecting Data*.** If the research will include data collection items on race and ethnicity, the categories identified above should be used. The collection of greater detail is encouraged. However, items that are more detailed should be designed in a way that they can be aggregated into these required categories. Self-reporting or self-identification using two separate questions is the preferred method for collecting data on race and ethnicity. When race and ethnicity are collected separately, ethnicity shall be collected first. Respondents shall be offered the option of selecting one or more racial designations. When data on race and ethnicity are collected separately, provision shall be made to report the number of respondents in each racial category who are Hispanic or Latino. When aggregate data are presented, the investigator shall provide the number of respondents who selected only one category, for each of the five racial categories. If data on multiple responses are collapsed, at a minimum the total number of respondents reporting "more than one race" shall be made available. Federal agencies shall not present data on detailed categories if doing so would compromise data quality or confidentiality standards.

ADDITIONAL INFORMATION TO BE PROVIDED FOR NIH-DEFINED PHASE III CLINICAL TRIALS:

Applies when Item 9 (Human Subjects Research) and Item 9c (NIH-Defined Phase III Clinical Trial) on the Face Page are marked "Yes."

If an **NIH-defined Phase III clinical trial** (see Section III.B on page 36 for definition) is proposed, address whether the applicant expects to find clinically important sex/gender and/or race/ethnicity differences in the intervention effect. The discussion may include supporting evidence and/or data derived from prior animal studies, clinical observations, metabolic studies, genetic studies, pharmacology studies, and observational, natural history, epidemiology and other relevant studies. The research plan must also include one of the following plans:

- Plans to conduct valid analyses to detect significant differences in intervention effect among sex/gender and/or racial/ethnic subgroups when prior studies strongly support these significant differences among subgroups, **OR**

- Plans to include and analyze sex/gender and/or racial/ethnic subgroups when prior studies strongly support no significant differences in intervention effect between subgroups. (Representation of sex/gender and racial/ethnic groups is not required as subject selection criteria, but inclusion is encouraged.), **OR**

- Plans to conduct valid analyses of the intervention effect in sex/gender and/or racial/ethnic subgroups (without requiring high statistical power for each subgroup) when the prior studies neither support nor negate significant differences in intervention effect between subgroups.

In conducting peer review for NIH-defined Phase III clinical trials, Scientific Review Groups (SRGs) will evaluate proposed plans for inclusion of women and minorities in clinical research and plans for sex/gender and racial/ethnic subgroup analyses, plans for recruitment/outreach and retention in the design of clinical trials, and any justifications for exclusion of a sex/gender or racial/ethnic subgroup. This evaluation will be a part of the "Approach" criterion. The evaluation of the inclusion plans will be factored into the overall score that the SRG assigns for scientific and technical merit of the application. In addition, awards will not be made if the proposed research does not comply with this policy.

COMPLETING THE TABLES FOR REPORTING RACE AND ETHNICITY DATA FOR SUBJECTS IN CLINICAL RESEARCH:

New Applications. Complete the Targeted/Planned Enrollment Table format page. Provide the study title and plans for the total number of subjects proposed for the study. Also provide the distribution by ethnic categories and by sex/gender according to the format in the Targeted/Planned Enrollment Table. If there is more than one study, provide a separate table for each study. List any proposed racial/ethnic subpopulations below the table. If the proposed research uses existing data, then applicants must use the formats for competing continuation applications.

Competing Continuation Applications. For **competing continuation applications** involving the collection of new/additional clinical data, use the Targeted/Planned Enrollment Table format page to estimate the distribution of subjects proposed for the study. Provide the study title and plans for the total (cumulative) number of subjects proposed for the study (total planned enrollment). Provide the distribution of subjects by ethnic and racial categories and by sex/gender according to the format in the Targeted/Planned Enrollment Table. If there is more than one study, provide a separate table for each study.

For **competing continuation or competing supplement applications** that do not involve the collection of new/additional clinical data, the data on ethnicity/race and sex/gender should be provided on the Inclusion Enrollment Report Table format page.

Note on use of the Inclusion Enrollment Report Table: Successful competing continuation applications involving collection of new/additional clinical data will be required to use the Inclusion Enrollment Report Table format page in subsequent annual progress reports. The Inclusion Enrollment Report Table format page contains two parts: Part A is for all subjects and Part B is for Hispanics or Latinos.

For Part A, provide the distribution of subjects by ethnic and racial categories and by sex/gender according to the format in the Inclusion Enrollment Report Table.

Part B should include information on the race of all Hispanics (or Latinos) enrolled as reported in Part A. If there is more than one study, provide a separate table for each study. Provide information on any proposed ethnic/racial subpopulations as an attachment to the table. In completing the Inclusion Enrollment Report Table, do not assume or guess a subject's ethnic or racial affiliation. Collect the data using instruments that, at a minimum, allow all respondents to select their ethnic and racial affiliation separately. Under racial affiliation, subjects must be provided the option of selecting more than one race. When reporting these data to NIH, subjects who selected only one of the five racial categories should be designated in that category. Subjects who selected more than one racial category should be reported in the "More than one race" category. For previously funded studies that used an earlier NIH reporting format, the earlier reporting format is **NOT** directly transferable to the new format. For additional information, review the instructions and frequently asked questions about using the new format at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-053.html.

Foreign Populations

If you are conducting clinical research outside of the U.S., you should design culturally sensitive and appropriate data collection instruments that allow participants to self-identify their ethnic and racial affiliation. These items, however, should be designed in a way that allows you to aggregate the information into the Office of Management and Budget (OMB) minimally required ethnic and racial categories and complete the Targeted/Planned Enrollment Table and/or the Inclusion Enrollment Report. When completing the Targeted/Planned Enrollment Table or the "Inclusion Enrollment Report, you should add an asterisk and footnote the report to indicate that data is from foreign participants. If your study includes both domestic and foreign participants, we suggest submitting two separate reports – one for domestic data and one for foreign data, with an asterisk and footnote explaining the foreign data.

Inclusion of Children

If Item 9 on the Face Page of the application is marked "Yes," create a subsection heading entitled **"Inclusion of Children."** Place it immediately following the **"Women and Minority Inclusion in Clinical Research"** subsection of the application.

NIH policy requires that children (i.e., individuals under the age of 21) must be included in all human subjects research conducted or supported by NIH, unless there are clear and compelling reasons not to include them. (For additional information, see http://grants.nih.gov/grants/funding/children/children.htm and the *NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects* [http://grants.nih.gov/grants/guide/notice-files/not98-024.html].) Therefore, applications for research involving human subjects must provide a description of plans for including children. If children will be excluded from the research, the application must present an acceptable justification for the exclusion.

Applications that fail to address the "Inclusion of Children" will be considered incomplete and will be returned without peer review.

In the subsection entitled **"Inclusion of Children,"** the applicant should provide either a description of the plans to include children or, if children will be excluded from the research, the application must present an acceptable justification (see below) for the exclusion.

If children are included, the description of the plan should include a rationale for selecting or excluding a specific age range of children.

When children are included, the plan also must include a description of the expertise of the investigative team for dealing with children at the ages included, of the appropriateness of the available facilities to accommodate the children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose of the study.

Scientific Review Groups (SRGs) will assess each application as being "acceptable" or "unacceptable" with regard to the age-appropriate inclusion or exclusion of children in the research project.

Justifications for Exclusion of Children

It is expected that children will be included in all research involving human subjects unless one or more of the following exclusionary circumstances can be fully justified:

1. The research topic to be studied is not relevant to children.

2. There are laws or regulations barring the inclusion of children in the research.

3. The knowledge being sought in the research is already available for children or will be obtained from another ongoing study, and an additional study would be redundant. Documentation of other studies justifying the exclusions should be provided. NIH or AHRQ program staff can be contacted for guidance on this issue if the information is not readily available.

4. A separate, age-specific study in children is warranted and preferable. Examples include:

    a. The relative rarity of the condition in children, as compared to adults (in that extraordinary effort would be needed to include children, although in rare diseases or disorders where the applicant has made a particular effort to assemble an adult population, the same effort would be expected to assemble a similar child population with the rare condition);

    b. The number of children is limited because the majority are already accessed by a nationwide pediatric disease research network; or

    c. Issues of study design preclude direct applicability of hypotheses and/or interventions to both adults and children (including different cognitive, developmental, or disease stages or different age-related metabolic processes). While this situation may represent a justification for excluding children in some instances,

consideration should be given to taking these differences into account in the study design and expanding the hypotheses tested, or the interventions, to allow children to be included rather than excluding them.

5. Insufficient data are available in adults to judge potential risk in children (in which case one of the research objectives could be to obtain sufficient adult data to make this judgment). While children usually should not be the initial group to be involved in research studies, in some instances, the nature and seriousness of the illness may warrant their participation earlier based on careful risk and benefit analysis.

6. Study designs aimed at collecting additional data on pre-enrolled adult study subjects (e.g., longitudinal follow-up studies that did not include data on children).

7. Other special cases justified by the investigator and found acceptable to the review group and the IC Director or Administrator, AHRQ.

Definition of a Child

For the purpose of implementing these requirements, a child is defined as an individual under the age of 21 years.

The definition of child described above will pertain to these guidelines (notwithstanding the FDA definition of a child as an individual from infancy to 16 years of age, and varying definitions employed by some States). Generally, State laws define what constitutes a "child," and such definitions dictate whether or not a person can legally consent to participate in a research study. However, State laws vary, and many do not address when a child can consent to participate in research.

45 CFR 46 (Subpart D, Sections 401-409) addresses HHS protections for children who participate in research and relies on State definitions of "child" for consent purposes. Consequently, the children included in this policy (persons under the age of 21) may differ in the age at which their own consent is required and sufficient to participate in research under State law. For example, some States consider a person that is 18 years of age to be an adult and, therefore, one who can provide consent without parental permission.

Data and Safety Monitoring Plan

If Item 9 on the Face Page is marked "Yes" and the proposed research involves a clinical trial (whether or not it involves an NIH-defined Phase III clinical trial as provided in Item 9c), create a subsection heading entitled "**Data and Safety Monitoring Plan.**" Place it immediately following the "Inclusion of Children" subsection.

NIH policy requires that investigators (including Kirschstein-NRSA Individual Fellowship applicants) submit a general description of the Data and Safety Monitoring Plan for clinical trials (biomedical and behavioral intervention studies) as part of applications for research and research training (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html). (See "Human Subjects" in Section III.B, Policies, Assurances, and Certifications, for definitions of clinical research, clinical trial, and NIH-defined Phase III clinical trial).

Applications that fail to include a Data and Safety Monitoring Plan, if applicable, will be considered incomplete and will be returned without peer review.

A general description of a monitoring plan establishes the overall framework for data and safety monitoring. It should describe the entity that will be responsible for monitoring, and how Adverse Events (AEs) will be reported to the Institutional Review Board (IRB) the NIH Office of Biotechnology Activities (OBA), and FDA in accordance with Investigational New Drug (IND) or Investigational Device Exception (IDE) regulations. Although no specific page limitation applies to this subsection of the application, be succinct.

In developing the Data and Safety Monitoring Plan, you should refer to the *NIH Policy for Data and Safety Monitoring* (http://grants.nih.gov/grants/guide/notice-files/not98-084.html).

The frequency of monitoring will depend upon the potential risks, complexity, and nature of the trial. Therefore, a number of options for

monitoring trials are available. These include, but are not limited to, monitoring by a:

- Principal Investigator (required)
- Independent individual/Safety Officer
- Designated medical monitor
- Internal committee or board with explicit guidelines
- Data and Safety Monitoring Board (DSMB - required for multi-site clinical trials)
- Institutional Review Board (IRB - required)

NIH specifically requires the establishment of DSMBs for multi-site clinical trials involving interventions that entail potential risk to the subjects and, generally, for Phase III clinical trials. Although Phase I and Phase II clinical trials also may use DSMBs, smaller clinical trials may not require this oversight format, and alternative monitoring plans may be appropriate. A detailed Data and Safety Monitoring Plan must be submitted to the sponsoring institution's IRB and subsequently to the funding NIH IC for approval prior to the accrual of human subjects (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html).

(6) Vertebrate Animals.

If Item 10a on the Face Page of the application is marked "Yes," create a section heading entitled **"Vertebrate Animals."** Place it immediately following the **"Literature Cited"** section of the application (or after **"Human Subjects Research,"** if applicable.)

Failure to address the following five points will result in the application being designated as incomplete and it will be returned without peer review.

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

1. Provide a detailed description of the proposed use of the animals in the work outlined in the "**Research Design and Methods**" section. Identify the species, strains, ages, sex, and numbers of animals to be used in the proposed work.

2. Justify the use of animals, the choice of species, and the numbers to be used. If animals are in short supply, costly, or to be used in large numbers, provide an additional rationale for their selection and numbers.

3. Provide information on the veterinary care of the animals involved.

4. Describe the procedures for ensuring that discomfort, distress, pain, and injury will be limited to that which is unavoidable in the conduct of scientifically sound research. Describe the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices, where appropriate, to minimize discomfort, distress, pain, and injury.

5. Describe any method of euthanasia to be used and the reasons for its selection. State whether this method is consistent with the recommendations of the Panel on Euthanasia of the American Veterinary Medical Association. If not, present a justification for not following the recommendations.

Item 30c, Respective Contributions.

Describe the collaborative process between the sponsor and the applicant in the development, review, and editing of the research training proposal described in Item 30b. Do not include the respective roles in accomplishing the proposed research.

Item 30d, Selection of Sponsor and Institution

(1) Explain why the **sponsor and institution** were selected to accomplish the research training goals.

(2) **Doctorate or Current Institution**. Since 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. Senior applicants requesting training at their employing institution 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**. 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 should be described. If applicable, the need for and level of proficiency in reading, speaking, and comprehending the foreign language should be addressed.

Item 30e, Responsible Conduct of Research

Applications must include the applicant'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.

While NIH does not establish specific curricula or formal requirements, applicants are encouraged to creatively tailor a plan to meet their own needs in relation to the proposed research training. It may include participating in formal activities like established courses as either an instructor or a student (for-credit or non-credit), or informal activities such as discussion groups. Suggested areas could 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.

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

7. Personal Data on Kirschstein-NRSA Individual Fellowship Applicant Page

Clip this form to the signed original of the application after the Checklist. **Do not duplicate**.

8. Checklist (Form Page 9) - Applicant Section

All applicants must complete Section I, Items A and B; senior applicants also should complete Item C, providing requested salary/stipend budgetary information. Pre- and postdoctoral applicants should complete Item D, providing requested budgetary information as applicable.

9. Assurances and Certifications

The following assurances and certifications must be verified by the signature of the applicant on the Face Page of the application (see Section III.B, Other Information, beginning on page 33).

Debarment and Suspension
Delinquent Federal Debt
Drug-Free Workplace

10. References

At least three completed, sealed references must be submitted with the application or it may be delayed or returned to the applicant without review.

The instructions tell referees to complete the form and return it in a sealed envelope to the applicant as soon as possible. Applicants should remind referees that their reports should be provided on the form and any continuation pages. Applicants are asked not to open the envelopes to ensure the confidentiality of such information. The sealed envelopes must be attached to the original application. **Applicants submitting a revised application or a competing continuation application also must submit these reference forms.**

Referees should be carefully selected. Only those individuals who can make the most meaningful comments about the applicant's 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 (Item 36). Where possible, select at least one respondent who is not in the applicant's current department. If not submitting a reference from the dissertation advisor or chief of service, explain in Item 26. Graduate or medical school respondents are preferred over those from undergraduate schools (except for predoctoral applicants).

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. Prospective applicants should send these reference forms to the referees well in advance of the application submission date.

D. SPECIFIC INSTRUCTIONS FOR SPONSORS (PART II)

The sponsor should give careful attention to these instructions. Insufficient information in Part II (Form Pages 7-9) of the application may seriously diminish the applicant's chances for funding. The sponsor also completes a portion of Part I of the application—Items 9-14 on the Face Page and Items 19, 20 and 21 on Form Page 2. Parts I and II must be submitted together. If you have any questions, contact the Division of Extramural Outreach and Information Resources (DEOIR), National Institutes of Health, (301) 435-0714, e-mail: GrantsInfo@nih.gov.

See Section I, Preparing the Application, General Instructions (page 3) and Section II, Submitting the Application (page 29) for further instructions.

Completing the Forms

1. Face Page

Item 9, Human Subjects

No Human Subjects

Check "No" if activities involving human subjects are not planned at any time during the proposed project period. If "No" is checked, the remaining parts of Item 9 are not applicable.

Human Subjects Involved

Check "'Yes" if activities involving human subjects are planned at any time during the proposed project period of the fellowship, either at the sponsoring institution or at any other performance site or collaborating institution. "Yes" should be checked even if the research is exempt from regulations for the protection of human subjects (See Exemption Categories, pages 13-14).

Item 9a. Exemptions from Human Subjects Regulations

Check "Yes" if the activities proposed are designated to be exempt from the regulations. Insert the exemption number(s) corresponding to one or more of the six exemption categories listed on pages 13-14 under "Exempt Human Subjects Research." If the proposed research corresponds to one or more of the exempt categories, then the remaining parts of Item 9 of the Face Page are not applicable.

Note: Inappropriate designations of the non-involvement of human subjects or of exempt categories of research may result in delays in the review of the application or the return of the application without review. NIH/AHRQ will make a final determination as to whether the proposed activities are covered by the regulations or are in an exempt category, based on the information provided in the Research Plan. In doubtful cases, consult with OHRP, HHS by accessing their website http://ohrp.osophs.dhhs.gov/ for guidance and further information.

Human Subjects Activities Not Exempt from Regulations

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

Item 9b. Human Subjects Assurance Number

If the sponsoring institution has an approved Federal-Wide Assurance (FWA), Multiple Project Assurance (MPA), Single Project Assurance (SPA) Number or Cooperative Project Assurance Number on file with the OHRP (http://ohrp.osophs.dhhs.gov/) that covers the

specific activity, insert the number in the space provided.

Insert "None" in Item 9b if the sponsoring institution does not have an approved assurance on file with OHRP. In this case, the sponsoring institution, by the signature on the Facilities and Commitment Page (Form Page 8), is declaring that it will comply with 45 CFR 46 and will obtain a human subjects assurance (see http://ohrp.osophs.dhhs.gov.)

Note: NIH no longer requires Institutional Review Board (IRB) approval and certification of the proposed research prior to NIH peer review of an application (see http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-031.html). As part of the peer review process, the peer review group carefully considers protections from research risk and assesses the adequacy of safeguards of the rights and welfare of research participants based on the information in the application. See Instructions for the Research Training Proposal, Section (5); Human Subjects Research; (page 12); and Facilities Commitment Page (Form Page 8).

Following NIH peer review, applicants and their sponsoring institutions will be notified of the need for review and certification of the proposed research by an OHRP-registered IRB. See http://ohrp.osophs.dhhs.gov to register an IRB. It is the responsibility of the sponsoring institution to submit the certification. Upon request, the certification of IRB approval from an official signing for the sponsoring institution must be sent to and received by the Grants Management Office identified in the request. The IRB certification must include the NIH/AHRQ application number, title of the research training proposal, name of the applicant, sponsoring institution, assurance number, the IRB registration number, date of IRB approval, and appropriate signatures. The form entitled "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption" may be used to provide IRB certification.

Any modifications of the Research Plan (Item 30b) or in Item 37 of Facilities and Commitment Statement, as required by the IRB, must be submitted with the certification.

When a year (12 months) will have elapsed between the initial IRB review date and the anticipated award date, the NIH IC or AHRQ will require re-review by the IRB and certification prior to award.

In many instances, the applicant (prospective fellow) will be participating in research supported by research project grants for which the IRB review of human subjects is already complete or an exemption has been designated. This review or exemption designation is sufficient, provided that the IRB determines that participation of the applicant does not substantially modify the research. The appropriate grant(s) must be identified along with their IRB review dates or exemption designation. To do so if Item 9 is checked "Yes," enter "Item 37" in 9b and provide the information in Item 37 under the Facilities and Commitment Statement. If the sponsoring institution has an approved FWA, MPA, SPA or Cooperative Project Assurance Number on file with OHRP that covers the specific activity, provide the number and the latest date of approval by the IRB of the proposed activities. This date must be no earlier than one year before the receipt date for which the application is submitted. The information in Items 9a, 9b and Item 37, and the appropriate signatures, fulfill the requirement for certification of IRB approval.

If an award is made, human subjects may **not** be involved until a certification of the date of IRB approval or a designation of exemption has been submitted to the NIH IC or AHRQ.

Item 9c. NIH-Defined Phase III Clinical Trial

Check the appropriate box to indicate whether the project is an NIH-defined Phase III clinical trial. See "Human Subjects" in Section III.B, Policies, Assurances, and Certifications, for definitions of clinical research, clinical trial, and NIH-defined Phase III clinical trial. Phase III clinical trials require a Data and Safety Monitoring Board. See Data and Safety Monitoring Plan on page 20 under Item 30b, Research Training Proposal.

Item 10a, Vertebrate Animals

Check "No" if activities involving vertebrate animals are not planned at any time during the

proposed project period. Item 10b is then not applicable.

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

NIH policy requires the submission of Institutional Animal Care and Use Committee (IACUC) approval when animal studies are involved.

Note: NIH no longer requires Institutional Animal Care and Use Committee approval of the proposed research before NIH peer review of an application (http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-064.html**). As part of the peer review process, the peer review group will continue to address the adequacy of animal usage and protections in the review of an application, and will continue to raise any concerns about animal welfare issues. Verification of IACUC approval will be required in a “just-in-time” fashion prior to award.**

It is the responsibility of the sponsoring institution to submit the required verification of approval. If the IACUC verification of approval is not submitted with the application, the verification must include: the NIH application number, title of research training proposal, name of applicant, sponsoring institution, Animal Welfare Assurance number, date of IACUC approval, and appropriate signatures.

Any modifications of the Research Plan (Item 30b) or in Item 37 under the Facilities and Commitment Statement, required by the IACUC, must be submitted with the verification of IACUC approval.

Item 10b, Animal Welfare Assurance

If the sponsoring institution has an approved Animal Welfare Assurance on file with the Office of Laboratory Animal Welfare (OLAW), enter the Assurance number of the sponsoring institution in Item 10b. See http://grants.nih.gov/grants/olaw/olaw.htm.

Insert “None” in Item 10b if the sponsoring institution does not have an approved Animal Welfare Assurance on file with OLAW. **Do not insert the Animal Welfare Assurance of any collaborating institution in the space provided**. By inserting “None” and, by signing on the Facilities and Commitment Page, the sponsoring institution is declaring that it will comply with PHS policy regarding the care and use of animals by establishing an IACUC and submitting an Animal Welfare Assurance and verification of IACUC approval when required by the PHS policy or requested to do so by OLAW.

Project Previously Reviewed by the IACUC

In many instances, the fellow will be participating in research supported by research project grants for which the IACUC review has been obtained. This review is sufficient, provided the IACUC determines that participation of the fellow does not substantially modify the research. The appropriate grant(s) must be identified along with the IACUC review date(s). To supply this information, check "Yes" in Item 10a and enter "Item 37," and provide the Information in Item 37 under the Facilities and Commitment Statement.

Indefinite Project

If the sponsoring institution has an approved Animal Welfare Assurance on file with OLAW but, at, the time of application, plans for the involvement of vertebrate animals are so indefinite that IACUC review and approval are not feasible, check "Yes" and insert "Indefinite" in Item 10a. If an award is made, vertebrate animals may not be involved until a verification of the date of IACUC approval has been submitted to the NIH IC or AHRQ.

Item 11a, Sponsor

Name the one individual who will provide research training and be responsible for the scientific and technical direction of the project. Include office telephone and fax numbers. If the sponsor can receive e-mail, enter the appropriate e-mail address. If applicable, identify the co-sponsor(s) in Item 13 and provide biographical and other required information as specified under the instructions for Form Page 7.

Item 11b, Proposed 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 11c, 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.

Item 11d, Major Subdivision (of which the component named in Item 11c is a part)

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."

Item 12, 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 HHS for payment and accounting purposes. If a number has not yet been assigned by HHS, 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://grants1.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, Different Advisor/Different Training Site

Complete if different from Item 11a and/or Item 11b. Include advisor's name, if other than the sponsor listed in Item 11a, and include office phone number. If there are unusual circumstances involved in the research training situation, such as field work or a degree sought from an institution other than the one in which the research training will take place, and these are not described elsewhere in the application, give a detailed description in Item 34.

Item 14, Business Official

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

2. Form Page 2

(Complete Items 19, 20, and 21)

3. Biographical Sketch (Form Page 7)

The information requested is identical to the Biographical Sketch page in the Application for Public Health Service Grant (PHS-398). Therefore the PHS-398 page may be substituted for Form Page 7. If the PHS-398 page is used, place the name of the applicant in the upper right corner. **The Biographical Sketch may not exceed four pages. Items A (Positions and Honors) and B (Selected peer-reviewed publications) may not exceed two of the four pages.**

If this application involves an advisor or co-sponsor who has a substantial involvement and/or critical role in the Research Training Proposal, include a Biographical Sketch; a letter of commitment from that individual; and required information for Items 32 and 33, which are addressed below.

4. Facilities and Commitment (Form Page 8)

Item 32, 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.

Item 33, 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.

Items 34-37, Facilities and Commitment Statement

Complete these items (34-37) as comprehensively as possible so that a meaningful evaluation of the training environment can be made by the reviewers. Use continuation pages as needed.

Item 34, Training Plan, Environment, Research Facilities

Describe the research training plan for the applicant. 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.

Item 35, Number of Fellows/Trainees to be Supervised During the Fellowship

Indicate whether pre- or postdoctoral.

Item 36, Applicant's Qualifications and Potential for a Research Career

Self-explanatory.

Item 37, Human Subjects/Vertebrate Animals Use and Description

Kirschstein-NRSA Individual Fellowship applications are subject to the same human subjects and animal welfare policies and review considerations as research project grant applications. **If this application involves these subject areas and the applicant's Research Training Proposal (Item 30b) does not contain sufficient information to respond to the instructions contained on pages 11-21, provide the necessary information, ensuring that it is consistent with the information in Item 30b.** In addition, for research involving human subjects be sure that the research design includes the appropriate inclusion of women, minorities, and children as subject populations and a data safety and monitoring plan. No response is necessary if the application does not involve these areas or sufficient information has been provided.

Human Subjects

If Items 9 and 9a on the Face Page are marked "Yes," provide sufficient information to allow a determination that the designated exemption(s) is appropriate. Research that is exempt from coverage under the regulations is discussed under "Human Subjects Research" (see pages 13-14).

Even if a Kirschstein-NRSA Individual Fellowship application is exempt from these regulations, it must, nevertheless, address the issues of gender/race/ethnicity and children composition of the subject population (see pages 15-20).

If Item 9 on the Face Page of the application is marked "Yes" and Item 9a is marked "No," provide sufficient information to address the use of human subjects as instructed on pages 12-21 under Item 30b, Research Training Proposal.

If the research includes a clinical trial, whether or not Item 9c on the Face Page of the application is marked "Yes," provide information regarding the required data and safety monitoring plan as instructed on pages 20-21 under Item 30b, Research Training Proposal. **Although no specific page limitation applies to this section, be succinct.**

Vertebrate Animals

If Item 10a on the Face Page of the application is marked "Yes," provide sufficient information to address the use of vertebrate animals as instructed on page 21 under Item 30b, "Research Training Proposal." **Although no specific page limitation applies to this section, be succinct.**

Item 38, Official Signing for Sponsoring Institution

In signing the application, the duly authorized representative of the sponsoring institution certifies that the sponsoring institution will comply with all applicable assurances and certifications referenced in the application. Deliberate withholding, falsification, or misrepresentation of information could result in administrative actions, such as withdrawal of an application, the suspension and/or termination of an award, and debarment, as well as possible criminal penalties. The signer further certifies that the sponsoring institution will be accountable both for the use of any funds provided and for the performance of the grant-supported project or activities resulting from this application.

5. Checklist (Form Page 9) - Sponsoring Institution Section

The Checklist is the last page of the application. The sponsoring institution is responsible for Section II. The applicant completes Section I.

6. Assurances and Certifications

NIH and AHRQ require that, for each application, the assurances and certifications listed on the Checklist (see pages 33-39) be verified by the signature of the official signing for the sponsoring institution in Item 38. If unable to certify compliance, where applicable, provide an explanation.

SECTION II. SUBMITTING THE APPLICATION

A. INSTRUCTIONS

This section provides instructions for assembling the grant application, the application mailing address, and a schedule of the Ruth L. Kirschstein National Research Service Award Individual Fellowship application receipt, review, and award cycles.

1. Number of Copies, Binding, and Mailing Address

Submit the following materials in one package:

(1) The **original application**, single-sided, with required signatures on the Face Page and on Form Page 8. Do not staple or otherwise bind the original application. The pages must be assembled in the order specified in the Table of Contents (Form Page 3). The Personal Data Page should be placed 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.

(2) **Two exact, single-sided copies of the application**. Do not staple or otherwise bind the two copies of the original application. The copies should be made **after** all individuals have signed the application.

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

(4) **Three collated sets of appendix material** with items stapled, where appropriate, and each marked with the name of the applicant. A summary sheet listing all items included in the appendix is helpful. The Appendix material, and only the Appendix material, may be stapled or bound.

2. Application Mailing Address

Mailing labels are available. See MS Word or PDF.

Applications sent via the USPS EXPRESS or REGULAR MAIL should be sent to the following address:

Center For Scientific Review
National Institutes of Health
Suite 1040
6701 Rockledge Drive MSC 7710
Bethesda MD 20892-7710*

***For courier service (non-USPS), change the zip code to 20817. The telephone number is (301) 435-0715.**

***Note: Until further notice all applications and other deliveries to the Center for Scientific Review must come either via courier delivery or via the USPS. Applications delivered by individuals to the Center for Scientific Review will no longer be accepted. For additional information see** http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-012.html

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

Submit a complete application. Incomplete applications will be returned 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.

Unless specifically required by these instructions (e.g., verification of vertebrate animal (IACUC) approval), do **not** send supplementary or corrective material after the receipt date unless the Scientific Review Administrator of the SRG solicits or agrees to accept this information. The application must be complete and accurate at the time of submission as there is no guarantee that the peer reviewers will consider late material.

3. Application Receipt Dates

Applications submitted in response to a specific RFA or PA should be submitted using the receipt date listed in the announcement.

NIH and AHRQ use the following receipt, review, and award schedule:

RECEIPT, REVIEW, AND AWARD SCHEDULE

Application Receipt Dates	Initial Review Dates	Range of Likely Start Dates
Programs Other Than Minority and Disability Programs		
April 5	June/July	Sept./Dec.
August 5	Oct./Nov.	Jan./March
December 5	Feb./March	May/July
Minority and Disability Programs		
May 1	June/July	September
November 15	Jan./Feb.	May

An application will be considered on time if it is received by or mailed on or before the published receipt date and a proof of mailing is provided. 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.

If the receipt date falls on a weekend, it will be extended to the following Monday; if the date falls on a Federal holiday, it will be extended to the following workday.

Solicited applications (including those submitted in response to RFAs and PAs with specified receipt dates) must be received by the specified dates. However, an application received after the deadline may be acceptable if it carries a legible proof-of-mailing date, assigned by the carrier, and the proof-of-mailing date is not later than 1 week prior to the deadline date. The receipt date will be waived only in extenuating circumstances. To request a waiver, include an explanatory letter with the signed, completed application. **No request for a waiver will be considered prior to receipt of the application, and there is no guarantee that the waiver will be granted.**

B. THE PEER REVIEW PROCESS

1. Application Assignment Information

Kirschstein-NRSA Individual Fellowship applications for NIH and AHRQ consideration must be submitted through the Division of Receipt and Referral, Center for Scientific Review (CSR), NIH unless otherwise stated. Administrative information about the application is entered into a computer system. The application is then assigned to the appropriate SRG (often called a study section or review committee) and IC(s) or AHRQ. Assignment is based on the scientific content of the application using established referral guidelines.

As soon as possible after the application is received, usually within 4 weeks, CSR will send the applicant and the business official of the sponsoring institution: the application's assignment number; the name, address, and telephone number of the Scientific Review Administrator of the SRG to which the application has been assigned; and the assigned IC or AHRQ contact and phone number. If this information is not received within 4 weeks of the receipt date, contact the Division of Receipt and Referral, CSR, NIH, Bethesda, MD 20892-7720, (301) 435-0715. If there is a change in assignment, another notification will be sent.

2. Review Process

Most applications submitted to the NIH and AHRQ will receive two sequential levels of review. The first level of review will be performed by an SRG. The purpose of the SRG review is evaluation of the scientific and technical merit of applications. The SRG does not make funding decisions.

SRG members will be instructed to evaluate Kirschstein-NRSA Individual Fellowship applications by addressing four review criteria (see below) and assigning a single, global score for each scored application. RFAs/PAs or other mechanisms may have additional review criteria.

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

Note: Applicants must not contact reviewers regarding their applications since discussion of the content of an application or an attempt to influence review outcome will constitute a conflict of interest in the review. Reviewers are required to notify the Scientific Review Administrator if they are contacted by an applicant. Communication by the applicant with a reviewer will result in the return of the application without completion of the peer review.

3. Kirschstein-NRSA Individual Fellowship Application Evaluation Criteria

The criteria for reviewing Kirschstein-NRSA 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.

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.

C. INTERACTIONS BEFORE SUBMISSION

Additional information about the peer review process and NIH grant programs can be obtained from GrantsInfo, e-mail: GrantsInfo@nih.gov, (301) 435-0714. Information about charters and membership of SRGs, Councils, and Boards can be obtained from the appropriate NIH IC or from AHRQ.

Applicants are encouraged to contact NIH or AHRQ staff for advice in preparing an application and for information regarding programmatic areas of interest. Phone numbers for staff contacts are listed below:

NATIONAL INSTITUTES OF HEALTH

Fogarty International Center	301-496-1653
National Cancer Institute	301-496-3428
National Center for Complementary and Alternative Medicine	301-496-4792
National Center on Minority Health and Health Disparities	301-402-1366
National Center for Research Resources	301-496-6023
National Eye Institute	301-496-5301
National Heart, Lung, and Blood Institute	301-435-0260
National Human Genome Research Institute	301-496-7531
National Institute on Aging	301-496-9322
National Institute on Alcohol Abuse and Alcoholism	301-443-4375
National Institute of Allergy and Infectious Diseases	301-496-7291
National Institute of Arthritis and Musculoskeletal and Skin Diseases	301-594-2463
National Institute of Biomedical Imaging and Bioengineering	301-435-6138
National Institute of Child Health and Human Development	301-496-0104
National Institute on Deafness and Other Communication Disorders	301-496-1804
National Institute of Dental and Craniofacial Research	301-594-7710

National Institute of Diabetes and Digestive and Kidney Diseases	301-594-8834
National Institute on Drug Abuse	301-443-2755
National Institute of Environmental Health Sciences	919-541-7723
National Institute of General Medical Sciences	301-594-4499
National Institute of Mental Health	301-443-3367
National Institute of Neurological Disorders and Stroke	301-496-9248
National Institute of Nursing Research	301-594-6906
National Library of Medicine	301-496-4621
AGENCY FOR HEALTHCARE RESEARCH AND QUALITY	301-594-1447

D. Interactions After Submission

If the initial assignment seems inappropriate, the applicant may request reassignment. Such requests should be made in writing to the Division of Receipt and Referral, Center for Scientific Review, National Institutes of Health, Suite 2030, 6701 Rockledge Drive MSC 7720, Bethesda MD 20892-7720. Fax requests (301-480-1987) also are acceptable. Although these requests will be carefully considered, the final determination will be made by CSR.

Any other inquiries regarding assignment, review, or funding recommendations on applications are to be made only to NIH or AHRQ officials. It is inappropriate to contact consultants who serve on advisory or review committees regarding these questions.

E. Interactions After Review

Feedback to applicants is very important. Once the applicant receives the summary statement, s/he may contact the appropriate IC or AHRQ program official (noted on the summary statement) for an interpretation of the reviews and the disposition of the application.

SECTION III. OTHER INFORMATION

This section contains policies and additional guidance relating to submission of a Ruth L. Kirschstein-National Research Service Award Individual Fellowship application to NIH or AHRQ. Refer to the Foreword (page 2) for additional sources of information.

A. PATENTS AND INVENTIONS

As specified in 45 CFR Part 74 and in 37 CFR 401.1(b), fellowships that are funded primarily for educational purposes, where the training will occur other than at NIH, are not subject to invention reporting requirements. Also, no fellowship made by NIH to an awardee primarily for educational purposes, where the training will occur other than at NIH, may contain any provision giving NIH any rights to inventions made by the awardee.

B. POLICIES, ASSURANCES, AND CERTIFICATIONS

The policies, assurances, and certifications listed and explained below may or may not be applicable to the project covered by this application or to the type of sponsoring institution. In addition to those policies highlighted below, there are a number of additional public policy requirements with which applicants and recipients must comply. Refer to the sponsoring institution's business office or to the NIH Grants Policy Statement (or PHS Grants Policy Statement for AHRQ) for additional information. The *NIH and PHS Grants Policy Statements* may be found on the NIH Web site (http://grants.nih.gov/grants/policy/policy.htm).

In signing the application, the applicant and the duly authorized representative of the sponsoring institution (Official Signing for the Sponsoring Institution) certify that they will comply with the following policies, assurances and/or certifications, as applicable.

Human Subjects

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. The regulations governing the inclusion of human subjects in research extend to the use of human organs, tissues, and body fluids from individually identifiable human subjects as well as to graphic, written, or recorded information derived from individually identifiable human subjects.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject.

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (for example, a medical record). In order to constitute research involving human subjects, private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information).

The use of autopsy materials is governed by applicable state and local law and is not directly regulated by 45 CFR 46.

The HHS regulations for the protection of human subjects provide a systematic means, based on established, internationally recognized ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by HHS. The regulations stipulate that a sponsoring institution, whether domestic or foreign, bears responsibility for safeguarding the rights and welfare of human subjects in HHS-supported research activities. The regulations require that sponsoring institutions proposing to involve human subjects in non-exempt research file a written Assurance of Compliance with the Office for Human Research Protections (OHRP), establishing appropriate policies and procedures for the protection of human subjects. These regulations, 45 CFR 46, Protection of Human Subjects, are available from the OHRP, National

Institutes of Health, Rockville, MD 20892, (301) 496-7041, and at the OHRP web site at http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm.

Investigators who conduct research involving pregnant women, human fetuses and neonates, prisoners, or children must follow the provisions of the regulations in Subparts B, C, and D of 45 CFR 46, which describe the additional protections required for these subjects.

No HHS award for non-exempt research involving human subjects will be made to a sponsoring institution unless that institution is operating in accord with an approved Assurance of Compliance and provides certification that an appropriate Institutional Review Board (IRB) has reviewed and approved the proposed activity in accordance with the HHS regulations. No award to an individual will be made unless that individual is affiliated with an assured institution that accepts responsibility for compliance with the HHS regulations. Foreign sponsoring institutions also must comply with the provisions of the regulations.

The Center of Biologics Evaluation and Research (CBER), FDA, regulates the use of biological products in humans, at the investigational and marketing phases, including somatic cell therapies and gene therapies. If your work involves these areas or preclinical research that will support later work in these areas, see the Office of Biotechnology Activities' Web site at http://www4.od.nih.gov/oba

Women and Minority Inclusion Policy

Research involving human subjects must comply with the "NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research." The following excerpts provide the key policy statements. Investigators should obtain full copies of the Guidelines from NIH staff, the *NIH Guide for Grants and Contracts* (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html) or the *Federal Register* (59 FR 11146-11151).

The policy of NIH is that women and members of minority groups and their subpopulations must be included in all NIH-supported biomedical and behavioral research projects involving clinical research, unless a clear and compelling rationale and justification establishes that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. Exclusion under other circumstances may be made based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research. All NIH-supported biomedical and behavioral research involving human subjects is defined as human subjects research. This policy applies to research subjects of all ages.

Awards will not be made if the research project does not comply with this policy. In addition, awardees must report annually on enrollment of women and men, and on the race and ethnicity of research participants in the Inclusion Enrollment Report Table format page.

Note: Under HHS regulations to protect human subjects from research risks (see above), certain research areas are exempt. Nonetheless, NIH-supported biomedical and behavioral research projects involving human subjects that are exempt from the human subjects regulations still must address the inclusion of women and minorities in the study design. Therefore, all biomedical and behavioral research projects involving human subjects will be evaluated for compliance with this policy. Research involving the collection or study of existing data, documents, records, pathological specimens, diagnostic specimens, or tissues that are individually identifiable also are to be included within the term "research involving human subjects."

Inclusion of Children Policy

NIH defines a child as an individual under the age of 21 years. It should be noted that this definition of child will pertain notwithstanding the FDA definition of a child as an individual from infancy to 16 years of age, and varying definitions employed by some States. Generally, State laws define what constitutes a "child," and such definitions dictate whether or not a person can legally consent to participate in a research study. However, State laws vary, and many do not address the age at which a child can consent to participate in research. Federal regulations (45 CFR 46, Subpart D, Sections

401-409) address HHS protections for children who participate in research, and rely on State definitions of "child" for consent purposes. Consequently, the children included in this policy (persons under the age of 21) may differ in the age at which their own consent is required and sufficient to participate in research under State law. For example, some States consider a person age 18 to be an adult and therefore one who can provide consent without parental permission.

Research involving children must comply with the "NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects," issued March 6, 1998. The following excerpts provide the key policy statements. Applicants should obtain full copies of the Policy and Guidelines from NIH staff, or from the *NIH Guide for Grants and Contracts* (http://grants.nih.gov/grants/guide/notice-files/not98-024.html).

NIH policy requires that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are clear and compelling reasons not to include them. This policy applies to all NIH conducted or supported research involving human subjects, including research that is otherwise "exempt" in accordance with Section 401 (b) of 45 CFR 46 Subpart A. The inclusion of children as subjects in research must be in compliance with all applicable subparts of 45 CFR 46 as well as with other pertinent federal laws and regulations. Therefore, proposals for research involving human subjects must include a description of plans for including children. If children will be excluded from the research, the application or proposal must present an acceptable justification for the exclusion.

Additionally, IRBs have special review requirements to protect the well-being of children who participate in research. These requirements relate to risk, benefit, parental/guardian consent, and assent by children, and to research involving children who are wards of the State or of another institution. The local IRB approves research that satisfies the conditions set forth in the regulations.

Clinical Research

NIH defines human clinical research as:

(1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are *in vitro* studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, or (d) development of new technologies.

(2) Epidemiologic and behavioral studies.

(3) Outcomes research and health services research.

Note: Studies falling under Exemption 4 for human subjects research (see page 14) are not considered clinical research by this definition.

Clinical Trial

For purposes of reviewing applications submitted to NIH, a clinical trial is operationally defined as a prospective biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices).

Clinical trials are used to determine whether new biomedical or behavioral interventions are safe, efficacious and effective. Clinical trials of experimental drug, treatment, device or behavioral intervention may proceed through four phases:

Phase I clinical trials are done to test a new biomedical or behavioral intervention in a small group of people (e.g., 20-80) for the first time to evaluate safety (e.g., determine a safe dosage range, and identify side effects).

Phase II clinical trials are done to study the biomedical or behavioral intervention in a larger group of people (several hundred) to determine efficacy and to further evaluate its safety.

Phase III studies are done to study the efficacy of the biomedical or behavioral intervention in large groups of human subjects (from several hundred to several thousand) by comparing the intervention to other standard or experimental interventions as well as to monitor adverse effects, and to collect information that will allow the intervention to be used safely.

Phase IV studies are done after the intervention has been marketed. These studies are designed to monitor effectiveness of the approved intervention in the general population and to collect information about any adverse effects associated with the widespread use.

NIH-Defined Phase III Clinical Trial

An NIH-defined Phase III clinical trial is a broadly based prospective Phase III clinical investigation, usually involving several hundred or more human subjects, for the purpose of evaluating an experimental intervention in comparison with a standard or control intervention or comparing two or more existing treatments. Often the aim of such investigation is to provide evidence leading to a scientific basis for consideration of a change in health policy or standard of care. The definition includes pharmacologic, non-pharmacologic, and behavioral intervention given for disease prevention, prophylaxis diagnosis, or therapy. Community trials and other population-based intervention trials also are included.

Research on Transplantation of Human Fetal Tissue

In signing the application, the duly authorized representative of the sponsoring institution certifies that if research on the transplantation of human fetal tissue is conducted, the sponsoring institution will make available for audit by the Secretary, HHS, the physician statements and informed consents required by Section 498A(b)(2) and (c) of the Public Health Service Act, 42 U.S.C. 289g (b)(2) and (c), or ensure HHS access to those records, if maintained by an entity other than the sponsoring institution.

Research Using Human Embryonic Stem Cells

http://stemcells.nih.gov/index.asp

In signing the application Face Page, the duly authorized representative of the sponsoring institution certifies that, if research using human embryonic stem cells is proposed, the sponsoring institution will be in compliance with the "Notice of Extended Receipt Date and Supplemental Information Guidance for Applications Requesting Funding that Proposes Research with Human Embryonic Stem Cells" (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-006.html).

Vertebrate Animals

The *PHS Policy on Humane Care and Use of Laboratory Animals* requires that sponsoring institutions proposing to use vertebrate animals file a written Animal Welfare Assurance with the Office of Laboratory Animal Welfare (OLAW), establishing appropriate policies and procedures to ensure the humane care and use of live vertebrate animals involved in research activities. The PHS policy stipulates that a sponsoring institution, whether domestic or foreign, bears responsibility for the humane care and use of animals in grant-supported research, including NIH-and AHRQ-supported research activities. This policy implements and supplements the *U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training*, and requires that institutions use the *Guide for the Care and Use of Laboratory Animals* as a basis for developing and implementing an institutional animal care and use program. This policy does not affect applicable State or local laws or regulations that impose more stringent standards for the care and use of laboratory animals. All institutions are required to comply, as applicable, with the Animal Welfare Act as amended (7 USC 2131 et seq.) and other Federal statutes and regulations relating to animals. These documents are available from the Office of Laboratory Animal Welfare, National Institutes of Health, Bethesda, MD 20892-7982; (301) 496-7163; Web site: http://grants.nih.gov/grants/olaw/olaw.htm

The PHS policy defines "animal" as "any live, vertebrate animal used or intended for use in research, research training, experimentation or biological testing or for related purposes."

No Kirschstein-NRSA Individual Fellowship involving vertebrate animals will be made to a sponsoring institution unless that institution is operating in accordance with an approved Animal Welfare Assurance and provides verification that the Institutional Animal Care and Use Committee (IACUC) has reviewed and approved the proposed activity in accordance with the PHS policy. Applications may be referred by the NIH or AHRQ back to the IACUC for further review in the case of apparent or potential violations of the PHS policy. No award to an individual will be made unless that individual is affiliated with an institution that has an Animal Welfare Assurance and that accepts responsibility for compliance with the PHS policy. Foreign institutions applying for Kirschstein-NRSA Individual Fellowships that will involve vertebrate animals are required to comply with PHS policy or provide evidence that acceptable standards for the humane care and use of animals will be met.

Debarment and Suspension

Executive Order 12549, "Debarment and Suspension," mandated development of a Government-wide debarment and suspension system for nonprocurement transactions with Federal agencies. Executive Order 12689 and Section 2455 of the Federal Acquisition Streamlining Act of 1994 further required Federal agencies to establish regulations for reciprocal Government-wide effect across procurement and nonprocurement debarment and suspension actions. This reciprocity rule is effective for any debarment, suspension or other Government-wide exclusion initiated on or after August 25, 1995. HHS regulations implementing Executive Orders 12549 and 12689, and Section 2455 of the Federal Acquisition Regulation are provided in 45 CFR 76, "Government-wide Debarment and Suspension (Nonprocurement) and Government-wide Requirements for Drug-Free Workplace (Grants)." Accordingly, before a grant award can be made, the sponsoring institution must make the following certification (Appendix A of the HHS regulations):

1. The prospective primary participant certifies to the best of its knowledge and belief, that it and its principals (including research personnel):

   a. Are not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded by any Federal department or agency;

   b. Have not within a three-year period preceding this proposal been convicted of or had a civil judgment rendered against them for commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, State, or local) transaction or contract under a public transaction; violation of Federal or State antitrust statutes or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, or receiving stolen property;

   c. Are not presently indicted for or otherwise criminally or civilly charged by a governmental entity (Federal, State, or local) with commission of any of the offenses enumerated in paragraph 1.b of this certification; and

   d. Have not within a three-year period preceding this application/proposal had one or more public transactions (Federal, State, or local) terminated for cause or default.

2. If the individual is unable to certify to the statements in the certification, he or she should sign the application in Item 15 on the Face Page of the application and attach an explanation to the Checklist. If the sponsoring institution is unable to make the required certification, the Official Signing for the Sponsoring Institution should sign the application in Item 38 and attach an explanation to the Checklist.

Drug-Free Workplace

The Drug-Free Workplace Act of 1988 (Public Law 100-690, Title V, Subtitle D) requires that all grantees receiving grants from any Federal agency certify to that agency that they will maintain a drug-free workplace. HHS regulations

implementing the Act are provided in 45 CFR 76, "Government-wide Debarment and Suspension (Nonprocurement) and Government-wide Requirements for Drug-Free Workplace (Grants)." Accordingly, before an Individual NRSA Fellowship can be awarded, the individual applying for the award must make the certification set forth below (Appendix C of the HHS regulations). The certification is a material representation of fact upon which reliance will be placed by the NIH IC and AHRQ. False certification or violation of the certification shall be grounds for suspension of payments, suspension or termination of grants, or Government-wide suspension or debarment.

"The grantee certifies that, as a condition of the grant, he or she will not engage in the unlawful manufacture, distribution, dispensing, possession or use of a controlled substance in conducting any activity with the grant."

Nondelinquency on Federal Debt

The Federal Debt Collection Procedure Act, 28 U.S.C. 3201 (e), provides that an organization or individual that is indebted to the United States, and has a judgment lien filed against it, is ineligible to receive a Federal grant. NIH and AHRQ cannot award a Kirschstein-NRSA Individual Fellowship unless the applicant certifies, by means of his/her signature on the application, that he or she is not delinquent in repaying any Federal debt. Indebtedness to the United States may include, but is not limited to, delinquency in payment of Federal income taxes or failure to repay federally secured student loans in accordance with the terms of the loan agreement. If the applicant discloses delinquency on a debt owed to the Federal Government, NIH or AHRQ may not award the grant until the debt is satisfied or satisfactory arrangements are made with the Federal agency to which the debt is owed.

Research Misconduct

Each institution that applies for or receives a research, research training, or research-related grant or cooperative agreement under the Public Health Service Act must certify that the institution has established administrative policies as required by (1) 42 CFR Part 50, Subpart A, "Responsibilities for PHS Awardee and Applicant Institutions for Dealing with and Reporting Possible Misconduct in Science," and (2) 42 CFR 94, "Public Health Service Standards for the Protection of Research Misconduct Whistleblowers (effective on the date set forth in the final rule).

The signature of the official signing for the sponsoring institution serves as certification that:

1. The institution will comply with the requirements of the regulations for dealing with reporting possible scientific misconduct under 42 CFR Part 50, Subpart A, and for protecting research misconduct whistleblowers under 42 CFR Part 94;

2. The institution has established policies and procedures incorporating the provisions set forth in 42 CFR Part 50, Subpart A, and 42 CFR Part 94;

3. The institution will provide its policies and procedures to the Office of Research Integrity upon request; and

4. The institution will submit an Annual Report on Possible Research Misconduct (Form 6349). A copy of Form 6349, covering the previous year, will be automatically sent to the sponsoring institution by the Office of Research Integrity each January.

For this purpose, “misconduct in science" and "research misconduct" are defined as "fabrication, falsification, plagiarism or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting or reporting research. It does not include honest error or honest differences in interpretation or judgments of data."

For further information, contact the Office of Research Integrity, Division of Education and Integrity, Rockwall II, Suite 700, 5515 Security Lane, Rockville, MD 20852, (301) 443-5300, fax: (301) 594-0042.

Assurance of Compliance (Civil Rights, Handicapped Individuals, Sex Discrimination, Age Discrimination)

Before a Kirschstein-NRSA Individual Fellowship can be awarded, a domestic sponsoring institution must certify that it has filed with the HHS Office for Civil Rights: an Assurance of

Compliance (Form HHS-690) with Title VI of the Civil Rights Act of 1964 (P.L. 88-352, as amended), which prohibits discrimination on the basis of race, color, or national origin; Section 504 of the Rehabilitation Act of 1973 (P.L. 93-112, as amended), which prohibits discrimination on the basis of handicaps; Title IX of the Education Amendments of 1972 (P.L. 92318, as amended), which prohibits discrimination on the basis of sex; and the Age Discrimination Act of 1975 (P.L. 94-135), which prohibits discrimination on the basis of age.

The Assurance of Compliance (Form HHS-690) is available from GrantsInfo, e-mail GrantsInfo@nih.gov, (301) 435-0714.

Note: The Assurance of Compliance (Form HHS 690) is now used in lieu of individual assurances: Form HHS 441, Civil Rights; Form HHS 641, Handicapped Individuals; Form HHS 639-A, Sex Discrimination; and Form HHS 680, Age Discrimination.

Financial Conflict of Interest

NIH and AHRQ require grantees and investigators to comply with the requirements of 42 CFR Part 50, Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought." These requirements promote objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research funded under NIH and AHRQ grants or cooperative agreements will be biased by any conflicting financial interest of an investigator. This policy applies equally to Kirschstein-NRSA Individual Fellowships.

The signature of the official signing for the sponsoring institution serves as certification of compliance with the requirements of 42 CFR Part 50, Subpart F, including that:

1. There is in effect, at the institution, a written and enforced administrative process to identify and manage, reduce, or eliminate conflicting financial interests with respect to research and research training projects for which NIH or AHRQ funding is sought.
2. Prior to the expenditure of any NIH or AHRQ funds awarded under a new Kirschstein-NRSA Individual Fellowship, the institution will inform NIH or AHRQ of the existence of any conflicting financial interests of the type covered by 42 CFR 50.605 and assure that the interest has been managed, reduced, or eliminated in accordance with the regulations;
3. The institution will continue to make similar reports on subsequently identified conflicts; and it will make information available to NIH or AHRQ, upon request, as to how identified conflicting interests have been handled.

Metric Program

Consistent with Government-wide implementing regulations, 15 CFR Part 19, Subpart B and/or any other Government-wide requirements, NIH and AHRQ policy is to support Federal transition to the metric system and to use the metric system of measurement in all grants, cooperative agreements, and all other financial assistance awards. Likewise, measurement values in reports, publications, and other communications regarding grants will be in metric.

Government Use of Information Under the Privacy Act

The Privacy Act of 1974 (5 U.S.C. 552a regulates the collection, maintenance, use, and dissemination of personal information by Federal agencies. In accordance with the Act, NIH and AHRQ are required to provide the following notification to each individual whom it asks to supply information.

The NIH and AHRQ maintain applications and grant records pursuant to their statutory authorities for awarding grants. The purpose of the information collection is to aid in the review, award, and administration of agency programs. Provision of information is voluntary; however, a lack of sufficient information may hinder the agency's ability to review applications, monitor grantee performance, or perform overall management of grant programs.

The Privacy Act authorizes discretionary disclosure of this information within HHS and outside the agency, including to the public, as required by the Freedom of Information Act and the associated HHS regulations (45 CFR 5).

This includes disclosure to Congress acting within its legislative authority, the National Archives, the General Accounting Office, the Bureau of Census, law enforcement agencies, and pursuant to a court order.

Information also may be disclosed outside HHS, if necessary, for the following purposes:

1. To a Congressional office at the request of the record subject;

2. To the Department of Justice as required for litigation;

3. To the cognizant audit agency for auditing;

4. To qualified experts not within the definition of Department employees as prescribed in HHS regulations (45 CFR 5b.2) for opinions as part of the application review/award process;

5. For an authorized research purpose under specified conditions;

6. To contractors for the purpose of processing, maintaining, and refining records in the system. Contractors will be required to maintain Privacy Act safeguards with respect to such records;

7. To a Federal agency, in response to its request, in connection with the letting of a contract, or the issuance of a license, grant, or other benefit by the requesting agency, to the extent that the records are relevant and necessary to the requesting agency's decision on the matter; and

8. To the sponsoring institution in connection with the review of an application or performance or administration under the terms and conditions of the award, or in connection with problems that might arise in performance or administration if an award is made.

Information Available to the Applicant

Under the provisions of the Privacy Act, individuals may request copies of records pertaining to their applications from the NIH IC or AHRQ. Individuals are given the opportunity under established procedures to request that the records be amended if they believe they are inaccurate, untimely, incomplete, or irrelevant. If the agency concurs, the records will be amended.

Information Available to the General Public

NIH and AHRQ make information about awarded Kirschstein-NRSA Individual Fellowships available to the public, including the title of the project, the sponsoring institution, the name of the fellow, and the amount of the award. The description, on Form Page 2 of a funded research grant application is sent to the National Technical Information Service (NTIS), U.S. Department of Commerce, where the information is used for the dissemination of scientific information and for scientific classification and program analysis purposes. These descriptions are available of the public from the NTIS.

The Freedom of Information Act and implementing HHS regulations (45 CFR Part 5) require the release of certain information about grants upon request, irrespective of the intended use of the information. Trade secrets and commercial, financial, or otherwise intrinsically valuable information that is obtained from a person or organization and that is privileged or confidential information may be withheld from disclosure. Information that, if disclosed, would be a clearly unwarranted invasion of personal privacy also may be withheld from disclosure. Although the sponsoring institution and the individual will be consulted about any such release, the final determination will be made by NIH or AHRQ. Generally available for release, upon request, except as noted above, are all **funded** Kirschstein-NRSA Individual Fellowship applications; **pending and funded** progress reports; and final reports of any review or evaluation of an individual's performance conducted or caused to be conducted by the HHS. Generally not available for release to the public are: **competing** Kirschstein-NRSA Individual Fellowship applications (initial, competing continuation) for which awards have not been made; evaluative portions of site visit reports; and summary statements of findings and recommendations of review groups.

Recombinant DNA and Human Gene Transfer Research

The *National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)* apply to NIH-funded and non-NIH-funded gene transfer projects that are conducted at or sponsored by an institution that receives NIH support for recombinant DNA research. As defined by the *NIH Guidelines*, recombinant DNA molecules are either: (1) molecules which are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell; or (2) DNA molecules that result from the replication of those described in (1). The *NIH Guidelines* set forth principles and standards for safe and ethical conduct of recombinant DNA research and apply to both basic and clinical research studies. Specific guidance for the conduct of human gene transfer studies appears in the appendix of the document (Appendix M.) The *NIH Guidelines* should be carefully reviewed to ensure compliance with all other requirements for the conduct of projects involving recombinant DNA research and human gene transfer. Failure to comply with the *NIH Guidelines* may result in suspension, limitation, or termination of NIH funds for recombinant DNA research at the organization or a requirement for NIH prior approval of any or all recombinant DNA projects at the organization. A copy of *the NIH Guidelines* is posted at the following URL: http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html and may be obtained from the NIH Office of Biotechnology Activities, 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892, 301-496-9838.

C. Information Resources

A partial list of those NIH program guidelines and other publications available on the NIH Web site is included at http://www.nih.gov/index.html and is available from http://grants.nih.gov/grants/index.cfm. Applicants may contact GrantsInfo, by e-mail: GrantsInfo@nih.gov, or by phone (301) 435-0714.

D. Extramural Program Guidelines

Guidelines for Kirschstein-NRSA Individual Fellowships may be found on the NIH Web Site at http://grants.nih.gov/training/nrsa.htm.

SECTION IV. KIRSCHSTEIN-NRSA FIELDS OF TRAINING

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

1100 BIOCHEMISTRY
1110 Biological Chemistry
1120 Bioenenergetics
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

6000 II. <u>PREDOMINANTLY CLINICAL RESEARCH TRAINING</u> (any category can include <u>any</u> 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 CLINICAL DENTISTRY

6500 MEDICAL 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

SECTION V. KIRSCHSTEIN-NRSA 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. Note that 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, which appeared in the NIH Guide for Grants and Contracts, Volume 26, Number 21, June 20, 1997. These guidelines can be accessed on the NIH Web site at http://grants.nih.gov/training/nrsa.htm. 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 them a payback obligation. I hereby agree to engage in a month of health-related research, health-related research training, or health-related teaching for each month I receive a Kirschstein-NRSA Individual Fellowship for postdoctoral research training up to and including 12 months or, 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 research or teaching shall be on a continuous basis and shall average more than 20 hours per week of a full work year.

II. 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. above. 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) 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;

   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.

SECTION VI. GLOSSARY

AHRQ. Agency for Healthcare Research and Quality, which is a component of HHS.

CFR. Code of Federal Regulations.

Competing Continuation Application. A request for financial assistance to extend for one or more additional budget periods a project period that would otherwise expire. Competing continuation applications compete with other competing continuation, competing supplemental, and new applications for funds.

HHS. U.S. Department of Health and Human Services.

IC. An Institute or Center of the National Institutes of Health.

Institutional Review Board (IRB). A committee at the sponsoring institution that is required to review and approve all non-exempt research activities involving human subjects.

NIH. National Institutes of Health, which is a component of HHS.

Noncompeting Continuation Application. A request for financial assistance for a second or subsequent budget period within a previously approved project period.

NRSA Individual Fellowship . Ruth L. Kirschstein National Research Service Award provided to individuals for research training in biomedical and behavioral research.

OHRP. Office for Human Research Protections.

OLAW. Office of Laboratory Animal Welfare.

Payback. Requirement that the recipient engage in biomedical or behavioral health-related research and/or health-related teaching or subsequent Kirschstein-NRSA-supported research training for a period equal to the period during which he or she received a postdoctoral Kirschstein-NRSA fellowship up to and including 12 months or, if more than 12 months, in the 13th month and each subsequent month of Kirschstein-NRSA-supported postdoctoral research training, or else reimburse the Government for the Kirschstein-NRSA funds paid the during this period.

Program Announcement (PA). A formal statement that describes and gives notice to the of the existence of an extramural research activity/interest or announces the initiation of a new or modified activity/interest or mechanism of support and invites applications on a continuing basis.

Request for Applications (RFA). A formal statement that invites grant or cooperative agreement applications to accomplish a specific program purpose, indicates the amount of funds set aside for the competition, and generally identifies a single application receipt date.

Revised (Amended) Application. Resubmission of an unfunded application that has been changed significantly in response to the previous review.

Scientific Review Administrator. Health Scientist Administrator who manages a Scientific Review Group (SRG).

Second-Level Review (Council). Kirschstein-NRSA Individual Fellowship applications are not required by law to be reviewed by the pertinent NIH National Advisory Council; but they receive a second review by IC staff, who consider program relevance and the SRG's recommendation in advising the IC on funding.

Sponsor. A designated individual responsible for providing the applicant with research training and career guidance throughout the grant award period.

Sponsoring Institution. Institution legally responsible for committing facilities for the Kirschstein-NRSA Individual Fellowship applicant and financially responsible for the use and disposition of fellowship funds.

SRG. Scientific Review Group or Study Section, which is a panel of primarily non-Federal scientific experts that provide the initial review for scientific merit of applications.

Summary Statement. Written record of an SRG's evaluation of an application. Summary statements are automatically sent to principal investigators/applicants following the SRG's review meeting.