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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 Progress Report for Continuation Support
Form PHS 416-9

IMPORTANT CHANGES, AND OTHER INFORMATION

CHANGES IN FORMAT AND PROCESS

The PHS 416-9 is available in electronic format only. The PHS 416-9 has have been modified to enable the fields to be completed (filled) using Adobe Acrobat Reader software. The sections of this form are identified as PDF files. In addition, this form may be completed using any word processing software that can read "rich text format" (rtf) files. **Note: PDF documents can be saved only if you have obtained Adobe Acrobat. However, many word processing software packages will allow the users to save a document in the RTF format using the "Save As" function.**

The PHS 416-9 form is available in electronic PDF and RTF format. Form pages are available separately on the NIH Web Site http://grants.nih.gov/grants/forms.htm. Sponsors and sponsoring institutions are encouraged to bookmark this site for future submissions.

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

Fellows and sponsoring institutions should monitor the *NIH Guide for Grants and Contracts* for future developments in the electronic transfer of progress reports for continuation support.

NIH now provides electronic access to information on annual progress report due dates at http://era.nih.gov/userreports/pr_due.cfm. Using this site, sponsoring institution officials can run a report of all progress reports due in the next few months. For more information on this change in process, see Notice OD-02-066 published in the *NIH Guide for Grants and Contracts* on August 13, 2002 (http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-066.html).

CHANGES IN THE REPORT FORM PAGES

New Forms:

Targeted/Planned Enrollment Table and Inclusion Enrollment Report.

CHANGES IN THE INSTRUCTIONS

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 the PHS 416-1.

REMINDER

Type size and format specifications must be followed or the report will be considered incomplete, which may result in a delay in continuation funding.

INFORMATION

GrantsInfo, National Institutes of Health

The Division of Extramural Outreach and Information Resources (DEOIR) is the central source for general information about NIH extramural research and

research training programs, funding mechanisms, the peer review system, and progress report procedures. The NIH grants Web site is at http://grants.nih.gov/grants/oer.htm. Information about NIH training grant programs may be found at the NIH training page at http://grants.nih.gov/training/extramural.htm. The e-mail address is: GrantsInfo@nih.gov. The phone number is (301) 435-0714.

SECTION I. REQUIREMENTS FOR THE PROGRESS REPORT FOR CONTINUATION SUPPORT

An annual progress report (the PHS 416-9) serves as the basis for determining whether to fund each year (after the initial year) of recommended support under a Ruth L. Kirschstein National Research Service Award (NRSA) Individual Fellowship from the National Institutes of Health (NIH) or the Agency for Healthcare Research and Quality (AHRQ). The report must include information related to the current year's progress as well as plans for the coming year.

The PHS 416-9 must be submitted to the cognizant grants management office. For NIH fellowships the progress report is due 2 months before the beginning date of the next budget period. For AHRQ fellowships the progress report is due 4 months before the beginning date of the next budget period.

The Office of Extramural Research (OER), NIH, now hosts a web site at http://era.nih.gov/userreports/pr_due.cfm that provides due date information for all NIH progress reports due over a period of several months. Sponsoring institution officials are encouraged to check the site on a regular basis. New records are added on or about the 30th of each month. For more information on this change in process, see Notice OD-02-066 published in the *NIH Guide for Grants and Contracts* on August 13, 2002 (http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-066.html). In addition to this website, e-mail reminders are sent to the fellow.

For sponsoring institutions and individual fellows registered in the NIH eRA Commons, the progress report due information is available in the Commons Status system. Commons-registered institutions and individual fellows also have access to pre-populated face pages via Status. For more information on the NIH Commons, see: https://commons.era.nih.gov/commons/index.jsp.

Computer-generated facsimiles may be substituted for any of the forms. Substitute forms should be printed in black ink, and maintain the exact wording and format of the Government-provided forms, including all captions and spacing.

In preparing the report, 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.

You must use English and should avoid jargon. If a term is 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.

The progress report must be clear and readily legible. The type size used throughout the progress report must conform to the following three requirements, and the margins, in all directions, must be at least 1/2 inch:

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 must be within a vertical inch. Type requirements should be checked on the printed document 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.

Number all pages consecutively. Do not bind or staple the original. An incomplete or incorrectly prepared progress report for continuation support may result in a delay in award of additional funds.

Submit the completed, signed original progress report for continuation support and two copies (with required signatures) directly to the grants management office of the awarding NIH Institute or Center (IC) or AHRQ. For mailing addresses see http://grants1.nih.gov/grants/type5_mailing_addresses.htm**. Notify the NIH IC or AHRQ immediately if you do not intend to request continuation support.**

Form PHS 416-1, Ruth L. Kirschstein National Research Service Award Individual Fellowship Application (revised 06/02), should be used to apply for support not previously recommended.

Any questions concerning completion of this progress report for continuation support should be directed to the grants management specialist identified on the current Kirschstein-NRSA Individual Fellowship award notice.

NIH estimates that it will take approximately 7 hours to complete this report. This estimate does not include time for development of the research training plan. Items such as human subjects are cleared and accounted for separately, and are not part of the time estimate for completing this report. 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, Attention: PRA (0925-0002). **DO NOT RETURN THE COMPLETED REPORT TO THIS ADDRESS.**

SECTION II. PREPARING THE PROGRESS REPORT FOR CONTINUATION SUPPORT

A. SPECIFIC INSTRUCTIONS FOR THE KIRSCHSTEIN-NRSA FELLOW (PART I)

Part I - Form Page 1 (Face Page)

Use the Form Page 1, which is available in PDF or RTF format at the NIH Web site: http://grants.nih.gov/grants/forms.htm.

Items 1-6. . Items 1-4 and item 6 are self-explanatory. Item 5, the Entity Identification Number (EIN), should be checked or supplied by the business official of the sponsoring institution. The EIN is assigned by the Department of Health and Human Services (DHHS) for payment and accounting purposes. The EIN is not used for fellows at Federal laboratories.

Items 7-8. To be completed by the sponsor. See Section B (Part I).

Item 9. Training Site(s). Complete only if different from the Sponsoring Institution listed in Item 4.

Item 10a. Permanent Mailing Address. If the information in Item 2a is not a permanent address, state the address where the Kirschstein-NRSA Fellow can always be contacted. **Changes should be reported promptly to the NIH IC or AHRQ grants management office.**

Item 11. Corrections. Reserved.

Item 12. Certification and Acceptance. Each progress report for continuation support to NIH or AHRQ requires that the following certifications be verified by the Kirschstein-NRSA Fellow's signature. See the PHS 416-1 application instructions for information concerning these certifications.

Debarment and Suspension
Delinquent Federal Debt

In signing the Face Page, the Kirschstein-NRSA Fellow certifies compliance with these certifications. Deliberate withholding, falsification, or misrepresentation of information could result in administrative actions, such as withholding of an award, suspension and/or termination of an award, or debarment of an individual, or in possible criminal penalties. Failure to sign Item 12 will preclude the possibility of a continuation award and additional funding.

Part I - Form Page 2

Item 13. Summary of Activities. Identify each part of this item (13A. B., and C.) by letter and title. Do not exceed three pages for the entire summary.

Human Subjects

If Item 7 on the face page is marked "Yes," provide the following information in Item 13C.

If studies involving human subjects are planned, and they were not part of the originally proposed research design, then you must comply with the requirements described in Item 30b of the PHS 416-1 application and provide the information to NIH or AHRQ. Additional information on the intended involvement of human subjects also may be found in the Department of Health and Human Services (HHS) regulations (45 CFR Part 46) available at (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm).

If human studies are different from those proposed in the original application or in your previous progress report, include an explanation of how they differ and provide a new or revised research training proposal (using the instructions for Item 30b in the PHS 416-1). Be sure to use the designated headings for "Non-Exempt" or "Exempt Human

Subjects Research", as appropriate, including "Women and Minority Inclusion in Clinical Research," "Inclusion of Children," and "Data and Safety Monitoring Plan." New protocols or protocol changes will require Institutional Review Board (IRB) approval, in accordance with the HHS regulations for protection of human subjects. If requested by NIH or AHRQ, provide the protocol.

If human subject studies were identified in the Research Plan of the PHS 416-1 application, but were not adequately described because they were planned for a later time within the project period and you now plan to conduct them in the coming year, you must provide the "Human Subjects" information required by the PHS 416-1 instructions (as noted above).

Women and Minority Inclusion in Clinical Research.

Reporting Data on Inclusion to NIH

If you are conducting clinical research (see definition in Section III. B of the PHS 416-1), you must report the annual cumulative enrollment of subjects and their distribution by sex/gender and ethnicity/race, unless otherwise notified by the NIH or AHRQ program official. You should be using the **Inclusion Enrollment Report Format Page** for this purpose. This format page is included as part of the PHS 416-9. Detailed instructions for completing the Inclusion Enrollment Report and frequently asked questions may be found on the NIH Web site (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-053.html).

NOTE: Reporting data on inclusion is not included in the three-page limit. If there is more than one study, provide a separate table for each study. Information about ethnic/racial subpopulations included in the study should be provided as an attachment to the **Inclusion Enrollment Report Format Page**.

Changes to Targeted/Planned Enrollment. If there are changes from the Targeted/Planned Enrollment Table originally approved for funding, you should submit a revised **Targeted/Planned Enrollment Table** and an **Inclusion Enrollment Report** describing data collected to date. Explain the changes in an attachment to the progress report.

NIH-Defined Phase III Clinical Trial. If you are conducting an NIH-defined Phase III clinical trial (see definition in Section III.B of the PHS 416-1), you must report on the annual cumulative enrollment (as described above) and indicate if data analysis has begun for the trial. If so, you should report on progress made in conducting valid analyses for sex/gender and ethnic/racial differences.

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 **Inclusion Enrollment Report**. When completing 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.

NOTE: The enrollment data by race may be lower than the targeted/planned enrollment by race because some individuals may designate that they belong to more than one race and will report under "More Than One Race" category. In this case, you may discuss these discrepancies in an attachment to the **Inclusion Enrollment Report**.

Standards for Collecting Data from Study Participants

When you are planning collection of data on ethnicity and race, as well as sex/gender, you should use the categories listed below in obtaining the data from the individuals. The collection of greater detail is encouraged, e.g., on ethnic/racial subpopulations; however, any collection that uses more detail must be organized in such a way that the additional categories can be aggregated into these minimum categories for reporting data on ethnicity and race. Using self-report or self-identification to collect this information, you should use two separate questions, with ethnicity information collected first followed by the option to select more than one racial designation. When reporting these data in the aggregate, you should report:

(a) the number of subjects in each ethnic category;

(b) the number of subjects who selected only one category for each of the five racial categories;

(c) the total number of subjects who selected multiple racial categories reported as the "number selecting more than one race;" and,

(d) the number of subjects in each racial category who are Hispanic or Latino.

NIH and AHRQ are required to use these definitions to allow comparisons to other federal databases, especially the census and national health databases. Federal agencies shall not present data on detailed categories if doing so would compromise data quality or confidentiality standards. (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-053.html)

NOTE: The Inclusion Enrollment Report is not designed for use as a data collection instrument. You should collect data using instruments prepared for the study and use the information from the study database to fill out the enrollment report. Study participants who select two or more racial categories should be reported in the aggregate in the "More Than One Race" category.

The Office of Management and Budget (OMB) Directive No. 15 (www.whitehouse.gov/omb/fedreg/ombdir15.html) defines minimum standards for maintaining, collecting, and presenting data on ethnicity and race for all Federal (including NIH and AHRQ) reporting purposes. 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 two ethnic categories: "Hispanic or Latino," and "Not Hispanic or Latino." There are five racial categories: American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, and White. Reports of data on ethnicity and race should use these categories. NIH and AHRQ are required to use these definitions so that the data collected will allow comparisons to other Federal databases, especially the census and national health databases. The following definitions apply for the ethnic and racial categories:

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 maintains tribal affiliation or community attachment.

Asian: A person having origins in any of the original peoples of the Far East, Southern 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.

Ethnic/racial subpopulations. In addition to the OMB ethnic and racial categories, NIH uses the following definition for ethnic/racial subpopulations:

Subpopulations. Each ethnic/racial group contains subpopulations that are delimited by geographic origins, national origins, and/or cultural differences. It is recognized that there are different ways of defining and reporting racial and ethnic subpopulation data. The subpopulation to which an individual is assigned depends on self-reporting of specific origins and/or cultural heritage. Attention to subpopulations also applies to individuals who self identify with more than one ethnicity or race. These ethnic/racial combinations may have biomedical, behavioral, and/or social-cultural implications related to the scientific question under study. (http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm)

Vertebrate Animals

If Item 8 is marked "Yes" and vertebrate animals were not involved in the original application or last progress report, or if significant changes regarding the use of animals are now proposed, provide a description of the intended involvement of animals in accord with the PHS policy for use of vertebrate

animals in research (see instructions for completing Item 30b in the PHS 416-1, and the *NIH Grants Policy Statement* or the *PHS Grants Policy Statement*.) Examples of significant changes might include substitution of one animal model for another or changing from noninvasive to invasive procedures.

B. Specific Instructions for Sponsor (Parts I and II)

Part I - Form Page 1

Item 7. Human Subjects. Policy on research involving human subjects can be found in the *NIH Grants Policy Statement*, the *PHS Grants Policy Statement*, or the PHS 416-1 application instructions. Definitions pertaining to Human Subjects Research, including clinical trials, may be found in Section III.B of the PHS 416-1.

If activities involving human subjects are **not** planned **at any time** during the proposed period of the Kirschstein-NRSA Individual Fellowship, check "No." The remaining parts of Item 7 are then not applicable.

Check "Yes" if activities involving human subjects, whether or not exempt from Federal regulations for the protections of human subjects, are planned **at any time** during the requested budget period of the Kirschstein-NRSA Individual Fellowship, either at the sponsoring institution or at any other performance site.

Appropriately designating whether human subjects are involved facilitates processing of an award. Information about how the regulations apply to the proposed research may be obtained from the Office for Human Research Protections (OHRP), Department of Health and Human Services, or the program official in the NIH IC or AHRQ. NIH/AHRQ will make a final determination as to whether the proposed activities are covered by the regulations (i.e., non-exempt) or are in an exempt category.

Exempt Research. If the activities are designated to be exempt from the regulations, insert the exemption number(s) corresponding to one or more of the six exemption categories listed in the *NIH Grants Policy Statement*, the *PHS Grants Policy Statement*, the PHS 416-1 application instructions, or the Protection of Human Subject Regulations (45 CFR 46.101(b)). The remaining parts of Item 7 are then not applicable.

Non-Exempt Research. If the planned activities involving human subjects are not exempt, complete the remaining parts of Item 7. If the applicant organization has an approved Human Subjects Assurance on file with OHRP, insert the Assurance number and the most recent date of approval by the Institutional Review Board (IRB) for the proposed activities. This date must not be earlier than one year before the start date of the continuation award for which the Progress Report is submitted. **No Progress Report for Continuation Support should be submitted until the necessary certification of annual IRB review has been obtained.**

Check the type of IRB review in the appropriate box. An IRB of an institution with a Federal-Wide Assurance (FWA) or Multiple Project Assurance (MPA) may review a progress report through an expedited review procedure only if it complies with Section 46.110 of the Human Subjects Regulations at 45 CFR 46.

In many instances, a Kirschstein-NRSA Fellow will be participating in research supported by a research project grant for which IRB review of human subjects is already complete or for which an exemption is already designated. This review or exemption designation is sufficient provided the research would not be substantially modified by participation of the fellow. The appropriate grants must be identified along with their IRB review dates or exemption designation. This date must not be earlier than one year before the start date for which the progress report for continuation support is submitted. If space is insufficient in Item 7, enter "Item 15B" and provide additional information there.

Indefinite Project

If the sponsoring institution has an approved Human Subjects Assurance on file with OHRP but, at the time of this report, plans for the involvement of human subjects are so indefinite that IRB review and approval are not feasible, check "Yes" and insert "Indefinite." If continuation support is provided on the basis of this progress report, human subjects may **not** be involved until a certification of the date of IRB approval or a designation of exemption has been submitted to NIH or AHRQ.

Item 8. Vertebrate Animals

Policy on research activities involving vertebrate animals can be found in the *NIH Grants Policy Statement*, the *PHS Grants Policy Statement* or the PHS 416-1 application instructions. Information is

also available from the Office of Laboratory Animal Welfare (OLAW), (http://grants.nih.gov/grants/olaw/olaw.htm).

If activities involving vertebrate animals are **not** planned **at any time** during the proposed budget period, check "No." The remaining parts of Item 8 are then not applicable.

Check "Yes" if activities involving vertebrate animals are planned **at any time** during the budget period for which continuation support is sought at the sponsoring institution or at any other performance site. Insert the Animal Welfare Assurance number in Item 8b if the sponsoring institution has an approved Assurance on file with OLAW. In addition, **provide the latest date of approval** by the Institutional Animal Care and Use Committee (IACUC).

In many instances, a Kirschstein-NRSA Fellow will be participating in research supported by a research project grant for which the IACUC review has been obtained. This review is sufficient, provided the research would not be substantially modified by the participation of the fellow. The appropriate grant(s) must be identified along with the Assurance number and the IACUC review dates. If space is insufficient in Item 8, enter "Item 15B" and provide additional information there.

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 were indefinite, provide information on vertebrate animals may not be involved until a verification of the date of IACUC approval has been submitted to the NIH IC or AHRQ.

No progress report for continuation support should be submitted until the necessary verification of IACUC review has been obtained.

Indefinite Project

If the sponsoring institution has an approved Animal Welfare Assurance on file with OLAW but, at the time of this report, plans for the involvement of vertebrate animals are so indefinite that IACUC review and approval are not feasible, check "Yes" and insert "Indefinite." If continuation support is provided on the basis of this progress report, vertebrate animals may **not** be involved until a verification of the date of IACUC approval has been submitted to NIH or AHRQ.

Part II - Form Page 3

Item 14. Supplementation of Stipend. This refers to the provision of funds to the Kirschstein-NRSA Fellow by the institution in addition to the stipend provided by the fellowship award. By policy, no Federal funds may be used to supplement the awards unless explicitly authorized under the terms of the program from which such funds are to be derived.

Item 15. Comments of Sponsor

A. Self-explanatory.

B. For research involving human subjects, complete Item B.1. Provide additional information, as necessary, to respond to the instructions contained in Item 13, Summary of Activities.

   For research involving vertebrate animals, complete Item B.2. Provide additional information, as necessary, to respond to the instructions contained in Item 13, Summary of Activities.

Item 16. Official Signing for Sponsoring Institution. Each progress report for continuation support requires that the following policies, assurances, and certifications be verified by the Official Signing for the Sponsoring Institution in Item 16. See the PHS 416-1 application instructions for information concerning these policies, assurances, and certifications. If unable to certify compliance where applicable, provide an explanation and place it after Part II, Form Page 3.

- Human Subjects
- Research on Transplantation of Human Fetal Tissue
- Women and Minority Inclusion Policy
- Inclusion of Children Policy
- Research Using Human Embryonic Stem Cells
- Recombinant DNA and Human Gene Transfer Research
- Vertebrate Animals
- Debarment and Suspension
- Research Misconduct
- Civil Rights
- Handicapped Individuals
- Sex Discrimination
- Age Discrimination
- Financial Conflict of Interest

In signing the progress report for continuation support, the duly authorized representative of the

sponsoring institution certifies that the sponsoring institution will comply with all applicable policies, assurances, and certifications. Deliberate withholding, falsification, or misrepresentation of information could result in administrative actions such withholding of support, 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 as a result of this progress report for continuation support and for the performance of the grant-supported project or activities.