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 (PHS 416-9)

Instructions for PHS 416-9
Rev. 10/2008

Form Approved Through 10/31/2011
OMB No. 0925-0002

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NOTABLE CHANGES AND OTHER INFORMATION

Changes in Form Pages

416-9 Face Page

- Human Subjects Assurance No. changed to Federalwide Assurance No.
- Deleted fields for Full IRB or Expedited Review.
- Training Sites field updated to collect information for each project/performance site as required by the Federal Financial Accountability and Transparency Act (FFATA) of 2006 (P.L. 109-282). Addition of DUNS and Congressional District fields.
- Eliminated Applicant and Sponsor Signatures from face page. The only required signature is that of the official signing for applicant organization.

416-9 Form Page 2

- Included item for Select Agents requirement.

416-9 Form Page 3

- Updated field for Applicant Organization's Assurances/Certification.

Changes in the Instructions

Only the signed original Progress Report is required to be submitted to the centralized mailing address. No additional copy is required.

Select Agent Research

- Implementing specific requirements for Select Agents Research

NIH Public Access Policy

- Included NIH requirement of citing articles that fall under the NIH Public Access Policy when listing publications in the Progress Report summary.

Changes to instructions are highlighted as follows:

Implementation of Grants.Gov terminology

- As part of the ongoing effort to keep the PHS 416-1, 398 and the SF424 (R&R) synchronized, new terminology is implemented throughout this document. For reference, the following table is provided:

OLD TERM	NEW TERM
Competing continuation application	Renewal application
Revision or amendment [to application]	Resubmission application
Competing supplement	Revision application
Principal Investigator	Program Director/Principal Investigator
Key Personnel	Senior/key Personnel
Training Site	Project/Performance Site
Duly authorized representative	Authorized Organization Representative

Reminders

Registration Reminders

DUNS Registration for the Organization & Subaward/Consortium Organizations

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

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

FFATA also includes a requirement for reporting on subaward information. Therefore an accurate DUNS number for each additional subaward/consortium organization must also be provided.

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

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

CCR Registration for the Organization

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

CCR is a government-wide registry for organizations doing business with the U.S. Government. The registry collects, validates, stores, and disseminates data in support of agency acquisition missions,

including Federal agency contract and assistance awards. The CCR registry will be used by Federal agencies to validate the DUNS number provided. Validation of the DUNS number will be critical for agencies to comply with the requirements of the *Federal Financial Assistance Transparency Act (FFATA) of 2006* (P.L. 109-282).

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

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.

Research Training, AHRQ

Research Training activities are administered by the Division of Research Education in the Office of Extramural Research, Education and Priority Populations (OEREP). For further information on any AHRQ research training program, please contact the research training technical assistance website at http://www.ahrq.gov/fund/training/trgstaff.htm.

The PHS 416-9 form is available in electronic PDF and Word formats. 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 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.

1. Submitting your Progress Report

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 in research training based upon the stated application goals of the fellow as well as plans for the coming year.

1.1 NIH Submissions

For NIH fellowships the PHS 416-9 progress report is due 2 months before the beginning date of the next budget period and must be submitted *to the centralized mailing address*:

Division of Extramural Activities Support, OER
National Institutes of Health
6705 Rockledge Drive, Room 2207, MSC 7987
Bethesda, MD 20892-7987 (for regular or US Postal Service Express mail)
Bethesda, MD 20817 (for other courier/express mail delivery only)
Phone Number: (301) 594-6584

Submit the completed, signed original progress report (with required signature). Notify the NIH Institute/Center (IC) or AHRQ immediately if you do not intend to request continuation support.

Progress reports should only be sent to this centralized mailing address. They should no longer be submitted directly to the NIH awarding component.

NIH sponsoring institutions access a website to determine which progress reports are due. The Office of Extramural Research (OER), NIH, hosts the web site at: http://era.nih.gov/userreports/ pr_due.cfm. Sponsoring institution officials are responsible for periodically checking the list, which is updated on/around the 30th of each month. 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 of the 416-9 via Status. For more information on the NIH Commons, see: https://commons.era.nih.gov/ commons/index.jsp.

1.2 AHRQ Submissions

For AHRQ fellowships the PHS 416-9 progress report s are generally due 4 months before the beginning date of the next budget period. Grantees should check the Notice of Award and the AHRQ website for specific guidance. Progress reports must be submitted to:

Agency for Health Care Research and Quality (AHRQ)
Grants Management Branch
John M. Eisenberg Building
540 Gaither Road
Rockville, MD 20850
Phone: (301) 427-1447
Fax: (301) 427-1462

1.3 Format Specifications

For all submissions, you may substitute computer-generated facsimiles 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.

Use English only and avoid jargon and unusual abbreviations. 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.

Prepare the progress report single-sided and single-spaced staying within the margin limitations indicated on the form. *The use of an Arial, Helvetica, Palatino Linotype or Georgia typeface, a black font color and a font size of 11 points or larger are required.* These fonts will conform to appropriate formatting specifications. The print must be clear and legible.

Figures, charts, tables, figure legends, and footnotes may be smaller in size but must be black ink, readily legible, and follow the font typeface requirement.

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.

If additional support over that previously recommended is needed, use Form PHS 416-1, Ruth L. Kirschstein National Research Service Award Individual Fellowship Application (revised 10/08). You are encouraged to discuss this with your Program Official before submitting another application.

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

1.4 Grants Policy Statements

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

AHRQ uses the *HHS Grants Policy Statement* in administering its grant awards. It serves as a term and condition of award and is a compilation of the salient features of policies and various policy issues regarding the administration of PHS awards, excluding NIH awards.

1.5 Paperwork Burden

NIH estimates that it will take approximately 15 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*.

2. Preparing Your Progress Report

2.1 Specific Instructions for the Fellow (Section I)

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

Form Page 1 (Face Page)

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 in consultation with your sponsor and administrative officials at the sponsoring institution.

Item 7. Human Subjects. Policy on research involving human subjects can be found in the PHS 416-1 application instructions. Definitions pertaining to Human Subjects Research, including clinical trials, may be found in Part III, Policies, Assurances, Definitions and Other Information, 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 Training 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 at 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 Part III, Human Subjects, of 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 Federalwide 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. 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 NIH or AHRQ.

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 approval 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. Provide this additional information on continuation pages in Item 16B of the Progress Report.

If the sponsoring institution has an approved Federalwide Assurance on file with OHRP but, at the time of this progress 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 PHS 416-1 application instructions. Information is also available from the NIH 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). If an award is made, vertebrate animals may **not** be involved until a verification of the date of IACUC approval has been submitted to NIH or AHRQ.

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 approval dates. Provide this additional information on continuation pages in Item 16B of the Progress Report.

If the sponsoring institution has an approved Animal Welfare Assurance on file with OLAW but, at the time of this progress 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.

Item 9. Training Site(s). Complete only if different from the Sponsoring Institution listed in Item 4. If more than one Training (Project/Performance) Site, list all the sites, as required by the Federal Financial Accountability and Transparency Act (FFATA). One of the sites indicated must be the applicant organization.

If including a NEW Training Site where either human subjects or vertebrate animals will be involved, indicate a change on the Progress Report Summary, Form Page 2, and address the change in the Summary of Activities section, as appropriate. The applicant organization is responsible for ensuring that Training Sites operate under approved applicable Federalwide or Animal Welfare Assurances.

Item 10. Official Signing for Applicant Organization. Name of individual authorized to act for the applicant organization and to assume the obligations imposed by the Federal laws, requirements, and

conditions for a grant or grant application, including the applicable Federal regulations. Provide name, title and contact information for the signing official.

Item 11. Fellow's Telephone Contact Information. Self-explanatory.

Item 12. Corrections. If you are using a pre-populated Face Page from the eRA Commons, use this space to show any corrections to the system-generated information.

Item 13. Applicant Organization Certification and Acceptance. Original signature, in ink, is required. "For" signatures are acceptable; i.e., if the official designated to sign for the applicant organization is not available to sign, only another institutional official with formal delegated authority to act in his/her behalf may sign as "acting for" such official. However, "Per" signatures (signing as the designated official or without the formal delegation) are not acceptable. The date of signature must be included. In signing the Face Page, the authorized organization representative of the sponsoring organization certifies that the applicant organization will comply with all applicable assurances and certifications listed below. The sponsoring organization is responsible for verifying the accuracy, validity, and conformity with the most current institutional guidelines of all the administrative, fiscal, and scientific information in the progress report. Deliberate withholding, falsification, or misrepresentation of information could result in administrative actions, such as withdrawal of a progress report, suspension and/or termination of an award, debarment of individuals, as well as possible criminal penalties. The signer further certifies that the applicant organization will be accountable both for the appropriate use of any funds awarded and for the performance of the grant-supported project or activities resulting from this progress report. The sponsoring institution may be liable for the reimbursement of funds associated with any inappropriate or fraudulent conduct of the project activity.

Assurances and Certifications

Each progress report for continuation support requires that the following policies, assurances, and certifications be verified by the Sponsor and the Official Signing for the Sponsoring Institution in Item 13. See the Part III, Policies, Assurances, Definitions and Other Information, of the PHS 416-1 for information concerning these policies, assurances, and certifications. If unable to certify compliance where applicable, provide an explanation and place it after Form Page 3.

Grantees must comply with a number of additional public policy requirements. Refer to your institution's research grant administrative office or the *NIH Grants Policy Statement* (available from the NIH website at http://grants.nih.gov/grants/policy/nihgps_2003/index.htm) for additional information.

The policies, assurances and certifications listed below may or may not be applicable to your project, program, or type of applicant organization:

Human Subjects Research

Research on Transplantation of Human Fetal Tissue

Research Using Human Embryonic Stem Cells

Women and Minority Inclusion Policy

Inclusion of Children Policy

ClinicalTrials.gov Requirements

Vertebrate Animals

Debarment and Suspension

Drug-Free Workplace

Lobbying

Non-Delinquency on Federal Debt

Research Misconduct

Civil Rights

Handicapped Individuals

Sex Discrimination

Age Discrimination

Recombinant DNA Research, including Human Gene Transfer Research

Financial Conflict of Interest

Smoke-Free Workplace

Prohibited Research

Select Agent Research

Impact of Grant Activities on the Environment and Historic Properties

In signing the progress report for continuation support, the authorized organization 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.

Form Page 2

Item 14a. Permanent Mailing Address. If the information in Item 2a on the Face Page 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 Institute/Center or AHRQ grants management office*.

Item 14b. Permanent Phone Number. Self-explanatory.

Item 15. Human Subjects & Vertebrate Animals & Select Agents

To be completed in consultation with your sponsor.

Complete items A, B, and C if the research involves Human Subjects, Vertebrate Animals, or Select Agents. If “Change” is checked, provide the information below. Although no specific page limitation applies to the information on Human Subjects, Vertebrate Animals, or Select Agents, be succinct.

Human Subjects (Item A)

Check “No Change” on Form Page 2 if the protocols planned for the coming year are not different from the previous submission.

Check "Change" on the Form Page 2 if the protocols are different from those proposed in the previous submission. In item 16.C (Research Training Plans), include an explanation of how they differ and provide a new or revised Section E. “Human Subjects” from the PHS 416-1 instructions reflecting these changes; use the designated headings for Non Exempt or Exempt Human Subjects Research, as appropriate, including “Protection of Human Subjects,” “Exempt Human Subjects Research,” “Women and Minority Inclusion in Clinical Research,” ”Inclusion of Children,” and “Data and Safety Monitoring Plan.” New Protocols or Protocol changes will require IRB approval, in accord with the DHHS regulations for protection of human subjects. Provide a protocol upon request.

If human subject studies planned for the coming year were identified in the Research Training Plan of the PHS 416-1 application, but were not adequately described because they were planned for a later time within the project period, provide the “Human Subjects Research” information from the PHS 416-1 instructions as noted above.

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 Research Training Plan Section E of the PHS 416-1 application and provide the information to NIH or AHRQ.

Women and Minority Inclusion in Clinical Research

Reporting Data on Inclusion to NIH

If you are conducting clinical research (see definition in Part II, Human Subjects, 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).

Reporting data on inclusion is not included in the two-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 table.

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 Part II, Human Subjects, 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.

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)

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. An example of a format for collecting information from a study participant can be found in the "Ethnic Origin and Race" section of the Personal Data Form Page in the PHS 416-1 (http://grants.nih.gov/grants/funding/416/phs416.htm).

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 (Item B)

If there has been no change, check "No Change" on the Form Page 2.

If vertebrate animals were not involved in the original application or last progress report but are now to be included, 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 and check "Change" on the Form Page 2. Examples of significant changes might include substituting one animal model for another or changing from noninvasive to invasive procedures. If studies involving Vertebrate Animals are planned, and they were not part of the originally proposed research design, then you must comply with the requirements of Section 2.3, 7.F. "Vertebrate Animals" described in the PHS 416-1 instructions and provide the required information to NIH or AHRQ.

Select Agent Research (Item C)

Check "No Change" on Form Page 2 if the activities planned for the coming year are not different from the previous submission.

Check "Change" if proposed research involving Select Agents is different from that proposed in the previous submission. Include an explanation of how research plans differ and provide a new or revised section in Item 16.C (Research Training Plans) reflecting these changes.

If Select Agent Research planned for the coming year was described in the Research Training Plan of the PHS 416-1 application, but had not been approved by regulatory authorities, provide the Select Agent Research information requested in the PHS 416-1 instructions.

If studies involving Select Agents are planned, but were not part of the originally proposed research design, then you must provide a section on Select Agents as instructed by the PHS 416-1 Instructions.

Item 16. Summary of Activities. Identify each part of this item (16.A., B., and C.) by letter and title. Do not exceed three pages for the entire summary.

A. CHANGES

Since submission of the last application/progress report, have any significant changes occurred in the research training program, particularly the research project, academic status, or time distribution of activities (i.e., percentage of time devoted to research project, course work, teaching, etc.)? If so, explain.

B. PROGRESS

Describe concisely the research performed and research training obtained during the past year.

Responsible Conduct of Research. Every fellow must receive instruction in the responsible conduct of research (http://grants.nih.gov/grants/guide/notice-files/not92-236.html), as described in the PHS 416-1 Instructions, Research Training Plan 2.3, 7.L. Attach a description, limited to no more than one page, describing the completed instruction in the responsible conduct of research. This must include the rationale, subject matter, appropriateness, format, frequency and duration of instruction. The amount and nature of faculty participation must be described.

List all courses and publications. When citing articles that fall under the NIH Public Access Policy, http://publicaccess.nih.gov/, were authored or co-authored by the Fellow and arose from NIH support, provide the NIH Manuscript Submission reference number (e.g., NIHMS97531) or the PubMed Central (PMC) reference number (e.g., PMCID234567) for each article. If the PMCID is not yet available because the Journal submits articles directly to PMC on behalf of their authors, indicate "PMC Journal - In Process." A list of these Journals is posted at: http://publicaccess.nih.gov/submit_process_journals.htm. This policy applies to all peer-reviewed articles resulting from research supported in whole or in part with direct costs from NIH.

C. RESEARCH TRAINING PLANS

Describe concisely the research and research training planned for the requested budget period, including any course work. Include in this section any changes in Human Subjects, Vertebrate Animals, or Select Agents as noted in items 15.A, B, or C above.

2.2 Specific Instructions for Sponsor (Section II)

Form Page 3

Item 17. 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 18. Comments of Sponsor. Evaluate the quality of the research training (including academic work) and research progress made by the fellow during the past year. Include performance on cumulative and qualifying examinations, if applicable.