



*Progress Report for an Individual Fellowship*

# Ruth L. Kirschstein National Research Service Award

PHS 416-9

**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)**

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# NOTABLE AND UPCOMING CHANGES

Agencies that support research and research-related activities are mandated to implement the Research Performance Progress Report (RPPR), a uniform format for use in submission of required annual or other interim performance reporting to Federal agencies on Federally-funded grant and cooperative agreement awards. The RPPR website, <http://www.nsf.gov/bfa/dias/policy/rppr/index.jsp>, provides background information and the DHHS/NIH (and Other PHS Agencies) Implementation Plan, updated January 2012. As indicated in the Plan, the PHS implementation of the RPPR will take place over a period of time beginning in the fall of 2012 and will be implemented electronically through a module in the eRA Commons. When the RPPR is implemented for Fellowship awards it will replace use of the PHS 416-9 Ruth L. Kirschstein National Research Service Award Individual Fellowship Progress Report for Continuation Support. At that time Fellowship progress reports will be required to be submitted electronically through the eRA Commons RPPR module.

## Reminders

### Registration Reminders

#### DUNS Registration for the Grantee Organization & Subaward/Consortium Organizations

A 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 Funding Accountability and Transparency Act (FFATA) of 2006* (P.L. 109-282).

FFATA also includes a requirement for reporting on subaward information (see NIH Guide Notice [NOT-OD-11-005](#)). 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 Grantee Organization

Prior to submission of all progress reports, organizations are required to be registered in the Central Contractor Registration Database (CCR). Organizations must maintain active registration in the Central Contractor Registration Database (CCR) 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 Funding Accountability and 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/>.

For additional information regarding the use of DUNS numbers and maintaining an active CCR registration, see NIH Guide Notice NOT-OD-11-004.

## Information

### GrantsInfo, National Institutes of Health

[NIH Grants Information](#) is a communications resource service for NIH grant-related inquiries. The e-mail address is: [GrantsInfo@nih.gov](mailto:GrantsInfo@nih.gov). The phone number is (301) 435-0714, TTY (301) 451-5936.

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>.

### 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.

# 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/commons/quick\\_queries/index.cfm#progress](http://era.nih.gov/commons/quick_queries/index.cfm#progress). 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 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 eRA Commons, see: <https://commons.era.nih.gov/commons/index.jsp>.

## 1.2 AHRQ Submissions

For AHRQ fellowships the PHS 416-9 progress reports 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

## 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 the [SF424 \(R&R\) Individual Fellowship Application Guide](#). 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](#) (NIHGPS) 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 [SF424 \(R&R\) Individual Fellowship Application Guide](#). Definitions pertaining to Human Subjects Research, including clinical trials, may be found in the [Supplemental Instructions](#) to the SF424 (R&R) Individual Fellowship Application Guide.

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 [Human Subjects](#) in the Supplemental Instructions to the SF424 (R&R) Individual Fellowship Application Guide, 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 SF424 (R&R) Individual Fellowship Application Guide. 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 Funding 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 [Supplemental Instructions](#) of the SF424 (R&R) Individual Fellowship Application Guide 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](#) 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](#)

[Fellow and Sponsor Assurance](#)

[Impact of Grant Activities on the Environment and Historic Properties](#)

[Kirschstein-NRSA Payback Assurance](#)

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 as 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. Any change in mailing address of a Kirschstein-NRSA recipient must be reported promptly to the Payback Service Center until the service obligation is fully discharged. Notification of changes can be made by telephone (1-866-298-9371), e-mail to [NRSAPaybackCenter@mail.nih.gov](mailto:NRSAPaybackCenter@mail.nih.gov), or letter to:

NRSA Payback Service Center  
6011 Executive Blvd., Room 206  
Bethesda, MD 20892-7650

Any change in mailing address of an AHRQ Kirschstein-NRSA recipient should be reported promptly to the AHRQ grants management office.

Note: An eRA Commons ID is required for those in a postdoctoral role. Individuals in a postdoctoral role are strongly encouraged to maintain up-to-date contact information (including permanent address) in the Personal Profile of their eRA Commons accounts.

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

**Item 15. Human Subjects & Vertebrate Animals & Select Agents & Human Embryonic Stem Cells**

*To be completed in consultation with your sponsor.*

Complete items A, B, C, and D if the research involves Human Subjects, Vertebrate Animals, Select Agents or Human Embryonic Stem Cells. If “Change” is checked, provide the information below. Although no specific page limitation applies to the information on Human Subjects, Vertebrate Animals, Select Agents or Human Embryonic Stem Cells, 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 “Human Subjects” section in the Research Training Plan from the SF424 (R&R) Individual Fellowship Application Guide 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,” “Inclusion of Women and Minorities,” “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 SF424 (R&R) Individual Fellowship 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 [SF424 \(R&R\) Individual Fellowship Application Guide](#) 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 of the SF424 (R&R) Individual Fellowship Application Guide and provide the information to NIH or AHRQ.

**Women and Minority Inclusion in Clinical Research – Reporting Data on Inclusion to NIH**

Unless otherwise notified by the program official, reporting the cumulative enrollment of subjects and the distribution by sex/gender, race, and ethnicity is required for NIH-defined clinical research as defined in the [competing application instructions](#). If you have inclusion enrollment, update the Inclusion Enrollment Report, with the total cumulative data collected to-date. You may have more than one Inclusion Enrollment Report. If there are details or concerns related to your inclusion enrollment progress or if the enrollment data does not reflect the targeted enrollment by race, ethnicity, and/or sex/gender, the reasons for this should be addressed in the text of the progress report.

Below are instructions for how to collect and report data on the basis of sex/gender, race, and ethnicity with additional guidance for handling subpopulations, foreign populations, changes to target data, and NIH-defined Phase III clinical trials.

For questions about the NIH policies for inclusion, please refer to:

[http://grants.nih.gov/grants/funding/women\\_min/women\\_min.htm](http://grants.nih.gov/grants/funding/women_min/women_min.htm) or contact your program officer.

***Standards for Collecting Data from Study Participants:*** The [Office of Management and Budget \(OMB\) Directive No. 15](#) defines minimum standards for maintaining, collecting and presenting data on ethnicity and race for all Federal (including NIH) reporting purposes. The categories in this classification are social-political constructs and should not be interpreted as being 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. The definitions below 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.

**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.

**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, North Africa, or the Middle East.

*Reporting Data on Race and Ethnicity:* NIH is required to use the above standards and definitions for race and ethnicity 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.

When collecting data on ethnicity and race, as well as sex/gender, use the categories listed to obtain the data from individuals on the basis of self-identification. Participants should be asked to identify their ethnicity and their race. The OMB recommends collecting this information using two separate questions, with ethnicity information collected first followed by race, with the option to select more than one racial designation ([http://www.whitehouse.gov/omb/fedreg\\_directive\\_15](http://www.whitehouse.gov/omb/fedreg_directive_15)). **The Inclusion Enrollment Report format is not designed for use as a data collection instrument.** Collect the

data using instruments prepared for the study and use the information from the study database to fill out the Inclusion Enrollment Report. Study participants who self-identify with more than one race should be reported in the aggregate in the "More Than One Race" category.

When reporting these data to NIH, include the following items:

Part A of the Inclusion Enrollment Report:

- a) the total number of subjects in each ethnic category or who did not self-identify with an ethnic category (unknown or not reported);
- b) the total number of Hispanic or Latino and Not Hispanic or Latino subjects who selected only one category from each of the five racial categories;
- c) the total number of Hispanic or Latino and Not Hispanic or Latino subjects who selected more than one racial category reported as the number selecting "more than one race";
- d) the total number of Hispanic or Latino and Not Hispanic or Latino subjects who did not self-identify with any racial category (unknown or not reported); and,

Part B of the Inclusion Enrollment Report:

- a) the total number of Hispanic or Latino subjects who selected only one of the five racial categories as well as Hispanic or Latino subjects who selected more than one racial category or who did not self-identify with a racial category (unknown or not reported).

In completing the race sections of the Inclusion Enrollment Report, individuals who identify as Hispanic or Latino should be included in both race tables: the table where all participants' races are reported (Part A) and the table where only the race of individuals identifying as Hispanic or Latino is reported (Part B).

**Collecting and Reporting Data on 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. The collection of greater detail is encouraged, e.g., on ethnic/racial subpopulations; however, any collection that uses more detail needs to be organized in such a way that the additional categories can be aggregated into the OMB categories for reporting data on ethnicity, race, and more than one race. Investigators who have data on subpopulations are encouraged to provide that information in the Comments field of the Inclusion Enrollment Report and/or in the text of their progress report.

**Collecting and Reporting Data on Foreign Populations:** If conducting clinical research outside of the United States, design culturally sensitive and appropriate data collection instruments that allow participants to self-identify their ethnic and/or racial affiliation. These items, however, should be designed in a way that allows the information to be aggregated into the OMB minimally required ethnic and racial categories and which will allow you to complete the inclusion enrollment report(s).

**Enrollment of foreign participants should be reported to NIH in an Inclusion Enrollment Report separate from that for reporting domestic participants.**

**Changes to Targeted/Planned Enrollment:** If there are changes from the Targeted/Planned Enrollment Table originally approved for funding, contact your Program Officer to discuss

updating/revising your Targeted/Planned Enrollment Table and address the change in the text of your progress report.

**Reporting Data on NIH-defined Phase III Clinical Trials:** If conducting an NIH-defined Phase III Clinical Trial, report on the cumulative enrollment (as described above) and indicate if data analysis has begun for the trial. If analysis has begun, report on progress made in conducting valid analyses for sex/gender, racial, and/or ethnic differences.

### ***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 for Vertebrate Animals described in the SF424 (R&R) Individual Fellowship Application Guide 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 Individual Fellowship Application, but had not been approved by regulatory authorities, provide the Select Agent Research information requested in the SF424 (R&R) Individual Fellowship Application Guide.

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 SF424 (R&R) Individual Fellowship Application Guide.

### ***Human Embryonic Stem Cells (Item D)***

Check "No Change" on Form Page 2 (Individual Fellowship Progress Report for Continuation Support) if activities involving Human Embryonic Stem Cells (hESC) are not different from the previous submission.

Check "Change" on Form Page 2 (Individual Fellowship Progress Report for Continuation Support) if proposed research involving hESCs is different from that proposed in the previous submission, including use of a different cell line(s). Include an explanation of how research plans differ, and if different cell lines are to be used, provide a new or revised section in Item 16.C (Research Training Plans) reflecting these changes, including the cell line number(s). Only cell lines listed on the [NIH hESC Registry](#) as approved for use in NIH funded research may be used.

**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 (see NIH Guide Notice [NOT-OD-10-019](http://www.nih.gov/not-od-10-019)), as described in the Supplemental Instructions to the SF424 (R&R) Individual Fellowship Application Guide. 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](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, Select Agents or Human Embryonic Stem Cells as noted in items 15.A, B, C or D 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.