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Glossary & Acronyms	

NIH Grants Policy Statement

(10/11)

Part II: Terms and Conditions of NIH Grant Awards Subpart B: Terms and Conditions for Specific Types of Grants, Grantees, and Activities – File 3 of 11

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11 RUTH L. KIRSCHSTEIN NATIONAL RESEARCH SERVICE AWARDS

11.1 GENERAL

This chapter includes general information about Kirschstein-NRSA individual fellowships and institutional research training grants. Separate but all inclusive sections are provided for each; therefore some information may appear duplicative but is provided separately so that nuances between individual fellowships and institutional training grants are covered. Many of the requirements of IIA also apply; this chapter of IIB includes appropriate cross-references to IIA when applicable.

11.1.1 Background

Section 487 of the PHS Act (42 U.S.C. 288) provides authority for NIH to award Kirschstein-NRSA individual fellowships to support predoctoral and postdoctoral training of individuals to undertake biomedical, behavioral, or clinical research at domestic and foreign, public and private institutions (profit and non-profit). Section 487(a)(1)(B) authorizes Kirschstein-NRSA institutional research training grants and limits institutional Kirschstein-NRSA support to training and research at domestic public and non-profit private entities. The legislation requires recipients to pay back to the Federal government their initial 12 months of Kirschstein-NRSA postdoctoral support by engaging in health-related biomedical, behavioral and/or clinical research, research training, health-related teaching, or any combination of these activities. (See Payback Requirements in this chapter.) The regulations at 42 CFR part 66 apply to these awards.

11.1.2 Nondiscrimination

The Kirschstein-NRSA program is conducted in compliance with applicable laws that provide that no person shall, on the grounds of race, color, national origin, handicap, or age, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity (or, on the basis of sex, with respect to any education program or activity) receiving Federal assistance. Applicant organizations are required to have appropriate Assurance of Compliance forms filed with HHS's OCR before a grant may be made to that institution. The NIH awarding IC should be contacted if there are any questions concerning compliance. (See Public Policy Requirements and Objectives—Civil Rights in IIA for detailed requirements.)

11.2 INDIVIDUAL FELLOWSHIPS

11.2.1 General

The Kirschstein-NRSA program helps ensure that a diverse pool of highly trained scientists is available in adequate numbers and in appropriate research areas to carry out the Nation's biomedical and behavioral research agenda. Fellowship activities can be in basic biomedical or clinical sciences, in behavioral or social sciences, in health services research, or in any other discipline relevant to the NIH mission. Under this authority, NIH awards individual postdoctoral fellowships (F32) to promising applicants with the potential to become productive, independent investigators in fields related to the mission of the NIH ICs. Some specialized individual pre-doctoral fellowships (F31), and other unique fellowship programs also are provided under this authority. For individual predoctoral fellowships, NIH ICs have differing requirements; specific FOAs should be consulted for guidance.

Kirschstein-NRSA fellowships are awarded as a result of national competition for research training in specified health-related areas. All NIH ICs except FIC and NLM award Kirschstein-NRSA fellowships. FIC and NLM have unique funding authorities for fellowships that are not under the Kirschstein-NRSA authority.

11.2.2 Eligibility

11.2.2.1 Research Areas

Kirschstein-NRSA fellowships may be made for research training in areas that fall within the missions of the NIH ICs. Applications that do not address these areas will be returned. An increased emphasis has been placed on the research training of physicians. The HHS Secretary is required by law, in taking into account the overall national needs for biomedical research personnel, to give special consideration to physicians who agree to undertake a minimum of 2 consecutive years of biomedical, behavioral, or clinical research training. NIH recognizes the critical importance of training clinicians to become researchers and encourages them to apply. For those who have a doctoral-level health professional degree, the proposed training may be used to satisfy a portion of the degree requirements for a master's degree, a doctoral degree, or any other advanced research degree program.

11.2.2.2 Research Training Program

The Kirschstein-NRSA fellowship must be used to support a program of research training. It may not support studies leading to M.D., D.O., D.D.S., D.V.M., or other similar clinical, health professional degrees except when those studies are part of a formal combined research degree program such as the M.D./Ph.D. Similarly Kirschstein-NRSA fellowships may not support the clinical portion of residency training. Research

fellows in clinical areas are expected to devote full time effort to the proposed research training and to confine clinical duties to those that are part of the research training.

11.2.2.3 Degree Requirements

<u>Predoctoral Training.</u> Individuals must have received, as of the activation date of their Kirschstein-NRSA pre-doctoral fellowship award, a baccalaureate degree and must be enrolled in and training at the postbaccalaureate level in a program leading to the award of a Doctor of Philosophy of Science (Ph.D. or Sc.D.) or a combined clinical degree and Ph.D. degree such as M.D./Ph.D.

Postdoctoral Training. Before a Kirschstein-NRSA postdoctoral fellowship award can be activated, individuals must have received a Ph.D., M.D., D.D.S, D.M.D., D.C., D.O., D.V.M., O.D., D.P.M., Sc.D., Eng.D., Dr. P.H., D.N.Sc., D.P.T., Pharm.D., N.D., D.S.W., Psy.D., or equivalent doctoral degree from an accredited domestic or foreign institution. Also acceptable is a statement by an AOR of the degree-granting institution that all degree requirements have been met. It is the responsibility of the sponsoring institution, not the NIH, to determine if a foreign degree is equivalent.

Senior Fellows. As of the beginning date of their award, senior fellows must have a doctoral degree (as specified in Postdoctoral training referenced above) and at least 7 subsequent years of relevant research and professional experience. The senior fellowship is awarded to provide opportunities for experienced scientists to make major changes in the direction of their research careers or to broaden their scientific backgrounds by acquiring new research capabilities. In addition, these awards will enable individuals who are beyond the new investigator stage to take time from regular professional responsibilities to enhance their capabilities to engage in health-related research. Senior fellowships are made for full-time research training. Health professionals may use some of their time in clinical duties as part of their research training. More information on the senior fellowship program can be found in the NIH Kirschstein-NRSA Senior Fellows (F33) program announcement available on the NIH Web site at http://grants.nih.gov/training/nrsa.htm - fellowships.

11.2.2.4 Citizenship

The individual to be trained must be a citizen or a noncitizen national of the United States or have been lawfully admitted for permanent residence by the time of award. Noncitizen nationals are individuals, who, although not citizens of the United States, owe permanent allegiance to the United States. They generally are people born in outlying possessions of the United States (e.g., American Samoa and Swains Island). Individuals who have been lawfully admitted for permanent residence must have a currently valid Permanent Resident Card (USCIS Form I-551) or other legal verification of such status. For example, if an individual has the proper validation on his/her passport, a notarized photocopy of the passport could suffice. Because there is a 6-month limitation on this validation, it is the responsibility of the sponsoring institution to follow up and ensure that the individual receives the I-551 before the 6-month expiration date.

An individual expecting to be admitted as a permanent resident by the earliest possible award date listed in the Kirschstein-NRSA individual fellowship program announcement may submit an application for a fellowship. The submission of documentation concerning permanent residency is not required as part of the initial application. Any fellowship applicant selected to receive an award must provide a notarized statement of admission for permanent residence prior to award.

Fellowship applicants who have been lawfully admitted for permanent residence, i.e., have a Permanent Resident Card or other legal verification of such status, should check the Permanent Resident box in the citizenship section on the PHS Fellowship Supplemental Form of the fellowship application. Fellowship applicants who have applied for and have not yet been granted admission as a permanent resident should check the box indicating Permanent Resident of U.S. Pending.

Individuals with a Conditional Permanent Residency Status may still apply for individual fellowships. However, in all cases when permanent residency status is involved, it is the responsibility of the sponsoring institution to assure the individual remains eligible for NRSA support for the period of time of any award.

Individuals with Asylum/Refugee status do not automatically hold a type of permanent residency status; they have the opportunity to apply for permanent residency status once they have been in the U.S. for a period of time. Therefore, individuals with Asylum/Refugee status should only submit an individual fellowship application once they have applied for permanent residency status.

When an application involving Permanent Residency is selected to receive an award, prior to any award being issued, a notarized statement will be required that documents that a licensed notary has seen the individual's valid Permanent Resident Card or other valid verification from the U.S. Immigration and Naturalization Service of legal admission to the U.S.

Individuals on temporary or student visas are not eligible to apply for Kirschstein-NRSA individual fellowships unless they have begun the process for becoming a permanent resident and expect to be admitted as a permanent resident by the earliest possible award date.

11.2.2.5 Sponsorship

General. Before submitting a Kirschstein-NRSA individual fellowship application, the fellowship applicant must identify a sponsoring institution and an individual who will serve as a sponsor (also called mentor or supervisor) and supervise the training and research experience. The sponsoring institution may be domestic or foreign, public or private (for-profit or non-profit), including the NIH intramural programs, other Federal laboratories, and units of State and local governments. The sponsoring institution is legally responsible for providing facilities for the applicant and financially responsible for the use and disposition of any funds awarded based on the application. The sponsor should be an active investigator in the area of the proposed research who will directly supervise the fellow's research. The sponsor must document in the application the training plan for the applicant as well as the availability of staff, research support, and facilities for high-quality research training. In most cases, postdoctoral fellowships support research training experiences in new settings in order to maximize acquisition of new skills and knowledge. Therefore, postdoctoral fellowship applicants proposing training at their doctoral institution must document thoroughly the opportunity for new training experiences designed to broaden their scientific backgrounds. In addition, the application should propose research experiences that will allow the fellow to acquire new knowledge and/or technical skills that will enhance his/her potential to become a productive, independent investigator.

Foreign Sponsorship. An individual may request support for training abroad. In such cases, the fellowship applicant is required to provide detailed justification for the foreign training, including the reasons why the facilities, the mentor, or other aspects of the proposed experience are more appropriate than training in a domestic setting. The justification is evaluated in terms of the scientific advantages of the foreign training as compared to the training available domestically. Foreign training may require additional administrative reviews and will be considered for funding only when the scientific advantages are clear.

11.2.2.6 NIH Employees & Other Federal Sponsorship (Federal Fellows)

Both civil service employees and PHS commissioned officers at NIH and other Federal laboratories are permitted to compete for predoctoral and postdoctoral fellowships. The proposed training should be primarily for career development rather than for the immediate research needs

of NIH or the other Federal laboratory. When at an NIH laboratory, the employee's supervisor must disassociate himself/herself from the review and award process.

An individual at NIH or another Federal laboratory who is supported under an individual fellowship may not also hold an employee position with the Federal Government. Therefore, successful fellowship applicants for predoctoral or postdoctoral awards must either resign from NIH or the other Federal laboratory or take LWOP before activating the award. (There is no obligation or commitment by either the Federal agency or the fellow for future employment upon termination of the fellowship.)

Support provided for Federal fellows is similar to those at non-Federal sponsoring institutions; stipends, tuition (when applicable), and institutional allowance are provided. However, the administration and payment of these fellowships is unique. Specifics are noted in the applicable sections below.

11.2.2.7 Individuals on Active Military Duty

NIH does not restrict career military personnel from applying for Kirschstein-NRSA individual fellowship awards while on active military duty. At the time of application, the fellowship applicant's branch of the military service should submit a letter endorsing his/her application and indicating willingness to continue normal active duty pay and allowances during the period of the requested fellowship. If an award is made, the institutional allowance and necessary tuition and fees permitted on a postdoctoral program will be paid by NIH. However, stipends, health insurance, and travel allowances are not allowable charges to a Kirschstein-NRSA individual fellowship for career military personnel. Payment of concurrent benefits by NIH to active duty career military awardees is not allowed.

11.2.3 Application Requirements and Receipt Dates

11.2.3.1 Application

Each fellowship applicant must submit an application based on the application package provided as part of the FOA. Individual fellowship applications are submitted electronically through Grants.gov using an application package that combines form components from the SF424 (R&R) application with the PHS Fellowship Supplemental Form.

The major emphasis of the application should be the research training experience and broadening of scientific competence. The AOR of the sponsoring institution agrees to secure and retain, but need not submit to NIH, the assurance signatures of the fellowship applicant and sponsor. The assurance of the fellowship applicant includes certification that he or she has read the payback information and will meet any payback provisions required under the law as a condition for accepting the award.

Fellowship applicants and sponsoring institutions must comply with policies and procedures governing such requirements as civil rights; the protection of human subjects, including data and safety monitoring requirements; research misconduct; the humane care and use of live vertebrate animals; the inclusion of women, minorities and children in study populations; human embryonic stem cells; and recombinant DNA and gene transfer research. (For a complete list of applicable requirements, see Exhibit 4, Public Policy Requirements, Objectives and Appropriation Mandates in IIA.)

11.2.3.2 eRA Commons Registration

All fellowship applicants and sponsoring institutions must be registered in the eRA Commons. The fellowship applicant must be assigned the "PI Role" in the eRA Commons. Only the PI Role will provide the fellowship applicant with the appropriate access in the eRA Commons to the application and review information. When a prospective fellowship applicant is submitting an application through a sponsoring institution that is different than their current institution, that individual must be affiliated with the sponsoring institution. Additional information on eRA Commons registration and affiliating individuals with different institutions can be found at https://commons.era.nih.gov/commons/registration/registrationInstructions.jsp.

11.2.3.3 Letters of Reference

As part of an application submission, at least three (but no more than five) letters of reference on behalf the fellowship applicant also must be submitted. Electronic submission of the fellowship application incorporates a separate, yet simultaneous electronic submission process for reference letters through the eRA Commons. Reference letters are submitted directly by the referee through the eRA Commons and not as part of the electronic application submitted through Grant.gov. Reference letters will be joined with the electronic application within the eRA system once an application completes the submission process. Applications that are missing the required letters may be delayed in the review process or not accepted. Applicants must carefully follow the instructions provided in Part I, Section 5.4 of the Individual Fellowship Application Guide found at: http://grants.nih.gov/grants/funding/424/index.htm. The Application Guide includes specific instructions to be sent to prospective referees.

11.2.3.4 Responsible Conduct of Research

All fellowship applicants must include a plan to obtain instruction in the responsible conduct of research. This section plan should document prior instruction in responsible conduct of research during the applicant's current career stage (including the date of last occurrence) and propose plans to receive instruction in responsible conduct of research. Such plans must address the five instructional components, format, subject matter, faculty participation, duration of instruction, and frequency of instruction, as outlined and explained below. The plan may include career stage-appropriate, individualized instruction or independent scholarly activities that will enhance the applicant's understanding of ethical issues related to their specific research activities and the societal impact of that research. The role of the sponsor/mentor in responsible conduct of research instruction must be described. Applications lacking a plan for instruction in responsible conduct of research will be considered incomplete and may be delayed in the review process.

- Format. Substantial face-to-face discussions between the fellow, other individuals in a similar training status and sponsors plus a
 combination of didactic and small-group discussions (e.g. case studies), are highly encouraged. While on-line courses can be a
 valuable supplement to instruction in responsible conduct of research, online instruction is not considered adequate as the sole
 means of instruction. A plan that employs only online coursework for instruction in responsible conduct of research will not be
 considered acceptable.
- 2. <u>Subject Matter</u>. While there are no specific curricular requirements for instruction in responsible conduct of research, the following topics have been incorporated into most acceptable plans for such instruction:
 - a. conflict of interest personal, professional, and financial
 - b. policies regarding human subjects, live vertebrate animal subjects in research, and safe laboratory practices

- c. sponsor/fellow responsibilities and relationships
- d. collaborative research including collaborations with industry
- e. peer review
- f. data acquisition and laboratory tools; data management, sharing and ownership
- g. research misconduct and policies for handling misconduct
- h. responsible authorship and publication
- i. the scientist as a responsible member of society, contemporary ethical issues in biomedical research, and the environmental and societal impacts of scientific research

While courses related to professional ethics, ethical issues in clinical research, or research involving vertebrate animals may form a part of instruction in responsible conduct of research, they generally are not sufficient to cover all aspects of responsible research conduct.

- Faculty Participation. Sponsors and other appropriate faculty are highly encouraged to contribute both to formal and informal instruction in responsible conduct of research. Informal instruction occurs in the course of laboratory interactions and in other informal situations throughout the year. Sponsors may contribute to formal instruction in responsible conduct of research as discussion leaders, speakers, lecturers, and/or course directors.
- 4. <u>Duration of Instruction</u>. Instruction should involve substantive contact hours between the fellow, sponsor and other appropriate faculty. Acceptable programs generally involve at least eight contact hours. A semester-long series of seminars/programs may be more effective than a single seminar or one-day workshop because it is expected that topics will then be considered in sufficient depth, learning will be better consolidated, and the subject matter will be synthesized within a broader conceptual framework.
- 5. Frequency of Instruction. Reflection on responsible conduct of research should recur throughout a scientist's career: at the undergraduate, post-baccalaureate, predoctoral, postdoctoral, and faculty levels. Individual fellows are strongly encouraged to consider how to optimize instruction in responsible conduct of research for the particular career stage(s) of the individual(s) involved. Instruction must be undertaken at least once during each career stage, and at a frequency of no less than once every four years. It is highly encouraged that initial instruction during predoctoral training occurs as early as possible in graduate school. Senior fellows may fulfill the requirement for instruction in responsible conduct of research by participating as lecturers and discussion leaders. To meet the above requirements, instruction in responsible conduct of research may take place, in appropriate circumstances, in a year when the fellow award recipient is not actually supported by an NIH grant. This instruction must be documented in the submitted plan.

11.2.3.5 Concurrent applications

An individual may not have two or more competing Kirschstein-NRSA individual fellowship applications pending review concurrently. In addition, CSR will not accept for review any application that is essentially the same as one already reviewed.

11.2.3.6 Receipt Dates

Kirschstein-NRSA individual fellowship applications undergo a review process that takes 5 to 8 months. The annual schedule for application receipt, review, and award can be found in a specific Funding Opportunity Announcement and at http://grants.nih.gov/grants/funding/submissionschedule.htm.

11.2.4 Review

Each new and renewal application will be evaluated for scientific merit by an NIH SRG.

11.2.4.1 Overall Impact

Reviewers will provide an overall impact/priority score to reflect their assessment of the likelihood that the fellowship will enhance the fellowship applicant's potential for, and commitment to, a productive independent scientific research career in a health-related field, in consideration of the scored and additional review criteria (as applicable for the project proposed).

Individual Fellowship programs are training awards and not research awards. Major considerations in the review are the candidate's potential for a productive career, the candidate's need for the proposed training, and the degree to which the research training proposed, the sponsor, and the environment will satisfy those needs.

11.2.4.2 Scored Review Criteria

Reviewers will consider each of the five review criteria below in the determination of scientific and technical merit, and give a separate score for each. The following review criteria are applicable primarily to F31 and F32 applications. For review criteria pertaining to other individual fellowship applications (e.g., F05, F30, F33), please refer to the specific FOA.

- *Fellowship Applicant*. Are the applicant's academic record and research experience of high quality? Does the applicant have the potential to develop as an independent and productive researcher in biomedical, behavioral or clinical science?
- **Sponsor(s)**. **Collaborator(s)**, and **Consultant(s)**. Are the sponsor(s) research qualifications (including successful competition for research support) and track record of mentoring appropriate for the proposed fellowship? Are there (1) evidence of a match between the research interests of the applicant and the sponsor (including an understanding of the applicant's research training needs) and (2) a demonstrated ability and commitment of the sponsor to assist in meeting these needs? Are the qualifications of any collaborator (s) and/or consultant(s), including their complementary expertise and previous experience in fostering the training of fellows, appropriate for the proposed research project?
- <u>Research Training Plan</u>. Is the proposed research plan of high scientific quality, and does it relate to the applicant's training plan? Is the training plan consistent with the candidate's stage of research development? Will the research training plan provide the applicant with individualized and supervised experiences that will develop research skills needed for his/her independent and productive research career?

- **Training Potential.** Does the proposed research training plan have the potential to provide the fellow with the requisite individualized and supervised experiences that will develop his/her research skills? Does the proposed research training have the potential to serve as a sound foundation that will lead the fellow to an independent and productive career?
- Institutional Environment and Commitment to Training. Are the research facilities, resources (e.g. equipment, laboratory space, computer time, subject populations), and training opportunities adequate and appropriate? Is the institutional environment for the scientific development of the applicant of high quality, and is there appropriate institutional commitment to fostering the fellows' training as an independent and productive researcher?

11.2.4.3 Additional Review Criteria

As applicable for the project proposed, reviewers will consider the following additional items in the determination of scientific and technical merit but will not give separate scores for these items.

• **Protections for Human Subjects.** For research that involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials.

- **Inclusion of Women, Minorities, and Children.** When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children.
- Vertebrate Animals. The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For additional information, see http://grants.nih.gov/grants/olaw/VASchecklist.pdf.
- **<u>Biohazards</u>**. Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.
- <u>Resubmission Applications</u>. When reviewing a Resubmission application the committee will evaluate the application as now
 presented, taking into consideration the responses to comments from the previous SRG and changes made to the project.
- **Renewal Applications.** When reviewing a Renewal application the committee will consider the progress made in the last funding period.

11.2.4.4 Additional Review Considerations

As applicable for the project proposed, reviewers will address each of the following items, but will not give scores for these items and should not consider them in providing an overall impact/priority score.

- <u>Training in the Responsible Conduct of Research.</u> Reviewers will evaluate plans for instruction in responsible conduct of research as well as the past record of instruction in responsible conduct of research, where applicable. Reviewers will specifically address the five Instructional Components (Format, Subject Matter, Faculty Participation, Duration of Instruction, and Frequency of Instruction) as detailed in Application Requirements—Responsible Conduct of Research in this chapter. Applications with unacceptable plans will not be funded until the applicant provides an acceptable, revised plan.
- <u>Select Agents Research</u>. Reviewers will assess the information provided in this section of the application, including; 1) the select agent(s) to be used in the proposed research, 2) the registration status of all entities where select agent(s) will be used, 3) the procedures that will be used to monitor possession use and transfer of select agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the select agent(s).
- <u>Resource Sharing Plans</u>. Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: 1) Data Sharing Plan; 2) Sharing Model Organisms; and 3) Genome Wide Association Studies (GWAS).
- **<u>Budget and Period Support</u>**. Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research training.
- **Foreign Sponsoring Institutions.** For applications at foreign sponsoring institutions the reviewers will also assess whether the research training experience presents special opportunities for the fellowship applicant through the use of talent (e.g., mentor) resources, populations (if applicable), or training environment that are not readily available in the U.S. or augment existing U.S. talent and/or resources.

11.2.4.5 Secondary Level of Review

Kirschstein-NRSA individual fellowship applications receive a secondary level of review by IC staff. Criteria used in making award decisions include the SRG's recommendation concerning the overall merit of the application, the relevance of the application to the IC's research training priorities and program balance, and the availability of funds.

11.2.5 Notification of Action

Shortly after the initial review meeting, each fellowship applicant receives an e-mail indicating that the SRG recommendation/priority score is available in the eRA Commons. The fellowship applicant is also notified via an e-mail when the summary statement is available in the eRA Commons.

The PO may notify the fellowship applicant about the final review recommendation. All questions about initial review recommendations and funding possibilities should be directed to the designated IC PO, not to the SRO of the SRG. Name and contact information of the assigned PO is also available in the eRA Commons. If the application is under consideration for funding, NIH will request any additional necessary information from the applicant. After all program and administrative issues have been resolved, the NoA will be issued for those selected for funding.

11.2.6 Period of Support

No individual may receive more than 5 years of aggregate Kirschstein-NRSA support at the predoctoral level and 3 years of aggregate Kirschstein-NRSA support at the postdoctoral level, including any combination of Kirschstein-NRSA support from institutional research training grants and individual fellowships.

Any exception to the maximum period of support requires a waiver from the NIH awarding IC based on review of a justification from the individual and sponsoring institution. The AOR of the sponsoring institution must make the request in writing to the NIH awarding IC on behalf of the fellow, and must secure and retain, but need not submit to NIH, the fellow and sponsor's signatures. The request must specify the amount of additional support for which approval is sought. Individuals seeking additional support beyond the third year of postdoctoral support are strongly advised to consult with their PO before submitting a waiver request.

Some generally recognized categories under which NIH may grant exceptions include the following:

- <u>Physicians/Clinicians.</u> Individuals requiring additional time to complete training, either as participants in a combined M.D./Ph.D. program or as clinicians (e.g., physicians, dentists, veterinarians) who are completing postdoctoral research training. An exception is contingent upon an assurance of the recipient's good academic standing and justified.
- **Interruptions (Break in Service).** Requests for additional time also will be considered if an event unavoidably alters the planned course of the research training, if the interruption has significantly detracted from the nature or quality of the planned research training, and if a short extension would permit completion of the training as planned. Such events include sudden loss of the preceptor's services or an accident, illness, or other personal situation, which prevent a fellow from effectively pursuing research training for a significant period of time. Requests for extension of support also will be considered if a short additional period would provide the fellow an opportunity to use an exceptional training resource directly related to the approved research training program.

Requests for additional time that do not arise from either of the above-described circumstances will be considered only if they are accompanied by an exceptionally strong justification.

11.2.7 Full-Time and Part-Time Training

All fellows are required to pursue their research training full time. Full-time is generally defined as devoting at least 40 hours per week to research training activities or as specified by the sponsoring institution in accordance with its own policies.

<u>Part-Time Training</u>. While NRSA fellows are required to pursue training full-time, under certain circumstances, a written request may be submitted to the NIH awarding IC to permit less than full-time training.

Written requests for part-time training will be considered on a case by case basis and must be approved by the NIH awarding IC in advance of each budget period. The circumstances requiring part-time training might include medical conditions, disability, or personal or family situations such as a child or elder care. Part-time training will not be approved to accommodate other sources of funding, job opportunities, clinical practice, clinical training, or responsibilities associated with the fellow's position at the sponsoring institution.

Each written request is submitted on behalf of the fellow by an AOR and must include documentation supporting the need for part-time training. The sponsoring institution must secure and retain, but need not submit to NIH, countersignatures of the fellow and sponsor prior to submission to NIH. The written request also must include an estimate of the expected duration of the period of part-time training and assurances that the fellow intends to return to full-time training when that becomes possible and intends to complete the proposed research training program. In no case will it be permissible for the fellow to be engaged in Kirschstein-NRSA support for less than 50 percent effort. Individuals who must reduce their commitment to less than 50 percent effort must take a leave of absence from Kirschstein-NRSA fellowship support.

NIH will issue a revised NoA with prorated stipend for the period of any approved part-time training. Part-time training may affect the rate of accrual or repayment of the service obligation for postdoctoral fellows.

11.2.8 Initiation of Support

11.2.8.1 Process

The NIH IC will notify the fellowship applicant of the intention to make an award and confirm the plans for the start of fellowship support. The individual may activate the fellowship on or after the issue date of the NoA up to the latest activation date shown in the NoA (generally 6 months after the award issue date). This timing allows the individual to make arrangements, such as the completion of degree requirements, coordination with the sponsor, and, if necessary, a move to the sponsoring institution. The latest activation date may be extended in unusual circumstances. Written requests for extensions should be submitted to the NIH awarding IC, by the AOR of the sponsoring institution. The sponsoring institution must secure and retain, but need not submit to NIH, signatures of the fellowship applicant and sponsor before the request is submitted to NIH.

The Activation Notice must be submitted to the NIH awarding IC as of the day the individual begins training. A Payback Agreement also must be completed and submitted but only by postdoctoral fellows in their first 12 months of Kirschstein-NRSA postdoctoral support. See Reporting Requirements—Activation Notice and Reporting Requirements—Payback Agreement in this chapter. A stipend may not be paid until the forms are submitted and the fellow begins training. If necessary for payroll purposes, the Activation Notice and Payback Agreement may be submitted up to 30 days before the start date. However, any change in the planned activation start date must be reported immediately to the sponsoring institution's business office and to the NIH awarding IC. If an award is conditioned upon completion of degree requirements, the fellow must submit, with the Activation Notice, proof of completion by the degree-granting institution.

Generally, individual fellowship support is approved for consecutive years of training. The initial award budget period is usually for 12 months. Subsequent periods of approved fellowship training are consecutive with the first year of support and are usually in 12-month increments (budget periods). Awards for less than 12 months will be prorated accordingly. If a fellow decides not to activate the award, or to terminate early, he or she must notify the institution's business office, the sponsor, and the NIH awarding IC immediately, in writing. NIH will make any necessary adjustments in the stipend and other costs, including the institutional allowance.

11.2.8.2 Payment

Domestic. Non-Federal sponsoring institutions receive an award for the stipend, institutional allowance, and tuition and fees (when applicable). The institution directly pays the fellow and disburses all other awarded costs.

Federal Laboratories. Fellows training at Federal laboratories are paid stipends directly by the NIH awarding IC through NIH's OFM. Reimbursement to the fellow for appropriate expenditures from the institutional allowance also is coordinated by the NIH awarding IC and paid through OFM. Note, if a fellow is training at a facility that is Government-owned but Contract operated, this is not considered a Federal laboratory. As with other grants to these types of facilities, the sponsoring institution would be the contractor.

Foreign. Fellows training at foreign sites receive stipends directly from NIH's OFM. However, the institutional allowance is awarded to and disbursed by the sponsoring institution.

11.2.9 Allowable and Unallowable Costs

11.2.9.1 Pre-award Costs

Pre-award costs to an individual fellowship are limited. Stipends and tuition and fees may not be charged to a fellowship award until a fellow has actually activated and the appropriate paperwork submitted to the NIH. Therefore, these costs may never be charged as pre-award to an individual fellowship. There are rare occasions when costs associated with the institutional allowance may be allowable as pre-award costs. Sponsoring institutions should consult with the NIH awarding IC when considering a pre-award cost.

11.2.9.2 Stipends

A stipend is provided as a subsistence allowance for Kirschstein-NRSA fellows to help defray living expenses during the research training experience. It is not provided as a condition of employment with either the Federal government or the sponsoring institution. Stipends must be paid in accordance with stipend levels established by NIH, which are based on a 12-month full-time training appointment. In the event of early termination, the stipend will be prorated according to the amount of time spent in training. The sponsoring institution will submit a Termination Notice reflecting the early termination and the NIH awarding IC will issue a revised NoA to decrease approved funding. The sponsoring institution must base its calculations on the applicable stipend level provided by the NIH.

11.2.9.3 Stipend Levels

Stipend levels are updated periodically in conjunction with an NIH annual appropriation. When increases are approved, they are published in the *NIH Guide for Grants and Contracts*. Current levels are posted at http://grants.nih.gov/training/nrsa.htm. The NIH awarding IC will adjust fellowship awards on their anniversary dates to include the currently applicable stipend amount.

General information related to stipends follows:

- Predoctoral. One stipend level is used for all pre-doctoral candidates, regardless of the level of experience.
- <u>Postdoctoral</u>. The stipend level for the entire first year of support is determined by the number of full years of relevant postdoctoral experience when the award is issued. Relevant experience may include research experience (including industrial), teaching assistantship, internship, residency, clinical duties, or other time spent in a health-related field beyond that of the qualifying doctoral degree. Once the appropriate stipend level has been determined, the fellow must be paid at that level for the entire grant year. The stipend for each additional year of Kirschstein-NRSA support is the next level in the stipend structure and does not change mid-year.
- Senior Fellows. The amount of the Kirschstein-NRSA stipend to be paid must be commensurate with the base salary or
 remuneration that the individual receiving the award would have been paid by the institution with which he or she has permanent
 affiliation on the issue date of the fellowship award. In no case shall the stipend award exceed the current Kirschstein-NRSA stipend
 limit set by NIH. The level of Kirschstein-NRSA support will take into account concurrent salary support provided by the institution
 and the policy of the sponsoring institution. NIH support does not provide fringe benefits for senior fellows.

11.2.9.4 Institutional Allowance

NIH awards an institutional allowance to help support the costs of training. The specific levels of allowance for predoctoral and postdoctoral support, including those for individuals training at Federal laboratories, for-profit organizations, or foreign institutions, are published in the *NIH Guide for Grants and Contracts*. They also are available on the NIH Web site at http://grants.nih.gov/training/nrsa.htm#fellowhsips.

The institutional allowance is a fixed amount. Expenditures under institutional allowances are not subject to NIH prior approval requirements, and the institution is not required to account for these expenditures on an actual cost basis. Allowable uses of the Institutional Allowance are described below.

Except for fellows at Federal training sites, consistent with NIH policy governing the type of expenditures appropriate for the institutional allowance, the sponsoring institution authorizes the expenditure of the institutional allowance on behalf of the fellow according to the institution's policy. The institution is entitled to expend up to the full institutional allowance upon official activation of the award. However, if an individual fellow is not in a training status for more than 6 months of the award year, only one-half of that year's institutional allowance may be charged to the grant. The NoA will be revised and the stipend and institutional allowance balances must be refunded to NIH.

For fellows at Federal training sites, the NIH awarding IC authorizes the expenditure of the allowance. Payment is made through NIH's OFM.

The type of sponsoring institution dictates what costs may be charged to this category and how the funds are to be administered:

Non-Federal Public and Private Non-Profit Institutions (Domestic and Foreign). The allowance is intended to defray
expenses for the individual fellow such as research supplies, equipment, travel to scientific meetings, and health insurance and to

otherwise offset, insofar as possible, appropriate administrative costs of training. Funds are paid directly to and administered by the sponsoring institution.

- *Federal Laboratories.* The allowance is intended to cover the costs of scientific meeting travel, health insurance, and books. Funds are administered by the NIH awarding IC and disbursed by OFM.
- *For-Profit Institutions.* The allowance is intended to cover the costs of scientific meeting travel, health insurance, and books. Funds are paid directly to the sponsoring institution for disbursement to the fellow.

The following are guidelines for the use of the institutional allowance:

• <u>Travel</u>. Payment for travel to scientific meetings is appropriate when it is necessary for the individual's training and when the costs are incurred within the period of grant-supported training.

For fellows at Federal laboratories, reimbursement of travel costs must be in accordance with applicable Federal travel regulations.

Funds may not be expended to cover the costs of travel between the fellow's place of residence and the domestic training institution, except that the sponsoring institution may authorize the cost of a one-way travel allowance in an individual case of extreme hardship.

- <u>Health Insurance</u>. A fellow's health insurance is an allowable cost only if applied consistently to all individuals in a similar training status regardless of the source of support. Family health insurance is an allowable cost for fellows who have families and are eligible for family health insurance coverage at the sponsoring institution. Self-only health insurance is an allowable cost for fellows without families. Health insurance can include coverage for costs such as vision and/or dental care if consistent with organizational policy. Historically predoctoral fellowships included health insurance as part of the tuition and fees category. This is no longer the policy. For any fellowship (predoctoral and postdoctoral) that competed and was awarded in FY2007 and beyond, health insurance will continue to be awarded as part of the Tuition and Fees category.
- <u>Medical Liability and Other Special Insurance</u>. Medical liability (malpractice) insurance or other special insurance is an allowable cost to NRSA grants only if nature of the research training requires such special insurance. For instance, medical liability would be allowable if the research training experience involves direct contact with patients or human subjects. In all cases, for the cost to be charged to the NRSA grant, it must be consistently required for all in a similar training status, regardless of the source of support. Special insurances that are routinely offered as optional employee benefits (such as disability insurance, life insurance, or workman's compensation insurance), are not normally allowable charges (see separate section on Employee Benefits) unless the nature of the research training requires such special insurance.
- Extraordinary Costs. Additional funds may be requested by the institution when the training of a fellow involves extraordinary costs for travel to field sites remote from the sponsoring institution or accommodations for fellows who are disabled, as defined by the Americans with Disabilities Act. The funds requested for extraordinary costs must be reasonable in relationship to the total dollars awarded under a fellowship and must be directly related to the approved research training project. Such additional funds shall be provided only in exceptional circumstances that are fully justified and explained by the institution in the application or as part of a special written request.

11.2.9.5 Tuition and Fees

Tuition and fees are provided under the following policy:

- For individual predoctoral fellowships (F30 and F31), an amount equal to 60% of the level requested by the sponsoring institution, up to \$16,000 per year, will be provided. If the program supports formally combined dual-degree training (e.g., M.D.-Ph.D., D.D.S.-Ph.D.), the amount provided will be up to \$21,000 per year. Note the new policy moves health insurance into the Institutional Allowance budget category for predoctoral fellowships. This is now consistent with the treatment of this cost for postdoctoral fellowships
- For individual postdoctoral fellowships (F32) and individual senior fellowships (F33), an amount equal to 60% of the level requested by the applicant institution, up to \$4,500 per year, will be provided. If the program supports postdoctoral individuals in formal degree -granting training, the amount provided will be up to \$16,000 per year. For postdoctoral fellows, costs associated with tuition and fees are allowable only if they are required for specific courses in support of the research training. Health insurance is not included in this budget item because costs for it are to be charged as institutional allowance.

For fellowships that competed and were awarded before FY2007, tuition was awarded using a different formula. For predoctoral fellowships the tuition and fees category also included health insurance. When administering a fellowship that competed and was awarded prior to FY2007, consult the NIH awarding IC if there are questions concerning the awarding of tuition, fees, and health insurance.

11.2.9.6 Travel to Foreign Training Sites

For fellows at foreign training sites, in addition to the institutional allowance, awards may include a single economy or coach round-trip travel fare. No allowance is provided for dependents. U.S. flag air carriers must be used to the maximum extent possible when commercial air transportation is the means of travel between the United States and a foreign country or between foreign countries. This requirement shall not be influenced by factors of cost, convenience, or personal travel preference. For additional information regarding foreign travel, see Cost Considerations—Allowability of Costs/Activities-Selected Items of Cost-Travel/Employees in IIA.

11.2.9.7 Employee Benefits

Since Kirschstein-NRSA fellowships are not provided as a condition of employment with either the Federal government or the sponsoring institution, institutions may not seek funds, or charge individual fellowship awards, for costs that normally would be associated with employee benefits (for example, FICA, workman's compensation, life insurance, union dues, and unemployment insurance). Concerning union dues or other similar costs otherwise paid personally by the fellow; if a fellow requests the institution deduct such a cost from the stipend amount, the institution can provide the fellow such a service. However, in no case can such a deduction from the stipend be made automatically without the approval of the fellow.

11.2.9.8 Rebudgeting of Funds

Individual fellowship awards are formula based, generally restricted for the specific budget category of the award, and cannot be rebudgeted without prior written approval from the NIH awarding IC.

- Stipends must be expended using the stipend level provided in the award; no funds can be rebudgeted into the stipend category to accommodate a stipend level different from the established NIH level. When a fellowship terminates early, any unexpended stipends must be returned and cannot be rebudgeted into any other budget category.
- Institutional allowance is a fixed amount of money with a number of allowable costs. In the rare case where institutional allowance may be unexpended, it can only be rebudgeted into the tuition and fees category when tuition and fees have been awarded.
- When tuition and fees is awarded, it is generally restricted and cannot be rebudgeted without prior written approval from the NIH awarding IC.

11.2.10 Supplementation of Stipends, Compensation, and Other Income

11.2.10.1 Stipend Supplementation

Kirschstein-NRSA fellows receive stipends to defray living expenses. Stipends may be supplemented by an institution from non-Federal funds provided this supplementation is without any additional obligation for the fellow. An institution can determine the amount of stipend supplementation, if any, it will provide according to its own formally established policies governing stipend support. These policies must be consistently applied to all individuals in a similar status regardless of the source of funds. Federal funds may not be used for stipend supplementation unless specifically authorized under the terms of the program from which funds are derived. Under no circumstances may PHS funds be used for supplementation.

An individual may use Federal educational loan funds or VA benefits when permitted by those programs as described in Other Income: Educational Loans or GI Bill in this chapter.

11.2.10.2 Compensation

NIH recognizes that Kirschstein-NRSA fellows may seek part-time employment incidental to their training program to offset further their expenses. Funds characterized as compensation may be paid to fellows only when there is an employer-employee relationship, the payments are for services rendered, and the situation otherwise meets the conditions for compensation of students as detailed in Cost Considerations— Selected Items of Cost—Salaries and Wages—Compensation of Students in IIA. In addition, compensation must be in accordance with organizational policies applied consistently to both federally and non-federally supported activities and must be supported by acceptable accounting records that reflect the employer-employee relationship. Under these conditions, the funds provided as compensation (salary, fringe benefits, and/or tuition remission) for services rendered, such as teaching or laboratory assistance, are not considered stipend supplementation; they are allowable charges to Federal grants, including PHS research grants. However, NIH expects that compensation from research grants will be for limited part-time employment apart from the normal full-time training activities.

Compensation may not be paid from a research grant that supports the same research that is part of the fellow's planned training experience as approved in the Kirschstein-NRSA individual fellowship application.

<u>Stipend Supplementation & Compensation</u>. Under no circumstances may the conditions of stipend supplementation or the services provided for compensation interfere with, detract from, or prolong the fellow's approved Kirschstein-NRSA training program. Fellowship sponsors must approve all instances of employment on research grants to verify that the circumstances will not detract from or prolong the approved training program.

11.2.10.3 Other Income: Concurrent Benefits

A Kirschstein-NRSA individual fellowship may not be held concurrently with another federally sponsored fellowship or similar Federal award that provides a stipend or otherwise duplicates provisions of the Kirschstein-NRSA.

11.2.10.4 Other Income: Educational Loans or GI Bill

An individual may accept concurrent educational remuneration from the VA (GI Bill) and Federal educational loan funds. Such funds are not considered supplementation or compensation.

11.2.10.5 Other Income: NIH Loan Repayment Program

Postdoctoral fellows may also be eligible to participate in the NIH Loan Repayment Program. Information on this program is available at http://www.lrp.nih.gov/.

11.2.10.6 Taxability of Stipends

Section 117 of the Internal Revenue Code (26 U.S.C. 117) applies to the tax treatment of scholarships and fellowships. In general, degree candidates may exclude from gross income (for tax purposes) any amount used for qualified tuition and related expenses such as fees, books, supplies, and equipment required for courses of instruction at a qualified educational organization. Non-degree candidates are required to report as gross income any monies paid on their behalf for stipends or any course tuition and fees required for attendance.

The IRS and Treasury Department released regulations in January 2005 (Revenue Procedures 2005-11) clarifying the student exception to the FICA (Social Security and Medicare) taxes for students employed by a school, college, or university where the student is pursuing a course of study. NIH's understanding is that these final regulations do **not** apply to or impact Kirschstein-NRSA programs or awards.

The taxability of stipends in no way alters the relationship between Kirschstein-NRSA fellows and sponsoring institutions. Kirschstein-NRSA stipends are not considered salaries. In addition, recipients of Kirschstein-NRSA individual fellowships are not considered to be in an employee -employer relationship with NIH or the sponsoring institution solely as a result of the Kirschstein-NRSA award. The interpretation and implementation of the tax laws are the domain of the IRS and the courts. NIH takes no position on what the status may be for a particular taxpayer, and it does not have the authority to dispense tax advice. Individuals should consult their local IRS office about the applicability of the law to their situation and for information on their tax obligations.

11.2.10.7 Form 1099

Although stipends are not considered salaries, these funds are subject to Federal and, sometimes, State income tax. Such income may be reported by the sponsoring institution on IRS Form 1099, Statement of Miscellaneous Income. Normally, the business office of the sponsoring institution will be responsible for annually preparing and issuing IRS Form 1099 for fellows paid through the institution (fellows at domestic non-Federal institutions). Sponsoring institutions are not required to issue a Form 1099, but it is a useful form of documentation of funds received and it serves as a reminder to the fellow that some tax liability may exist. Fellows are reminded that, even if the sponsoring institution does not issue a Form 1099, they still are required to report Kirschstein-NRSA stipends. NIH will issue a Form 1099 for each fellow training at a Federal or foreign laboratory and receiving a stipend check from the NIH.

11.2.11 Reporting Requirements

The submission of the forms described in this subsection is critical to establishing and paying stipends and other costs and determining possible payback service. All of these forms are available in PDF-fillable and Word formats at http://grants.nih.gov/grants/forms.htm. The NIH awarding IC may provide copies of applicable forms with the NoA or reference this Web site in the NoA.

11.2.11.1 Activation Notice

Immediately upon the initiation of training, the individual must complete and sign the Ruth L. Kirschstein Individual Fellowship Activation Notice (Form PHS 416-5), obtain the signature of the AOR, and forward the notice along with the Payback Agreement (required only for postdoctoral fellows in their first 12 months of Kirschstein-NRSA support) to the NIH awarding IC.

For Kirschstein-NRSA fellows paid directly by NIH, the Activation Notice is required at the start of each award year. The form should not be submitted before the fellow actually begins training. Stipend checks are issued when both the Activation Notice and the Payback Agreement (required only for postdoctoral fellows in their first 12 months of Kirschstein-NRSA support) are received by the NIH awarding IC.

For fellows whose stipend is paid through the institution, the Activation Notice is required for the initial year only. The Activation Notice may be submitted up to 30 days before the individual begins training if necessary for payroll purposes. However, the institution must not release any funds until the individual has started training. Furthermore, if the individual does not begin research training on the day indicated, the institution must notify the NIH awarding IC immediately. Competing continuation awards must be activated on the day following the end of the last budget period of the previous award.

11.2.11.2 Payback Agreement

A Ruth L. Kirschstein National Research Service Award Payback Agreement (Form PHS 6031) that covers the initial 12 months of Kirschstein-NRSA postdoctoral support must be signed by each person who is to receive an individual postdoctoral fellowship. This form is not required if the individual has already received 12 months of postdoctoral Kirschstein-NRSA support under any Kirschstein-NRSA institutional research training grant or fellowship award. For details on Kirschstein-NRSA payback, see Payback Reporting Requirements in this chapter.

No Payback Agreement is required for predoctoral fellows.

11.2.11.3 Termination Notice

The Ruth L. Kirschstein National Research Service Award Termination Notice (Form PHS 416-7) (along with the Activation Notice and the NoA) is the basis for validating the total period of Kirschstein-NRSA support and establishing the amount of payback obligation for each Kirschstein-NRSA fellow. For individual fellowships, a reminder of this reporting requirement may be sent to the fellow by the NIH awarding IC before the scheduled termination date. For early terminations, the completed form will be required immediately upon receipt of notification from the fellow or an AOR. The termination notice must be submitted within 30 days of the termination date even if the fellow is not available for signature. In all cases, the information on the form must be verified by the sponsor and an institutional business official. The lack of timely and accurate information on early termination, see Changes in the Project below. Effective with Termination Notices submitted on/after January 1, 2011, all Termination Notices for individual fellowships are required to be submitted electronically using the eRA Commons xTrain application.

11.2.11.4 Consecutive Support

If a fellow switches from one Kirschstein-NRSA grant mechanism to another (e.g., from an institutional research training grant to an individual fellowship or from one NIH IC to another), the requirement for payback service incurred is deferred until the total period of Kirschstein-NRSA support is completed. All fellowship applications are reviewed to determine if previous Kirschstein-NRSA support has been provided.

11.2.11.5 Progress Reports

Annual progress reports must be submitted for non-competing continuation support in accordance with the instructions accompanying the Progress Report for Continuation Support (Form PHS 416-9). Progress report forms and instructions are available from the NIH Web site at http://grants.nih.gov/grants/forms.htm. Report form pages are available in PDF-fillable and Word formats. Inadequate or incomplete progress reports may be returned to the fellow for revision and may result in a delay of continued support. For Kirschstein-NRSA individual fellowship awards, the final progress report information is required as part of the Termination Notice.

11.2.11.6 Financial Reporting

An annual or final FFR to report expenditure information is not required for Kirschstein-NRSA individual fellowship awards. However, sponsoring institutions must still complete the quarterly reporting of Federal cash transactions using the FFR and submit that information directly to PMS.

11.2.12 Changes in the Project

Individual fellowship awards are made for training at a specific institution under the guidance of a particular sponsor. The approval of the NIH awarding IC is required for a transfer of the award to another institution, a change in sponsor, or a project change. As part of the approval process, if a fellow sponsored by a domestic non-Federal institution requests a transfer to another domestic non-Federal institution before the end of the current award year, the institutions are responsible for negotiating which will pay the stipend until the end of the current year. Disposition of the institutional allowance is also negotiable between the two sponsoring institutions. No Activation Notice is required from the new sponsoring institution.

Transfers involving Federal or foreign sponsoring institutions require unique administrative procedures and approvals. Because each transfer varies depending on individual circumstances, the sponsoring institution should contact the NIH awarding IC for specific guidance.

Any proposed change in the individual's specified area of research training must be reviewed and approved in writing by the NIH awarding IC to ensure that the training continues to be within the scientific scope of the original peer-reviewed application.

When the sponsor plans to be absent for a continuous period of more than 3 months, an interim sponsor must be named by the institution and approved in writing by the NIH awarding IC.

11.2.13 Other Terms and Conditions

11.2.13.1 Leave

<u>Vacations and Holidays</u>. Kirschstein-NRSA fellows may receive the same vacations and holidays available to individuals in comparable training positions at the sponsoring institution. Fellows shall continue to receive stipends during vacations and holidays. At academic institutions, the time between semesters or academic quarters generally is considered an active part of the training period and is not considered to be a vacation or holiday.

<u>Sick Leave and Other Leave</u>. Kirschstein-NRSA fellows may continue to receive stipends for up to 15 calendar days of sick leave per year. Under exceptional circumstances, this period may be extended by the NIH awarding IC in response to a written request from an AOR. Sick leave may be used for medical conditions related to pregnancy and childbirth.

Parental Leave. Kirschstein-NRSA fellows may receive stipends for up to 60 calendar days (equivalent to 8 work weeks) of parental leave per year for the adoption or the birth of a child when individuals in comparable training positions at the sponsoring institution have access to this level of paid leave for this purpose. Either parent is eligible for parental leave. The use of parental leave requires approval by the sponsor.

Terminal Leave. A period of terminal leave is not permitted, and payment may not be made from grant funds for leave not taken.

<u>Unpaid Leave</u>. Individuals requiring extended periods of time away from their research training experience, that is, more than 15 calendar days of sick leave or more than 60 calendar days of parental leave, must seek approval from the NIH awarding IC for an unpaid leave of absence. A request letter must be submitted by the AOR on behalf of the fellow and must advise the NIH awarding IC of the dates of the leave of absence. Upon approval of the request, the NIH awarding IC will issue a revised NoA extending the ending date of the current budget/project period by the appropriate number of days or months of unpaid leave time. Recipients are precluded from spending award funds during the leave of absence; although continued coverage of health insurance would be allowable if in accordance with policy of the sponsoring institution.

During a leave of absence, documentation to suspend the award and/or the accrual of service for calculating the payback obligation must be completed and retained by the sponsoring institution. When the fellowship is eventually terminated, the leave of absence must be clearly documented on the Termination Notice.

11.2.13.2 Termination

NIH may terminate a Kirschstein-NRSA individual fellowship before its scheduled expiration date if it determines that the recipient has materially failed to comply with the terms and conditions of the award or to carry out the purpose for which it was made. If an award is terminated for cause, NIH will notify the fellow in writing of the determination, the reasons for the determination, the effective date, and the right to appeal the decision.

NIH also may terminate an award at the request of the sponsoring institution or the individual fellow. The NIH awarding IC must be notified immediately if a sponsoring institution wants to terminate an individual fellow or the fellow decides to terminate training before the scheduled expiration date.

If a fellow receives another NIH award, e.g., as a PD/PI on an R03, then the fellow is no longer eligible for the fellowship and the sponsoring institution should contact the awarding IC concerning early termination.

If a Kirschstein-NRSA fellowship is terminated early, the stipend must be prorated according to the amount of time spent in training, and the NoA will be revised downward. In addition, if the length of the final budget period was 6 months or less, the balance of any institutional allowance (at least one-half) must be refunded.

11.2.13.3 Publications and Sharing of Research Results

NIH supports the practical application and sharing of outcomes of funded research. Therefore, recipients of Kirschstein-NRSA fellowships should make the results and accomplishments of their activities available to the research community and to the public at large. The sponsoring institution should assist the fellow in such activities, including the further development of discoveries and inventions for furthering research and benefiting the public. No restrictions should be placed on the publication of results.

Kirschstein-NRSA fellows are encouraged to submit reports of their findings to the journals of their choice for publication. Responsibility for direction of the project should not be ascribed to NIH. However, NIH awarding IC support must be acknowledged by a footnote in language similar to the following: "This research was supported by the National Institutes of Health under Ruth L. Kirschstein National Research Service Award (number) from the (name of NIH IC)." In addition, Federal funding must be acknowledged as provided in Appropriation Mandates— Acknowledgment of Federal Funding in IIA.

The Public Access Policy requirements described in Administrative Requirements—Availability of Research Results—NIH Public Access Policy in IIA apply to articles that are authored or co-authored by NRSA fellows and arose from NIH Support. Information on publications is included as part of the annual progress report.

11.2.13.4 Copyright

Except as otherwise provided in the conditions of the award, when a publication or similar copyrightable material is developed from work supported by NIH, the author is free to arrange for copyright without approval of the NIH awarding IC. Any such copyrighted materials shall be subject to a royalty-free, nonexclusive, and irrevocable license to the Federal government to reproduce, translate, publish, and use and dispose of such materials, and to authorize others to do so for Federal government purposes.

11.2.13.5 Inventions and Patents

Fellowships funded primarily for educational purposes are not subject to invention reporting requirements nor does NIH have any rights to inventions under those awards (as specified in 37 CFR part 401.1(b)). Kirschstein-NRSA fellows training at NIH represent an exception to this policy. Those fellows are subject to the provisions of EO 10096 and NIH determines the disposition of rights to any invention conceived or first actually reduced to practice during the period of the fellowship.

11.2.13.6 Disposition of Professional Fees

Fees resulting from clinical practice, professional consultation, or other comparable activities performed pursuant to the purpose of the award must be assigned to the sponsoring institution for disposition in accordance with established organizational policy. The term "professional fees" does not apply to honoraria, fees for scholarly writing, delivery of occasional outside lectures, or service in an advisory capacity to public or private non-profit organizations, which, if permitted by organizational policy, may be retained by the fellow.

11.2.13.7 Public Policy Requirements and Objectives

All Public Policy Requirements, Objectives, and Other Appropriation Mandates discussed in IIA apply to Individual Kirschstein-NRSA fellowships when appropriate. Applicants must comply with policies and procedures governing such requirements as civil rights; the protection of human subjects, including data and safety monitoring requirements and inclusion policies for women, minorities and children; the humane care and use of live vertebrate animals; human embryonic stem cells; and/or recombinant DNA and human gene transfer research. See IIA for a complete list of applicable requirements.

It is the sponsoring institution's responsibility to ensure that a fellow has received the proper training/education and is properly supervised particularly in the areas of human subjects research, vertebrate animal research, and occupational safety programs.

Additional information and any application requirements can be found in the Individual Fellowship Application Guide available at: http://grants.nih.gov/grants/funding/424/index.htm.

Information provided below is in addition to that provided in IIA where unique circumstances might exist for individual fellowships.

11.2.13.7.1 Human Subjects

<u>Indefinite Involvement.</u> If the sponsoring institution has an approved FWA on file with OHRP but, at the time of application, plans for the involvement of human subjects are indefinite, the assurance number should be provided in the application. If an award is made, human subjects may not be involved until a certification of IRB approval or designation of exemption has been submitted.

If the applicant organization does not have a FWA registered with the OHRP, that registration process must be completed prior to IRB approval.

11.2.13.7.2 Vertebrate Animals

Indefinite Involvement. If the sponsoring institution has an approved Assurance of Compliance on file with OLAW but, at the time of application, its plans for the involvement of vertebrate animals are so indefinite that IACUC review and approval are not feasible, the institution should indicate "Yes," to the involvement of Vertebrate Animals, include the animal welfare Assurance of Compliance number, and indicate "Indefinite." If an award is made, vertebrate animals may not be involved until verification of the IACUC approval date has been submitted to the NIH awarding IC.

If the applicant organization does not have an approved Assurance of Compliance on file with OLAW or for additional information on vertebrate animals, refer to the Individual Fellowship Application Guide or contact OLAW (see Part III).

11.2.13.8 Applicability of NIH Standard Terms of Award

Individual Fellowships are awarded under the NIH Standard Terms of Award however the provisions to extend the final budget period of a project period without additional funds and carryover of unobligated balances do not apply.

11.3 INSTITUTIONAL RESEARCH TRAINING GRANTS

11.3.1 General

NIH will award Kirschstein-NRSA institutional research training grants (T32, TL2, T34, and T35) to eligible institutions to develop or enhance research training opportunities for individuals, selected by the institution, who are training for careers in specified areas of biomedical, behavioral, and clinical research. The purpose of the Kirschstein-NRSA program is to help ensure that a diverse and highly trained workforce is available in adequate numbers and in the appropriate research areas and fields to carry out the nation's biomedical and behavioral research agenda. Training activities can be in basic biomedical or clinical sciences, in behavioral or social sciences, in health services research, or in any other discipline relevant to the NIH Mission. The Kirschstein-NRSA program supports predoctoral, postdoctoral, and short-term research training as well as limited specialized support at the prebaccalaureate level. All NIH ICs except FIC and NLM award Kirschstein-NRSA institutional research training grants. FIC and NLM have unique funding authorities for training grants that are separate from the Kirschstein-NRSA authority.

11.3.2 Eligibility

11.3.2.1 Applicant Eligibility

A domestic, non-profit public or private organization may apply for a grant to support a research training program in a specified area(s) of research. Support for predoctoral, postdoctoral, or a combination of trainees may be requested. (Specific program announcements should be consulted for IC guidelines.) Support for short-term training positions for students in health-professional degree programs also may be requested as indicated in Short-Term Research Training in this subsection. Each applicant institution must submit an application using the research training forms and instructions (see Application Requirements and Receipt Dates in this subsection).

11.3.2.2 Research Areas

Kirschstein-NRSA institutional research training grants may be made for research training in areas that fall within the missions of the NIH ICs. Applications that do not address these areas will be returned. An increased emphasis has been placed on the research training of physicians.