# **Department of Health and Human Services Part 1. Overview Information**

| Participating  | National Institutes of Health ( <u>NIH</u> )   |
|--|--|
| Organization(s)  |  |
| Components of Participating Organizations              | NIH Big Data to Knowledge Initiative (BD2K) National Human Genome Research Institute (NHGRI) National Cancer Institute (NEI) National Eye Institute (NEI) National Heart, Lung, and Blood Institute (NHLBI) National Institute on Aging (NIA) National Institute on Alcohol Abuse and Alcoholism (NIAAA) National Institute of Allergy and Infectious Diseases (NIAID) National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) National Institute of Biomedical Imaging and Bioengineering (NIBIB) Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) National Institute on Deafness and Other Communication Disorders (NIDCD) National Institute of Dental and Craniofacial Research (NIDCR) National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) National Institute on Drug Abuse (NIDA) National Institute of Environmental Health Sciences (NIEHS) National Institute of Mental Health (NIMH) National Institute of Nursing Research (NINR) National Institute of Nursing Research (NINR) National Institute on Minority Health and Health Disparities (NIMHD) National Library of Medicine (NLM) National Center for Complementary and Alternative Medicine (NCCAM) Office of Behavioral and Social Sciences Research (OBSSR) Office of Strategic Coordination (Common Fund) |
| Funding<br>Opportunity Title                           | Predoctoral Training in Biomedical Big Data Science (T32)  |
| Activity Code  | T32 Institutional National Research Service Award (NRSA)   |
| Announcement<br>Type                                   | New  |
| Related Notices  | NOT-HG-14-011; NOT-HG-14-022; NOT-HG-14-023  |
| Funding<br>Opportunity<br>Announcement<br>(FOA) Number | RFA-HG-14-004  |
| Companion<br>Funding<br>Opportunity                    | RFA-HG-14-005 T32 Institutional National Research Service Award (NRSA); RFA-HG-14-006 T15 Continuing Education Training Grants   |
| Number of<br>Applications                              | See Section III. 3. Additional Information on Eligibility.   |
| Catalog of Federal<br>Domestic                         | 93.361, 93.242, 93.853, 93.866, 93.307, 93.847, 93.273, 93.879, 93.865, 93.121, 93.279, 93.286, 93.173, 93.213, 93.867, 93.856, 93.855, 93.113, 93.865, 93.310, 93.846, 93.398, 93.879   |

| Assistance (CFDA) Number(s)       |  |
|-----------------------------------|--|
| Funding<br>Opportunity<br>Purpose | The purpose of this Funding Opportunity Announcement (FOA) is to solicit applications for graduate training programs in Big Data Science, for the expressed purpose of training the next generation of scientists who will develop computational and quantitative approaches and tools needed by the biomedical research community to work with biomedical Big Data in the biomedical sciences (see definition under Funding Opportunity Description). This proposed training initiative should prepare qualified individuals for careers in developing new technologies and methods that will allow biomedical researchers to maximize the value of the growing volume and complexity of biomedical data. |

# **Key Dates**

| Posted Date                          | April 22, 2014  |
|--------------------------------------|---|
| Open Date (Earliest Submission Date) | June 28, 2014   |
| Letter of Intent<br>Due Date(s)      | 30 days before the application due date   |
| Application Due Date(s)              | July 28, 2014; July 27, 2015, by 5:00 PM local time of applicant organization.  |
|                                      | Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date. |
| AIDS Application Due Date(s)         | Not Applicable  |
| Scientific Merit<br>Review           | October 2014; October 2015  |
| Advisory Council<br>Review           | January 2015; January 2016  |
| Earliest Start Date                  | March 2015; March 2016  |
| Expiration Date                      | July 28, 2015   |
| Due Dates for E.O.<br>12372          | Not Applicable  |

## **Required Application Instructions**

It is critical that applicants follow the instructions in the <u>SF424 (R&R) Application Guide</u> including the <u>Supplemental Instructions to the SF424 (R&R) for Preparing Institutional Ruth L. Kirschstein National Research Service Award (NRSA) Application</u>, except where instructed to do otherwise (in this FOA or in a Notice from the <u>NIH Guide for Grants and Contracts</u>). Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in <u>Section IV</u>. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions. Applications that do not comply with these instructions may be delayed or not accepted for review.

Apply for Grant Electronically

A compatible version of <u>Adobe Reader</u> is required for download. For Assistance downloading this or any Grants.gov application package, please contact Grants.gov Customer Support at <a href="http://www07.grants.gov/contactus/contactus.jsp">http://www07.grants.gov/contactus/contactus.jsp</a>.

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## Part 2. Full Text of Announcement

# **Section I. Funding Opportunity Description**

The overall goal of the NIH Ruth L. Kirschstein National Research Service Award (NRSA) program is to help ensure that a diverse pool of highly trained scientists is available in appropriate scientific disciplines to address the Nation's biomedical, behavioral, and clinical research needs. In order to accomplish this goal, NRSA training programs are designed to train individuals to conduct research and to prepare for research careers. More information about NRSA programs may be found at the <a href="Ruth L. Kirschstein National Research Service Award (NRSA)">Ruth L. Kirschstein National Research Service Award (NRSA)</a> website.

#### **Purpose and Background Information**

The NRSA program has been the primary means of supporting predoctoral and postdoctoral research training programs since enactment of the NRSA legislation in 1974. Research 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.

Institutional NRSA programs allow the Training Program Director/Principal Investigator (Training PD/PI) to select the trainees and develop a program of coursework, research experiences, and technical and/or professional skills development appropriate for the selected trainees. Each program should provide high-quality research training and offer opportunities in addition to conducting mentored research. The grant offsets the cost of stipends, tuition and fees, and training related expenses, including health insurance, for the appointed trainees in accordance with the approved NIH support levels.

The purpose of this FOA is to solicit applications for graduate training programs in Big Data Science, for the expressed purpose of training the next generation of scientists who will develop computational and quantitative approaches and tools needed by the biomedical research community to work with biomedical Big Data in the biomedical sciences. This proposed type of training should prepare qualified individuals for careers in developing new technologies and methods that will allow biomedical researchers to maximize the value of the growing volume and complexity of biomedical "big data." The career outcomes of individuals supported by NRSA training programs include both research-intensive careers in academia and industry and research-related careers in various sectors.

**Note:** The term "biomedical" in this FOA will be used in the broadest sense to include biological, biomedical, behavioral, social, environmental and clinical studies that relate to understanding health and disease.

#### Training for the BD2K Initiative

The long-term goal of the BD2K initiative (<a href="http://go.usa.gov/KH9Q">http://go.usa.gov/KH9Q</a>) is to support the advances in data science, other quantitative sciences, policy, and training that are needed for the effective use of Big Data in biomedical

research. To address the growing need and opportunities for skilled researchers to fully utilize the vast amount of heterogeneous biomedical Big Data, a series of BD2K FOAs have been designed to provide support for: 1) development of a sufficient cadre of researchers skilled in the science of Big Data; and 2) elevation of the general competencies in data usage and analysis across the biomedical research workforce. The portfolio of BD2K training activities will include opportunities for the full spectrum of scientists, from students to senior faculty, from developers of methods and tools to investigators who need to use Big Data tools.

The NIH issued a Request for Information (NOT-HG-13-003; Report) to solicit input from the extramural community on what types of knowledge and skills are needed by individuals to effectively manage and utilize Big Data. In addition, the NIH organized a workshop (Report) that addressed the knowledge, skills, and resources needed to organize, process, manage, analyze, and visualize large, complex data sets.

Due to the multifaceted challenges faced in meeting the opportunities provided by Big Data, the following principles were taken into account in designing the set of BD2K training FOAs:

- · A combination of skills is needed to utilize Big Data, both technical and "soft" skills.
- Technical skills are needed in (1) computer science or informatics, (2) statistics and mathematics, and (3) biomedical science.
- · Communication skills are critical to foster collaborations.
- The principles of study design and reproducible research (related to the practices that ensure the
- reproducibility of analyses of data) should be stressed.
- Big Data scientists must be prepared to be independent researchers, but at the same time, an
  interdisciplinary, team-science approach is frequently the optimal way to solve Big Data challenges or
  to use Big Data effectively.
- Individuals and scientists may need additional skills and knowledge to work effectively in interdisciplinary teams.
- Training in the quantitative sciences and experimental design will be increasingly important to researchers and clinicians.
- BD2K training programs should be designed to develop the ability of scientists to work at the intersection of multiple disciplines necessary to utilize Big Data.
- · Team mentoring is encouraged.
- Innovative approaches to training are encouraged, in order to take best advantage of the particular talents and expertise available at the institution(s).
- The training environment is critical and should include access to large data sets and ongoing research projects of multiple types.
- Career paths for data scientists that recognize and reward contributions in methodology, computation, or development of tools are important.
- Training individuals to participate across the full spectrum of scientific roles is encouraged, even though the jobs necessary to Big Data Science may not correspond to traditional scientific, particularly academic, jobs or fit neatly into existing departments.
- Recruitment of talent from diverse scientific backgrounds, such as computer science, engineering, informatics, mathematics, physics, and statistics, to biomedical Big Data Science is important.

In order to promote a diverse workforce and successfully reach scientists at all career levels, it is essential that training resources be widely disseminated, discoverable, and reusable. The active exchange of information is also an essential component of the BD2K initiative and will be facilitated by an annual BD2K consortium meeting in Bethesda, MD for PDs/PIs and trainees.

Applicants are encouraged to utilize all appropriate expertise for the purpose of training Big Data scientists, whether that expertise lies within one or more institutions or within the industrial or public sectors. Applicants are also encouraged to consider whether other BD2K training FOAs, such as <a href="RFA-HG-14-005">RFA-HG-14-005</a> and <a href="RFA-HG-14-005">RFA-HG-14-005</a> a

#### Predoctoral Training Programs in Biomedical Big Data Science

The BD2K initiative includes a multi-faceted approach to training, consisting of long- and short-term training and the development of open educational resources. This FOA focuses on long-term training of predoctoral students by soliciting applications for new graduate training programs in Big Data Science. These training

grants will help ensure that a diverse and highly trained workforce is available to assume leadership roles related to developing computational and quantitative approaches, technologies, methods, and tools needed by the biomedical research community to work with biomedical Big Data.

This predoctoral training initiative is different from most currently funded NIH training programs in that it will: (1) require that trainees work effectively at the intersection of these three scientific areas – computer science/informatics, statistics/mathematics, and biomedical science; (2) expect active participation of training faculty from all of these three scientific disciplines who will work collaboratively across disciplines as comentors of trainees in Big Data Science; and (3) develop the skills required to participate in a team approach to solving data-intensive biomedical problems, while also nurturing the skills necessary to be an independent investigator in Big Data Science. The purpose of the BD2K training program is to produce graduates who will have the required multidisciplinary skill sets for careers in which they will have the potential to develop new quantitative approaches and tools needed by the biomedical research community to harness the opportunities Big Data provides.

**Training Program Features**: The foundational training program should include courses, rotations in academic and industry, team approaches to interdisciplinary research, emphasis on principles and practices that promote reproducibility of results, and joint mentorship, all of which focuses on Big Data Science. Because Big Data Science is interdisciplinary in nature, it is expected that trainees will acquire during the training experience competency in all three relevant areas – computer science/informatics, statistics/mathematics, and biomedical science – and expertise in aspects of data science that are essential to biomedical science. The training should include those aspects of computer science/informatics and statistics/mathematics that are directly relevant to the biomedical sciences.

Programs are expected to identify trainees from a variety of undergraduate backgrounds such as the biomedical sciences, computer science, engineering, informatics, mathematics, physics, and statistics. It is anticipated that by the end of their training, trainees will have acquired the necessary experience to pursue research in biomedical Big Data Science.

Big Data Science Training Programs will prepare students to be independent researchers and at the same time prepare them to work in teams since solving the challenges presented by Big Data will often involve a team science approach to problem solving. Therefore, training programs are encouraged to provide trainees with the experience of working as part of a team of individuals with disparate domain knowledge and skill sets in order to solve important biomedical Big Data problems. In addition, training programs should ensure that trainees have multiple mentors, from disciplines necessary for capitalizing on biomedical Big Data.

Successful graduates of these programs will be prepared for research-oriented roles in academic institutions, not-for-profit research institutes, governmental and public health agencies, pharmaceutical and biomedical software companies, and health care organizations. This initiative is not intended to prepare trainees for careers emphasizing planning, deployment, maintenance, or administration of computer systems in health care, public health, medical education or research. The emphasis in this program is on the development of new knowledge that advances biomedical Data Science as a scientific discipline.

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 Training Program Director/Principal Investigator(s) (Training PD/PI(s)), together with participating training faculty, is responsible for developing the program's approaches -- selecting trainees and developing a curriculum of study and research experiences necessary to provide a high quality research training experience. Multiple PD/PI applications are strongly encouraged in order to include expertise in all three areas essential to biomedical Big Data Science. In most cases, the multiple PDs/PIs will have demonstrated evidence of strong prior collaboration.

The proposed Training Program in Big Data Science may complement other ongoing research training and career development programs at the applicant institution, but it must have a Big Data focus that distinguishes it from any other training programs at the applicant institution.

Applications for training programs that focus exclusively on one or two of the BD2K relevant scientific areas or on just a few diseases will not be considered responsive.

Primary Organizational Focus of the Training Program: Multiple PDs/Pls are encouraged.

NIH strongly encourages institutions with expertise in the three areas discussed above who have not previously received training grants from NIH to apply. NIH also encourages institutions that currently have multiple NIH training grants and who wish now to apply for a BD2K training grant to consider drawing on and taking advantage of existing training activities, through collaborative approaches to expand beyond what their current training programs offer to create a unique, effective Big Data training program.

Within the framework of the NRSA program's longstanding commitment to excellence and projected need for investigators in particular areas of research, attention must be given to recruiting trainees from racial or ethnic groups underrepresented in the biomedical, behavioral, and clinical sciences, individuals with disabilities, and individuals from disadvantaged backgrounds.

The Training PD/PI, together with participating training faculty, should limit appointments to individuals who are committed to a career in biomedical Big Data Science and who plan to remain on the training grant or in a non-NRSA research experience until completion of the doctoral degree. The Training PD/PI, together with participating training faculty, should also encourage and provide training in the skills necessary for trainees to apply for subsequent peer-reviewed support.

## Section II. Award Information

| Funding<br>Instrument                                  | Grant: A support mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity.   |
|--|---|
| Application Types<br>Allowed                           | New<br>Resubmission   |
|  | The OER Glossary and the SF424 (R&R) Application Guide provide details on these application types.  |
| Funds Available<br>and Anticipated<br>Number of Awards | The NIH plans to commit \$6 million dollars in FY15 to support three related approaches to institutional training grants under BD2K, as embodied in RFA-HG-14-004, RFA-HG-14-005, and RFA-HG-14-006. We anticipate that the average size of an award will be approximately \$350,000 total cost. It is expected that about 18 awards will be supported in FY15 in total under these three RFAs, depending on the quality of the applications.  Future year amounts will depend on annual appropriations.  The number of awards is contingent upon NIH appropriations and the submission of a sufficient number of meritorious applications.   |
| Award Budget   | Application budgets are not limited, but it is anticipated that each institutional training program may appoint up to 6 trainees annually. Budgets need to reflect the actual needs of the proposed project.  Grantees are expected to be familiar with and comply with applicable cost policies and the NRSA Guidelines ( <i>NIH Grants Policy Statement</i> - Institutional Research Training Grants). Funds may be used only for those expenses that are directly related to and necessary for the research training and must be expended in conformance with OMB Cost Principles, the <i>NIH Grants Policy Statement</i> , and the NRSA regulations, policies, guidelines, and conditions set forth in this document. |
| Award Project<br>Period                                | Awards will be made for five years.   |

## Other Award Budget Information

| Stipends, Tuition, and Fees | Kirschstein-NRSA awards provide stipends as a subsistence allowance to help defray living expenses during the research training experience. |
|-----------------------------|---|
|                             | NIH will contribute to the combined cost of tuition and fees at the rate in   |

|                              | place at the time of award.   |
|------------------------------|---|
|                              | The most recent stipend, tuition, and fee levels are described on the Ruth  L. Kirschstein National Research Service Award (NRSA) site. Visit NIH  Grants Policy Statement: Ruth L. Kirschstein National Research Service  Awards for more information.   |
| Trainee Travel               | Travel funds may be requested for up to two meetings per trainee while on the grant. One of those trips should be to attend an annual BD2K consortium meeting in Bethesda, MD, and the other to one scientific meeting in an area of Big Data Science.  |
|                              | Travel funds should also be requested for the travel of the PDs/PIs to attend the annual BD2K training meeting.   |
|                              | The travel cost should be limited to \$1500 per trip.   |
| Training Related<br>Expenses | NIH will provide funds to help defray other research training expenses, such as health insurance, staff salaries, consultant costs, equipment, research supplies, and faculty/staff travel directly related to the research training program. The most recent levels of training related expenses are described on the Ruth L. Kirschstein National Research Service Award (NRSA) site. Visit NIH Grants Policy Statement: Ruth L. Kirschstein National Research Service Awards for more information. |
|                              | Up to \$20,000 for development of new curriculum related to Big Data Science may be requested in the first year, if strongly justified.   |

NIH grants policies as described in the <u>NIH Grants Policy Statement</u> will apply to the applications submitted and awards made in response to this FOA.

# **Section III. Eligibility Information**

# 1. Eligible Applicants

# **Eligible Organizations**

**Higher Education Institutions** 

- Public/State Controlled Institutions of Higher Education
- · Private Institutions of Higher Education

The following types of Higher Education Institutions are always encouraged to apply for NIH support as Public or Private Institutions of Higher Education:

- · Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- · Alaska Native and Native Hawaiian Serving Institutions
- Asian American Native American Pacific Islander Serving Institutions (AANAPISIs)

#### Governments

- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized)

· U.S. Territory or Possession

#### Other

Native American Tribal Organizations (other than Federally recognized tribal governments)

The sponsoring institution must assure support for the proposed program. Appropriate institutional commitment to the program includes the provision of adequate staff, facilities, and educational resources that can contribute to the planned program.

The applicant institution(s) must have a strong and high quality research program in biomedical Big Data Science that includes diverse and complex data types, such as genomic, other -omic, imaging, phenotypic, exposure, etc., both in the biomedical sciences. The applicant institution(s) must have the requisite faculty and facilities to conduct the proposed institutional program. In many cases, it is anticipated that the proposed program will complement, but be distinct from, other ongoing research training programs occurring at the applicant institution. It is expected that a substantial number of program faculty will have active biomedical Big Data Science research projects involving a variety of data types in the biomedical sciences in which participating trainees may gain relevant experiences consistent with their research interests and goals.

## **Foreign Institutions**

Non-domestic (non-U.S.) Entities (Foreign Institutions) **are not** eligible to apply. Non-domestic (non-U.S.) components of U.S. Organizations **are not** eligible to apply. Foreign components, as <u>defined in the *NIH Grants Policy Statement*</u>, **are not** allowed.

## **Required Registrations**

#### **Applicant Organizations**

Applicant organizations must complete and maintain the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. All registrations must be completed prior to the application being submitted. Registration can take 6 weeks or more, so applicants should begin the registration process as soon as possible. The <a href="NIH Policy on Late Submission of Grant Applications">NIH Policy on Late Submission of Grant Applications</a> states that failure to complete registrations in advance of a due date is not a valid reason for a late submission.

- <u>Dun and Bradstreet Universal Numbering System (DUNS)</u> All registrations require that applicants be issued a DUNS number. After obtaining a DUNS number, applicants can begin both SAM and eRA Commons registrations. The same DUNS number must be used for all registrations, as well as on the grant application.
- System for Award Management (SAM) (formerly CCR) Applicants must complete and maintain an
  active registration, which requires renewal at least annually. The renewal process may require as
  much time as the initial registration. SAM registration includes the assignment of a Commercial and
  Government Entity (CAGE) Code for domestic organizations which have not already been assigned a
  CAGE Code.
  - NATO Commercial and Government Entity (NCAGE) Code Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
- <u>eRA Commons</u> Applicants must have an active DUNS number and SAM registration in order to
  complete the eRA Commons registration. Organizations can register with the eRA Commons as they
  are working through their SAM or Grants.gov registration. eRA Commons requires organizations to
  identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator
  (PD/PI) account in order to submit an application.
- <u>Grants.gov</u> Applicants must have an active DUNS number and SAM registration in order to complete the Grants.gov registration.

#### Program Directors/Principal Investigators (PD(s)/PI(s))

All PD(s)/PI(s) must have an eRA Commons account. PD(s)/PI(s) should work with their organizational officials to either create a new account or to affiliate their existing account with the applicant organization in eRA Commons.If the PD/PI is also the organizational Signing Official, they must have two distinct eRA Commons accounts, one for each role. Obtaining an eRA Commons account can take up to 2 weeks.

## Eligible Individuals (Program Director/Principal Investigator)

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research training program as the Training Program Director/Principal Investigator (Training PD/PI) is invited to work with his/her organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support.

For institutions/organizations proposing multiple PDs/PIs, visit the <u>Multiple Program Director/Principal Investigator Policy</u> and submission details in the Senior/Key Person Profile (Expanded) Component of the SF 424 (R&R) Application Guide.

The PDs/PIs should be established investigators in the scientific areas relevant to biomedical Big Data Science and capable of providing both administrative and scientific leadership to the development and implementation of the proposed training program. The PDs/PIs will be expected to monitor and assess the program and submit all documents and reports as required. Since the focus of the training is in the area of developing new approaches and tools for manipulating, analyzing, and interpreting Big Data, the PD/PIs for this type of training program should collectively encompass expertise from all three major scientific areas, including demonstrated research leadership in computer science/informatics, statistics/mathematics, and biomedical science.

The primary PD/PI must ensure that the appropriate faculty work collaboratively and in a sustained manner across scientific disciplines and organizational lines to jointly mentor trainees. Big Data Science is interdisciplinary and includes all three major scientific areas: (1) computer science or informatics; (2) statistics and mathematics; and (3) biomedical sciences. It is anticipated that the training program will have a sufficient number of mentors in all three areas, including biomedical sciences researchers, and will utilize the idea of multiple mentorship.

## 2. Cost Sharing

This FOA does not require cost sharing as defined in the NIH Grants Policy Statement.

# 3. Additional Information on Eligibility

## **Number of Applications**

NIH will not accept any application that is essentially the same as one already reviewed within the past thirty-seven months (as described in the NIH Grants Policy Statement), except for submission:

- To an RFA of an application that was submitted previously as an investigator-initiated application but not paid;
- · Of an investigator-initiated application that was originally submitted to an RFA but not paid; or
- · Of an application with a changed grant activity code.

#### **Preceptors/Mentors**

Program faculty should have strong records as researchers, including recent publications and successful competition for research support in the area of the proposed research training program. Program faculty should also have a record of research training, including successful, former trainees who have established productive careers relevant to the NIH mission. Researchers from diverse backgrounds, including racial and ethnic minorities, persons with disabilities, and women are encouraged to participate as mentors.

Big Data Science is interdisciplinary and includes three major scientific areas: (1) computer science or informatics; (2) statistics and mathematics; and (3) biomedical sciences. It anticipated that the training program will have a sufficient number of mentors in all three areas, including biomedical sciences researchers, and will utilize the idea of multiple mentorship. Participating training faculty should include investigators who develop new technologies and practical tools, who generate and utilize Big Data, and who have a variety of biomedical expertise, from clinical to basic sciences, and with multiple disease specialties. The primary PD (s)/PI(s) must ensure that the appropriate faculty work collaboratively and in a sustained manner across scientific disciplines and organizational lines to jointly mentor trainees.

#### **Trainees**

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 at the time of appointment. Additional details on citizenship, training period, and aggregate duration of support are available in the <u>NIH Grants Policy Statement</u>.

Predoctoral trainees must have received a baccalaureate degree in at least one of the three major scientific areas in Big Data Science (computer science or informatics, statistics and mathematics, biomedical sciences) or a related area by the beginning date of their NRSA appointment and must be enrolled in a research doctoral program in an area relevant to Big Data Science. Health-professional students who wish to interrupt their studies for a year or more to engage in full-time research training before completing their formal training programs are also eligible.

Because Big Data Science includes the three major scientific areas described above, the program should strive to have a mix of trainees with backgrounds in these three scientific areas. While a mix is important for preparing students for Team Science research in the future, students also must develop the skills to be independent researchers in biomedical Big Data Science.

All trainees are required to pursue their research training full time, normally defined as 40 hours per week, or as specified by the sponsoring institution in accordance with its own policies. Appointments are normally made in 12-month increments, and no trainee may be appointed for less than 9 months during the initial period of appointment, except with prior approval of the NIH awarding unit, or when trainees are appointed to approved, short-term training positions.

# **Section IV. Application and Submission Information**

# 1. Requesting an Application Package

Applicants must download the SF424 (R&R) application package associated with this funding opportunity using the "Apply for Grant Electronically" button in this FOA or following the directions provided at Grants.gov.

# 2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the <u>SF424 (R&R) Application Guide</u> except where instructed in this funding opportunity announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

For information on Application Submission and Receipt, visit <u>Frequently Asked Questions – Application Guide</u>, Electronic Submission of Grant Applications.

Letter of Intent

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows IC staff to estimate the potential review workload and plan the review.

By the date listed in <u>Part 1. Overview Information</u>, prospective applicants are asked to submit a letter of intent that includes the following information:

- · Descriptive title of proposed activity
- Name(s), address(es), and telephone number(s) of the PD(s)/PI(s)
- · Names of other key personnel
- Participating institution(s)
- · Number and title of this funding opportunity

The letter of intent should be sent to:

Michelle Dunn, Ph.D National Cancer Institute (NCI) Telephone: 240-276-6881

Email: bd2k training@mail.nih.gov

## **Page Limitations**

All page limitations described in the SF424 (R&R) Application Guide and the <u>Table of Page Limits</u> must be followed.

## **Required and Optional Components**

The forms package associated with this FOA includes all applicable components, required and optional. Please note that some components marked optional in the application package are required for submission of applications for this FOA. Follow the instructions in the SF424 (R&R) Application Guide to ensure you complete all appropriate "optional" components.

## **Instructions for Application Submission**

The following section supplements the instructions found in the SF424 (R&R) Application Guide and should be used for preparing an application to this FOA.

## SF424(R&R) Cover

Follow all instructions provided in the SF424 (R&R) Application Guide for Preparing Institutional Ruth L. Kirschstein National Research Service Award (NRSA).

## SF424(R&R) Project/Performance Site Locations

Follow all instructions provided in the SF424 (R&R) Application Guide for Preparing Institutional Ruth L. Kirschstein National Research Service Award (NRSA).

## SF424 (R&R) Other Project Information

Follow all instructions provided in the SF424 (R&R) Application Guide for Preparing Institutional Ruth L. Kirschstein National Research Service Award (NRSA), with the following additional modifications:

**Project Summary/Abstract.** Provide an abstract of the entire application. Include the objectives, rationale and design of the research training program, as well as key activities in the training plan. Indicate the planned duration of appointments, the projected number of trainees including their levels (i.e., predoctoral), and intended trainee outcomes.

Other Attachments. A plan must be provided for the appointment of an Advisory Committee to monitor progress. Composition, responsibilities, frequency of meetings, and other relevant information should be included. Do not name specific individuals who will be appointed to the Advisory Committee, but describe the composition of the Advisory Committee in terms of the role and the desired expertise of members. A plan for Advisory Committee approval and selection of participants should be included. Describe how the Advisory Committee will function in providing oversight of the development, implementation, and evaluation of recruitment strategies, the recruitment and retention of candidates, and the evaluation of the overall effectiveness of the program. As noted, the proposed Advisory Committee members should not be named in the application, particularly if they include individuals from outside the institution. Please name your file "Advisory\_Committee.pdf".

The filename provided for each "Other Attachment" will be the name used for the bookmark in the electronic application in eRA Commons.

#### SF424(R&R) Senior/Key Person Profile Expanded

Follow all instructions provided in the SF424 (R&R) Application Guide for Preparing Institutional Ruth L. Kirschstein National Research Service Award (NRSA).

## **PHS 398 Cover Page Supplement**

Follow all instructions provided in the SF424 (R&R) Application Guide for Preparing Institutional Ruth L. Kirschstein National Research Service Award (NRSA).

## PHS 398 Training Subaward Budget Attachment(s)

Follow all instructions provided in the SF424 (R&R) Application Guide for Preparing Institutional Ruth L. Kirschstein National Research Service Award (NRSA).

## **Training Budget**

Follow all instructions provided in the SF424 (R&R) Application Guide with the following additional modifications:

- Include all personnel other than the Training PD(s)/PI(s) in the Other Personnel section, including clerical and administrative staff.
- · Do not use the Research and Related (R&R) Budget Component

## PHS 398 Research Training Program Plan

All Supplemental Instructions to the SF424 (R&R) for Preparing Institutional Ruth L. Kirschstein National Research Service Award (NRSA) Application must be followed, with the following additional instructions:

Particular attention must be given to the required **Training Data Tables**.

## **Program Plan**

**Program Administration.** Describe the acknowledged strengths, leadership and administrative skills, training experience, scientific expertise, and active research of the PD/PI. Relate these strengths to the proposed management of the training program. Describe the planned strategy and administrative structure to be used to oversee and monitor the program. If there are multiple PDs/PIs, then the plan for Program Administration is expected to synergize with the "Multiple PD/PI Leadership Plan" section of the application.

Institutions with existing programs must explain what distinguishes this program from the others, how their programs will synergize with one another, if applicable, and that the pool of faculty, potential scholars, and resources are robust enough to support additional programs. When a program administrator position is planned, a description of the scientific expertise, leadership, and administrative capabilities essential to coordinate a program for developing investigators must be included in the application.

Applicants must clearly enumerate how the proposed programs will differ from or integrate with existing training programs with respect to: 1) applicant pool, recruitment, admissions, and appointment pathways; 2) faculty and how they will be selected; and 3) curriculum and other program activities.

**Program Faculty.** The application must include information about the program faculty who will be available to serve as preceptors/mentors and provide guidance and expertise appropriate to the level of trainees proposed in the application. Describe the complementary expertise and experiences of the proposed Program Faculty, including active research and other scholarly activities in which the faculty are engaged, as well as experience mentoring and training individuals at the proposed career stage(s). For any proposed Program Faculty lacking research training experience, describe a plan to ensure successful trainee guidance by these individuals. Describe the criteria used to appoint and remove faculty as Program Faculty and to evaluate their participation.

**Proposed Training.** Provide an overview of the proposed program. Outline the objectives of the program and the program activities that will be used to meet these objectives. Describe for whom the training program is intended, including the training level(s) of the trainees, the academic and research background needed to pursue the proposed training, and, as appropriate, plans to accommodate differences in preparation among trainees. Include information about planned courses, mentored research experiences, and any activities designed to develop specific technical skills or other skills essential for the proposed research training. Describe how trainees will be educated in the human health- and disease-related aspects of their research training.

The training program should be designed to ensure that by the end of the training period, trainees would have received sufficient breadth in knowledge and skills in the areas that complement their undergraduate degree, as well as depth in complementary BD2K areas. Because trainees will enter the program with different knowledge and skill sets, a trainee's program may have to be customized.

Some of the common elements of a successful training program should include the following:

- Courses: Courses should expose trainees to the basic concepts and working knowledge in the
  three scientific areas of Big Data Science. It is incumbent on the applicant to define a set of core
  concepts that graduating students will master, even if their research projects are highly
  specialized.
- Team Science Approach to Problem Solving: Trainees working together as a team or as part of an
  interdisciplinary research group effort to solve a Big Data Science challenge provides an
  opportunity for individuals from disparate domains of knowledge and skill sets to come together to
  solve important problems. Problem-based learning through a team approach should be seriously
  considered in the design of a core curriculum. Special attention should be paid to the
  reproducibility of results.
- Rotations and External Internships: Rotations are widely recognized as effective means to
  introduce students to the broadest range of the myriad types of data sets that are a challenge to
  Big Data Science. Rotations in basic, computer, and clinical laboratories are encouraged after
  trainees have had sufficient course work to provide basic training in all three relevant areas of Big
  Data Science. Experiences in academic, industrial, and other relevant settings are also
  encouraged as a way to introduce students to a variety of creative approaches to conducting Big
  Data research.
- Joint Mentorship: One way to enhance training and communication among disciplines is for
  trainees to have mentors from more than one of the three major scientific areas. Arrangements for
  joint mentorship of trainees should be considered as one of the goals of this training program.
   Peer-to-peer mentoring should also be encouraged between more senior trainees and more junior
  trainees.
- Reproducibility of Research Results: An emphasis on the practices that promote the reproducibility
  of results, such as scientific and rigorous design and implementation of experiments, usage of
  analysis methods based on scientifically sound statistical principles), and the sharing of code,
  data, protocols, and other information necessary for reproducing research.
- Forums for Intellectual Exchanges: It is important for trainees to have opportunities to interact with
  other trainees and faculty from other Big Data training programs to discuss published articles and
  research in progress and to interact with visiting scholars. Mechanisms for fostering intellectual
  exchanges may include journal clubs; seminars by students, faculty, and outside speakers; and
  annual retreats.
- Individual Development Plans (IDP): Each student is encouraged to have an IDP in place at the
  beginning of their appointment to the program. The IDP should be developed jointly by the trainee
  and her/his mentors and should be reviewed at a minimum annually
  (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-13-093.html).
- Transition from the Training Program to Dissertation Research: It is expected that at some point
  during the training, appointees should have the opportunity to continue their dissertation research
  under sponsors whose research is primarily involved with biomedical Big Data Science. Trainees
  should be encouraged to complete their dissertation research in the area of biomedical Big Data
  Science.
- If funds for curriculum development are requested, the applicant should describe the new courses, how they will differ from and build upon existing ones, and how they utilize appropriate

technology. The applicant should describe how course materials will be disseminated and shared widely and how they can be used, modified, and updated by others.

**Program Evaluation.** Describe a plan to review and determine the quality and effectiveness of the training program. This plan should include the metrics to be evaluated (including program activities completed, degree completion (if applicable), publications, fellowships/honors, and subsequent positions) as well as plans to obtain feedback from current and former trainees to help identify weaknesses and to provide suggestions for program improvements. Specified evaluation metrics should be tied to the goals of the program.

**Trainee Candidates.** Describe, in general terms, the size and qualifications of the pool of trainee candidates including information about the types of prior clinical and research training and career level required for the program. Do not name prospective Trainees. Describe specific plans to recruit candidates and explain how these plans will be implemented (see also section on Recruitment and Retention Plan to Enhance Diversity). Describe the nomination and selection process to be used to select candidates who would be offered admission to the program and criteria for trainees' reappointment to the program. Describe the backgrounds of the individuals you plan to recruit to this program. Describe your success/challenges in recruiting trainees with the required background.

Trainees should be appointed in the very early stages of their graduate program. Because trainees will have different scientific knowledge and experience and because of the great need for comprehensive knowledge and skills relevant to Big Data Science, trainees may be appointed for up to five years, contingent upon a strong rationale and justification. However, training programs are strongly encouraged to transition trainees to other support such as individual fellowships (F30 and F31) and research grants when feasible.

#### Institutional Environment and Commitment to the Program.

The sponsoring institution must assure support for the proposed program including assurance that sufficient time will be allowed for the PDs/PIs and other Program Faculty to contribute to the proposed program, The application must include a signed letter, on institutional letterhead, that describes the applicant institution's commitment to the planned program. Appropriate institutional commitment to the program includes the provision of adequate staff, facilities, and educational resources that can contribute to the planned program. This commitment may also include features such as PD/PI salary, stipend or tuition support for individuals involved in the proposed training program, or other commitments essential to a successful training program. Institutions with ongoing research training, student development, or career development programs that receive external funding should explain what distinguishes the proposed program from existing ones at the same trainee level, how the programs will synergize, if applicable, whether trainees are expected to transition from one support program to another, and how the training faculty, pool of potential trainees, and resources are sufficiently robust to support the proposed program in addition to existing ones.

#### **Recruitment and Retention Plan to Enhance Diversity**

Individuals are required to comply with the instructions for Recruitment and Retention Plan to Enhance Diversity as provided in Chapter 8 of the SF424 (R&R) Application Guide.

#### Plan for Instruction in the Responsible Conduct of Research

Individuals are required to comply with the instructions for Plan for Instruction in the Responsible Conduct of Research as provided in Chapter 8 of the SF424 (R&R) Application Guide.

#### **Appendix**

Do not use the Appendix to circumvent page limits. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

#### 3. Submission Dates and Times

<u>Part I. Overview Information</u> contains information about Key Dates. Applicants are encouraged to submit applications before the due date to ensure they have time to make any application corrections that might be necessary for successful submission.

Organizations must submit applications to <u>Grants.gov</u> (the online portal to find and apply for grants across all Federal agencies). Applicants must then complete the submission process by tracking the status of the application in the <u>eRA Commons</u>, NIH's electronic system for grants administration.

Applicants are responsible for viewing their application before the due date in the eRA Commons to ensure accurate and successful submission.

Information on the submission process and a definition of on-time submission are provided in the SF424 (R&R) Application Guide.

# 4. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review.

## 5. Funding Restrictions

All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the <u>NIH Grants Policy Statement</u>. The <u>National Research Service Award (NRSA) policies</u> apply to this program. An NRSA appointment may not be held concurrently with another Federally sponsored fellowship, traineeship, or similar Federal award that provides a stipend or otherwise duplicates provisions of the NRSA.

Pre-award costs are allowable only as described in the <u>NIH Grants Policy Statement</u>. Note, however, that pre-award costs are not allowable charges for stipends or tuition/fees on institutional training grants because these costs may not be charged to the grant until a trainee has actually been appointed and the appropriate paperwork submitted to the NIH awarding component..

# 6. Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in the SF424 (R&R) Application Guide. Paper applications will not be accepted.

Applicants must complete all required registrations before the application due date. Section III. Eligibility Information contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit Applying Electronically.

#### Important reminders:

All PD(s)/Pl(s) must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile Component of the SF424(R&R) Application Package. Failure to register in the Commons and to include a valid PD/Pl Commons ID in the credential field will prevent the successful submission of an electronic application to NIH.

The applicant organization must ensure that the DUNS number it provides on the application is the same number used in the organization's profile in the eRA Commons and for the System for Award Management (SAM). Additional information may be found in the SF424 (R&R) Application Guide.

See more tips for avoiding common errors.

Upon receipt, applications will be evaluated for completeness by the Center for Scientific Review and for responsiveness by the BD2K Subcommittee on Training. Applications that are incomplete and/or nonresponsive will not be reviewed.

#### **Post Submission Materials**

Applicants are required to follow the instructions for post-submission materials, as described in NOT-OD-13-030.

# **Section V. Application Review Information**

## 1. Criteria

Only the review criteria described below will be considered in the review process. As part of the <u>NIH mission</u>, all applications submitted to the NIH in support of biomedical and behavioral research are evaluated for scientific and technical merit through the NIH peer review system.

## **Overall Impact**

Reviewers will provide an overall impact/priority score to reflect their assessment of the likelihood that the proposed training program will prepare individuals for successful, productive scientific research careers and thereby exert a sustained influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

#### **Scored Review Criteria**

Reviewers will consider each of the review criteria below in the determination of the merit of the training program, and give a separate score for each. When applicable, the reviewers will consider relevant questions in the context of proposed short-term training. An application does not need to be strong in all categories to be judged likely to have major scientific impact.

# **Training Program and Environment**

- Are the research facilities and research environment conducive to preparing trainees for successful careers as Big Data research scientists?
- Are the objectives, design and direction of the proposed research training program likely to ensure effective training?
- Do the courses, where relevant, and research experiences provide opportunities for trainees to acquire state-of-the-art scientific knowledge, methods, and tools that are relevant to the goals of the training program?
- Does the program provide appropriate inter- or multidisciplinary research training opportunities?
- Is the proposed training program likely to ensure trainees will be well prepared for researchintensive and research-related careers?
- Is the level of institutional commitment to the training program, including administrative and research training support, sufficient to ensure the success of the program?
- Is it clear how the proposed training program is distinguished from other externally funded training programs at the institution?

#### In addition, for this FOA

- Does the program or training track prepare trainees to develop novel methodologies and techniques applicable to Big Data?
- Are innovative approaches used to build on existing programs? Does the research environment include large amounts of data of varying types and complexities?
- Curriculum (when applicable): Is the new curriculum novel and innovative? Are the plans to make these curricula widely and openly available adequate? Where applicable, are the training materials in a form that can be modified, updated, and tailored by others? Does the program utilize appropriate technology to enhance, facilitate, and personalize the learning process?

# Training Program Director(s)/Principal Investigator(s) (PD(s)/PI (s))

 Does the PD/PI have the scientific background, expertise, and administrative and training experience to provide strong leadership, direction, management, and administration of the proposed research training program?

- · Does the PD/PI plan to commit sufficient effort to ensure the program's success?
- · For applications designating multiple PDs/PIs:

Is a strong justification provided that the multiple PD/PI leadership approach will benefit the training program and the trainees?

• Is a strong and compelling leadership approach evident, including the designated roles and responsibilities, governance, and organizational structure consistent with and justified by the aims of the training program and the complementary expertise of the PDs/Pls?

#### In addition, for this FOA

- Do the Training PDs/PIs have the background, expertise, and experience in Big Data Science research?
- Is sufficient administrative and research training support provided for the program or training track?
- · Is leadership sufficiently strong to develop and maintain close collaborations across departments?

## **Preceptors/Mentors**

- Are sufficient numbers of experienced preceptors/mentors with appropriate expertise and funding available to support the number and level of trainees (including short-term trainees, if applicable) proposed in the application?
- Do the preceptors/mentors have strong records as researchers, including recent publications and successful competition for research support in areas directly related to the proposed research training program?o the preceptors/mentors have strong records of training individuals at the level of trainees (including short-term trainees, if applicable) proposed in the program? Are appropriate plans in place to ensure that preceptors lacking sufficient research training experience are likely to provide strong and successful mentoring?

#### In addition, for this FOA

- Is there evidence of collaboration amongst the preceptors/mentors in Big Data Science projects? Are all the preceptors/mentors involved in Big Data research?
- Do the preceptors'/mentors' expertise collectively cover all of the areas that are critical to biomedical Big Data science?

#### **Trainees**

- Is a recruitment plan proposed with strategies likely to attract well-qualified candidates for the training program?
- Is there a competitive applicant pool of sufficient size and quality, at each of the proposed levels (pre-doctoral), to ensure a successful training program?
- Are there well-defined and justified selection and re-appointment criteria as well as retention strategies?

#### **Training Record**

- How successful are the trainees (or, for new applications, other past students/postdoctorates in similar training) in completing the program?
- Has the training program ensured that trainees are productive (or, for new applications, other past students/postdoctorates in similar training) in terms of research accomplishments, publication of research conducted during the training period, and subsequent training appointments and fellowship or career development awards?
- How successful are the trainees (or, for new applications, other past students/postdoctorates in similar training) in achieving productive scientific careers as evidenced by successful competition for research science positions in industry, academia, government or other research venues; grants; receipt of honors, awards, or patents; high-impact publications; promotion to scientific leadership positions; and/or other such measures of success?

- To what extent do trainees' subsequent positions in industrial, academic, government, non-profit, or other sectors benefit from their NRSA-supported research training and directly benefit the broader biomedical research enterprise?
- Does the program propose a rigorous evaluation plan to assess the quality and effectiveness of the training? Are effective mechanisms in place for obtaining feedback from current and former trainees?

#### In addition, for this FOA

• If the training program/training track is new, how successful have previous trainees of the PDs/PIs been in the ways mentioned above.

#### **Additional Review Criteria**

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact score, but will not give separate scores for these items.

## **Protections for Human Subjects**

Generally not applicable. Reviewers should bring any concerns to the attention of the Scientific Review Officer.

## Inclusion of Women, Minorities, and Children

Generally not applicable. Reviewers should bring any concerns to the attention of the Scientific Review Officer.

#### **Vertebrate Animals**

Generally not applicable. Reviewers should bring any concerns to the attention of the Scientific Review Officer.

#### **Biohazards**

Generally not applicable. Reviewers should bring any concerns to the attention of the Scientific Review Officer.

#### Resubmissions

For Resubmissions, the committee will evaluate the application as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the project.

#### Renewals

Not Applicable

#### **Revisions**

Not Applicable

#### **Additional Review Considerations**

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

## **Recruitment & Retention Plan to Enhance Diversity**

Peer reviewers will separately evaluate the recruitment and retention plan to enhance diversity after the overall score has been determined. Reviewers will examine the strategies to be used in the recruitment and retention of individuals from underrepresented groups. The plan will be rated as **ACCEPTABLE** or **UNACCEPTABLE**, and the consensus of the review committee will be included in an administrative note in the summary statement.

## Training in the Responsible Conduct of Research

All applications for support under this FOA must include a plan to fulfill NIH requirements for instruction in the Responsible Conduct of Research (RCR). Taking into account the specific characteristics of the training program, the level of trainee experience, and the particular circumstances of the trainees, the reviewers will evaluate the adequacy of the proposed RCR training in relation to the following five required components: 1) *Format -* Does the plan satisfactorily address the format of instruction, e.g. lectures, coursework and/or real-time discussion groups, including face-to-face interaction? (*A plan involving only on-line instruction is not acceptable.*); 2) *Subject Matter -* Does the plan include a sufficiently broad selection of subject matter, such as conflict of interest, authorship, data management, human subjects and animal use, laboratory safety, research misconduct, research ethics? 3) *Faculty Participation -* Does the plan adequately describe how faculty will participate in the instruction? For renewal applications, are all training faculty who served as course directors, speakers, lecturers, and/or discussion leaders during the past project period named in the application? 4) *Duration of Instruction -* Does the plan meet the minimum requirements for RCR, i.e., at least eight contact hours of instruction? 5) *Frequency of Instruction -* Does the plan meet the minimum requirements for RCR, i.e., at least once during the predoctoral training program and at a frequency of no less than once every four years?

Plans and past record will be rated as **ACCEPTABLE** or **UNACCEPTABLE**, and the summary statement will provide the consensus of the review committee.

## Select Agent Research

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).

#### **Budget and Period of Support**

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research. If support for curriculum development is requested, reviewers will consider whether the budget is appropriately justified.

#### 2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s), convened by the Center for Scientific Review in accordance with NIH peer review policy and procedures, using the stated review criteria. Assignment to a Scientific Review Group will be shown in the eRA Commons.

As part of the scientific peer review, all applications:

- May undergo a selection process in which only those applications deemed to have the highest scientific
  and technical merit (generally the top half of applications under review) will be discussed and assigned
  an overall impact score.
- · Will receive a written critique.

Appeals of initial peer review will not be accepted for applications submitted response to this FOA.

Applications will be assigned to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications submitted in response to BD2K training program FOAs. Following initial peer review, recommended applications will receive a second level of review by the National Advisory Council for Human Genome Research. The following will be considered in making funding decisions:

- · Scientific and technical merit of the proposed project as determined by scientific peer review.
- · Availability of funds.
- · Relevance of the proposed project to program priorities.
- · Geographic considerations.

## 3. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) via the <u>eRA Commons</u>.

Information regarding the disposition of applications is available in the NIH Grants Policy Statement.

## **Section VI. Award Administration Information**

## 1. Award Notices

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant as described in the <u>NIH Grants Policy Statement</u>.

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the grants management officer is the authorizing document and will be sent via email to the grantee's business official.

Awardees must comply with any funding restrictions described in <u>Section IV.5. Funding Restrictions</u>. Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs.

Any application awarded in response to this FOA will be subject to the DUNS, SAM Registration, and Transparency Act requirements as noted on the <u>Award Conditions and Information for NIH Grants</u> website.

# 2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the <u>NIH Grants Policy Statement</u> as part of the NoA. For these terms of award, see the <u>NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General and Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Grantees, and Activities. More information is provided at <u>Award Conditions and Information for NIH Grants</u>.</u>

Institutional NRSA training grants must be administered in accordance with the current NRSA section of the *NIH Grants Policy Statement* - Institutional Research Training Grants.

#### **Leave Policies**

Note: The leave durations stated below apply to full-time trainees. Short-term trainee leave must be proportionally adjusted based on the duration of appointment.

In general, trainees may receive stipends during the normal periods of vacation and holidays observed by individuals in comparable training positions at the sponsoring institution. For the purpose of these awards, however, the period between the spring and fall semesters is considered to be an active time of research and research training and is not considered to be a vacation or holiday. Trainees may 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 the medical conditions related to pregnancy and childbirth. Trainees 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 grantee organization have access to this level of paid leave for this purpose. Either parent is eligible for parental leave. The use of parental leave must be approved by the PD/PI (see also: NOT-OD-08-064).

A period of terminal leave is not permitted, and payment may not be made from traineeship funds for leave not taken. Trainees requiring periods of time away from their research training experience longer than specified here, i.e., more than 15 calendar days of sick leave or more than 60 calendar days of parental leave, must seek approval from the NIH awarding component for an unpaid leave of absence. Approval for a leave of absence must be requested in advance by an AOR on behalf of the trainee. Trainees supported by academic institutions should refer to the NIH Institutional NRSA training grant guidelines in the <u>NIH Grants Policy</u> <u>Statement</u> for further guidance regarding vacations and requested leave.

## **Inventions and Copyrights**

Awards made primarily for educational purposes are exempted from the PHS invention requirements and thus invention reporting is not required, as described in the *NIH Grants Policy Statement*.

## **Cooperative Agreement Terms and Conditions of Award**

Not Applicable

## 3. Reporting

The Non-Competing Continuation Grant Progress Report (PHS 2590 or RPPR) and financial statements as described in the NIH Grants Policy Statement are required annually. Continuation support will not be provided until the required forms are submitted and accepted. Chapter 8 of the SF424 (R&R) Application Guide, Additional Instructions for Preparing a Progress Report for an Institutional Research Training Grant, Including Ruth L. Kirschstein National Research Service Awards, must be followed.

Failure by the grantee institution to submit required forms in a timely, complete, and accurate manner may result in an expenditure disallowance or a delay in any continuation funding for the award.

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All awardees of applicable NIH grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at <a href="https://www.fsrs.gov">www.fsrs.gov</a> on all subawards over \$25,000. See the <a href="https://www.fsrs.gov">NIH Grants Policy Statement</a> for additional information on this reporting requirement.

#### Other Reporting Requirements

- The institution must submit a completed Statement of Appointment (<u>PHS Form 2271</u>) for each trainee appointed or reappointed to the training grant. Grantees must submit the PHS 2271 data electronically using the xTrain system. More information on xTrain is available at <u>xTrain (eRA Commons)</u>. An appointment or reappointment may begin any time during the budget period, but not before the budget period start date of the grant year.
- A notarized statement verifying possession of permanent residency documentation must be submitted
  with the Statement of Appointment (<u>PHS Form 2271</u>). Individuals with a Conditional Permanent
  Resident status must first meet full (non-conditional) Permanent Residency requirements before
  receiving support.
- Termination Notice: Within 30 days of the end of the total support period, the institution must submit a
  Termination Notice (<u>PHS Form 416-7</u>) via <u>xTrain</u> for each trainee appointed for eight weeks or more.
  Trainees with service payback requirements must notify the NIH of any change in address and submit
  Annual Payback Activities Certification Forms (<u>PHS Form 6031-1</u>) until the payback service obligation
  is satisfied.

#### 4. Evaluation

In carrying out its stewardship of human resource-related programs, the NIH may request information essential to an assessment of the effectiveness of this program from databases and from participants themselves. Participants may be contacted after the completion of this award for periodic updates on various aspects of their employment history, publications, support from research grants or contracts, honors and awards, professional activities, and other information helpful in evaluating the impact of the program.

# **Section VII. Agency Contacts**

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

## **Application Submission Contacts**

eRA Commons Help Desk (Questions regarding eRA Commons registration, submitting and tracking an application, documenting system problems that threaten submission by the due date, post submission issues)

Telephone: 301-402-7469 or 866-504-9552 (Toll Free) Finding Help Online: http://grants.nih.gov/support/index.html

TTY: 301-451-5939

Email: commons@od.nih.gov

Grants.gov Customer Support (Questions regarding Grants.gov registration and submission, downloading

forms and application packages)

Contact Center Telephone: 800-518-4726

Web ticketing system: <a href="https://grants-portal.psc.gov/ContactUs.aspx">https://grants-portal.psc.gov/ContactUs.aspx</a>

Email: <a href="mailto:support@grants.gov">support@grants.gov</a>

GrantsInfo (Questions regarding application instructions and process, finding NIH grant resources)

Telephone: 301-435-0714 TTY 301-451-5936

Email: GrantsInfo@nih.gov

Frequently asked questions (FAQs) can be found at:

http://bd2k.nih.gov/faqs\_trainingFOA.html#sthash.DLc4z9UR.dpbs.

## Scientific/Research Contact(s)

Michelle Dunn, Ph.D.

National Cancer Institute (NCI) Telephone: 240-276-6881

Email: bd2k training@mail.nih.gov

Susan Lim, Ph.D.

National Cancer Institute (NCI) Telephone: 240-276-5630

Email: <a href="mailto:bd2k\_training@mail.nih.gov">bd2k\_training@mail.nih.gov</a>

Bettie J. Graham, Ph.D.

National Human Genome Research Institute (NHGRI)

Telephone: 301-496-7531

Email: bd2k training@mail.nih.gov

## Peer Review Contact(s)

Raymond Jacobson, Ph.D.

Center for Scientific Review (CSR)

Telephone: 301-996-7702

Email: bd2k training@mail.nih.gov

## Financial/Grants Management Contact(s)

Crystal Wolfrey

National Cancer Institute (NCI) Telephone: 240-276-6277

Email: bd2k\_training@mail.nih.gov

#### Section VIII. Other Information

Recently issued trans-NIH <u>policy notices</u> may affect your application submission. A full list of policy notices published by NIH is provided in the <u>NIH Guide for Grants and Contracts</u>. All awards are subject to the terms and conditions, cost principles, and other considerations described in the <u>NIH Grants Policy Statement</u>.

## **Authority and Regulations**

Awards are made under the authorization of Section 487 of the Public Health Service Act as amended (42 USC 288) and under Federal Regulations 42 CFR 66.

Weekly TOC for this Announcement
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