

Statistics and Research Design for the DNP Project

Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s) National Institutes of Health (NIH)

Components of Participating Organizations National Institute of General Medical Sciences (NIGMS) National Eye Institute (NEI) National Human Genome Research Institute (NHGRI) 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 Neurological Disorders and Stroke (NINDS) National Institute of Nursing Research (NINR) National Library of Medicine (NLM) National Center for Complementary and Integrative Health (NCCIH) National Cancer Institute (NCI) National Heart, Lung, and Blood Institute (NHLBI)

Funding Opportunity Title Academic Research Enhancement Award for Undergraduate-Focused Institutions (R15 Clinical Trial Not Allowed)

Activity Code R15 Academic Research Enhancement Award (AREA)

Announcement Type

Reissue of PAR-18-714

Related Notices See Notices of Special Interest associated with this funding opportunity NOT-OD-23-012 Reminder: FORMS-H Grant Application Forms and Instructions Must be Used for Due Dates On or After January 25, 2023 - New Grant Application Instructions Now Available NOT-OD-22-190 - Adjustments to NIH and AHRQ Grant Application Due Dates Between September 22 and September 30, 2022 May 3, 2022 - Understanding the Basic Mechanisms of Immune-related Adverse Events (irAEs) in Cancer Immunotherapy. See Notice NOT-CA-22-063. February 16, 2022 -Notice of Change to IC-Specific Interests for NINDS to PAR-21-155, "Academic Research Enhancement Award for Undergraduate-Focused Institutions (R15 Clinical Trial Not Allowed)". See Notice NOT-NS-22-080. January 18, 2022 - Notice of Information Regarding Eligibility of Schools of Engineering for Research Enhancement Award Program (REAP) Funding Opportunity Announcements. See Notice NOT-GM-22-028. October 28, 2021 - Reminder: FORMS-G Grant Application Forms & Instructions Must be Used for Due Dates On or After January 25, 2022 - New Grant Application Instructions Now Available. See Notice NOT-OD-22-018. September 13, 2021 - Updates to the Non-Discrimination Legal Requirements for NIH Recipients. See Notice NOT-OD-21-181. August 5, 2021 - New NIH "FORMS-G" Grant Application

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Forms and Instructions Coming for Due Dates on or after January 25, 2022. See Notice NOT-OD-21-169. August 5, 2021 - Update: Notification of Upcoming Change in Federal-wide Unique Entity Identifier Requirements. See Notice NOT-OD-21-170 April 20, 2021 - Expanding Requirement for eRA Commons IDs to All Senior/Key Personnel. See Notice NOT-OD-21-109 See Notices of Special Interest related to this opportunity October 25, 2021 - Notice of Correction to NOT-CA-21-101. See Notice NOT-CA-22-006.

- Notice of Correction to NOT-CA-21-101. See Notice NOT-CA-22-006. September 10, 2021 - Notice of NHLBI Participation in PAR-21-155. See Notice NOT-HL-21-032.

- Notice of NHLBI Participation in PAR-21-155. See Notice NOT-HL-21-032. June 22, 2021 - Reiterating Organization Eligibility and Application Submission for NIH Research Enhancement Awards (R15). See Notice NOT-OD-21-135.

Funding Opportunity Announcement (FOA) Number PAR-21-155

Companion Funding Opportunity

R15 Academic Research Enhancement Awards (AREA) PAR-21-154 - Academic Research Enhancement Award for Undergraduate-Focused Institutions (R15 Clinical Trial Required)

Number of Applications See Section III. 3. Additional Information on Eligibility.

Assistance Listing Number(s) 93.859, 93.242, 93.853, 93.361, 93.879, 93.847, 93.213, 93.855, 93.121, 93.394, 93.393, 93.395, 93.396, 93.399, 93.867, 93.172, 93.866, 93.273, 93.865, 93.846, 93.286, 93.279, 93.173, 93.113, 93.837, 93.838, 93.839, 93.840, 93.233

Funding Opportunity Purpose The purpose of this Academic Research Enhancement Award (AREA) for Undergraduate-Focused Institutions is to support small scale research grants at institutions that do not receive substantial funding from the NIH, with an emphasis on providing biomedical research experiences primarily for undergraduate students, and enhancing the research environment at applicant institutions. Eligible institutions must award baccalaureate science

degrees and have received no more than \$6 million dollars per year of NIH support (in both direct and F&A/indirect costs) in 4 of the last 7 fiscal years. For institutions composed of multiple schools and colleges, the \$6 million funding limit is based on the amount of NIH funding received by all the non-health professional schools and colleges within the institution as a whole. Help determining the Organization Funding Level can be found here or <https://grants.nih.gov/grants/funding/r15.htm>.

Key Dates

Posted Date May 19, 2021

Open Date (Earliest Submission Date) May 25, 2021

Letter of Intent Due Date(s) Not Applicable

The following table includes NIH standard due dates marked with an asterisk.

All applications are due by 5:00 PM local time of applicant organization. All types of non-AIDS applications allowed for this funding opportunity announcement are due on the listed date(s). 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.

Expiration Date May 08, 2024

Due Dates for E.O. 12372 Not Applicable

Required Application Instructions

It is critical that applicants follow the instructions in the Research (R) Instructions in the SF424 (R&R) Application Guide, except where instructed to do otherwise (in this FOA or in a Notice from NIH Guide for Grants and Contracts). 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 Section IV. 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.

Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

The National Institutes of Health (NIH) is continuing to make a special effort to stimulate research at educational institutions that provide baccalaureate and/or advanced degrees for a significant number of the Nation's research scientists, but that have not been major recipients of NIH support. Since Fiscal Year (FY) 1985, Congressional appropriations for the NIH have included funds for this initiative, which NIH has implemented through the Academic Research Enhancement Award (AREA) program. This funding opportunity announcement aims to support AREA grants to undergraduate-focused institutions that do not receive substantial funding from the NIH, in order to provide biomedical research experiences for undergraduate students and enhance the research environment at these institutions. AREA funds are intended to support new and renewal biomedical research projects proposed by faculty members of eligible institutions (see Part 2. Section III.1). The three objectives of this FOA are to: (1) provide support for meritorious research at undergraduate-focused institutions or institutional components; (2) strengthen the research environment at these institutions/components; and (3) give undergraduate students an opportunity to gain significant biomedical research experience through active involvement in the research. For the purpose of this announcement, an undergraduate-focused institution/component is one in which the undergraduate enrollment is greater than the graduate enrollment. The AREA program will enable qualified scientists to receive support for small-scale research projects. It is anticipated that investigators supported under the AREA program will benefit from the opportunity to conduct independent research; that the grantee institution will benefit from a research environment strengthened through AREA grants; and that students at recipient institutions will benefit from exposure to and participation in scientific research in the biomedical sciences so that they consider careers in biomedical research. This AREA FOA emphasizes the engagement and inclusion of undergraduates in research. The research project must involve undergraduate students, and the research team must be composed primarily of undergraduate students. Student involvement in research may include participation in the design of experiments and controls, collection and analysis of data, execution and troubleshooting of experiments, presenting at meetings, drafting journal articles, collaborative interactions, participation in lab meetings to discuss results and future experiments, etc. The AREA program is a research grant

program, not a training or fellowship program, and, as such, applications should not include training plans such as didactic training or non-research activities relating to professional development. Inclusion and support of masters and doctoral candidates in these research projects are allowable, but should be carefully considered. In all cases, the majority of students conducting research through the award must be undergraduates. Since diversity strengthens the research environment, AREA projects are encouraged to include students from diverse backgrounds, including those from groups underrepresented in the biomedical research workforce (See NOT-OD-20-031). This FOA does not provide for support of research from Health Professional Schools as defined in Section III.1 regardless of student composition. An AREA application submitted to this FOA may include other investigators, such as technicians, collaborators or consultants, or other individuals such as high school students, post baccalaureate participants, graduate students, or postdoctoral fellows. However, involvement of such individuals does not fulfill the goal to engage undergraduate students in eligible environments to research. Institute/Center-Specific Interests NIGMS will accept applications for research projects in areas within the Institute's mission. The NIGMS website provides information about the institute mission and areas of research interest. For additional scientific program information and for pre-application guidance, a potential applicant is encouraged to contact the NIGMS Scientific/Research Contact or the Program Director with portfolios with research interests relevant to the applicant's proposed topic. NIAAA supports basic, translational, and clinical research on the causes, consequences, prevention, diagnosis, progression, and treatment of alcohol-related problems across the lifespan. NIAAA encourages meritorious alcohol research projects in the broad areas of neuroscience and behavior, organ damage and other health effects, epidemiology and prevention, and treatment and recovery. Investigators who conduct original and innovative basic biomedical, social, behavioral, clinical, or population-based research directed toward eliminating health disparities are invited to apply to this FOA. Projects may include a focus on addressing disparities in disparity populations as a whole, a single health disparity population, or a subgroup within a health disparity population. Projects addressing the improvement of health in racial/ethnic minority populations (without a specific emphasis on disparities relative to other groups) are also accepted under this announcement. . More information about NIAAA's mission and research priorities is available in the NIAAA Strategic Plan at <https://www.niaaa.nih.gov/strategic-plan> . For specific programmatic questions, please contact the NIAAA point-of-contact listed in this FOA. NIAID supports basic and applied research to better understand, treat, and prevent infectious, immunologic, and allergic diseases, with the goal of developing new therapies, vaccines, diagnostic tests, and other technologies. Research areas include microbiology and infectious diseases, AIDS and AIDS -related research, immunology, allergy, transplantation, and biodefense. NLM supports innovative research and development in biomedical informatics and data science. The scope of NLM's interest in these research domains is broad, with emphasis on new methods and approaches to foster data driven discovery in the biomedical and clinical

health sciences as well as domain-independent, reusable approaches to discovery, curation, analysis, organization and management of health-related digital objects. Biomedical informatics and data science draw upon many fields, including mathematics, statistics, information science, computer science and engineering, and social/behavioral sciences. Application domains include health care delivery, basic biomedical research, clinical and translational research, precision medicine, public health, biosurveillance, health information management in disasters, and similar areas. NIDA supports innovative research addressing critical issues of neuroscience, genetics, behavior, prevention, treatment, epidemiology, etiology, health services, HIV/AIDS, and co-occurring opportunistic infections (e.g., viral hepatitis C, tuberculosis, sexually transmitted infections) associated consequences in substance using populations, medication development, or other research areas relevant to drug abuse. NIDA priorities are further described in the NIDA Strategic Plan (see <https://www.drugabuse.gov/about-nida/strategic-plan/directors-message>) and on the NIDA Notice of Special Interest webpage (see <https://www.drugabuse.gov/research/nida-research-programs-activities/nida-notice-special-interest-nosi>). Applicants are encouraged to contact a program official to discuss the proposed application. NICHD supports biological, behavioral, and clinical research related to conception and pregnancy, normal and abnormal development in childhood, reproductive health, population dynamics across the lifespan, and rehabilitation medicine (<https://www.nichd.nih.gov/grants-funding/opportunities-mechanisms/areas-research/Pages/default.aspx>). Research projects considered for funding by NICHD must fall within the scientific missions of the twelve Scientific Branches of the NICHD Division of Extramural Research (DER) or the National Center for Medical Rehabilitation Research (NCMRR). Information about those scientific missions and program staff contacts may be found on the web pages for the DER scientific branches at: <http://www.nichd.nih.gov/about/org/der/branches/Pages/index.aspx> and the NCMRR at: <http://www.nichd.nih.gov/about/org/ncmrr/Pages/overview.aspx>. Potential applicants are strongly encouraged to read these webpages for any updates in response to recent scientific advances or emerging public health topics. NICHD encourages applications that address its extramural program priorities and will consider how well research projects align with one or more of those priorities when making award decisions. A detailed list of NICHD high priority research areas may be found at <https://www.nichd.nih.gov/grants-funding/opportunities-mechanisms/areas-research/Pages/priorities.aspx> NCCIH has a mission to determine, through rigorous scientific investigation, the usefulness and safety of complementary health approaches, and their roles in improving health and healthcare. NCCIH will accept applications for research projects in areas within the Center's mission that are well-aligned with our strategic priorities (<https://www.nccih.nih.gov/about/strategic-plans-and-reports>). Studies may range from basic, through translational, epidemiological, health services, and other human subjects research. Investigators are strongly encouraged to discuss

their concepts with NCCIH program staff prior to applying NIDCR supports basic, translational, and clinical research in dental, oral, and craniofacial health and disease. Program areas include oral microbiota and bacterial disease; oral opportunistic pathogens and viral disease; salivary biology and immunology; oral and salivary gland cancers; neuroscience of orofacial pain and temporomandibular disorders; mineralized tissue physiology; dental materials and biomaterials; tissue engineering and regenerative medicine; genetics/genomics; developmental biology; data science; epidemiology; HIV/AIDS and oral health; oral health disparities and inequities; and mechanisms in the science of behavior change. Potential applicants are strongly encouraged to discuss their research plans with Program Staff in relevant areas. NIDCD supports applications that proposes research projects in the normal and disordered processes of hearing, balance, taste, smell, voice, speech, and language. Applicants are strongly encourage to learn more about NIDCD research areas at <https://www.nidcd.nih.gov/research/extramural>. NIA will accept applications for research projects in areas within the Institute's mission that includes genetic, biological, behavior, social, and economic research on aging. In addition, NIA encourages applications on Alzheimer's Disease (AD) and AD Related Dementias (ADRD). The NIA website provides additional information. about the Institute mission and areas of research interest. For additional scientific program information and for pre-application guidance, a potential applicant is encouraged to contact the NIA Program Director ([link](#)) whose portfolio covers the scientific topic of interest. NIBIB will accept applications for research projects that fall within one or more of its Scientific Program Areas. For additional guidance, potential applicants are encouraged to contact the NIBIB Scientific/Research Contact. NIMH has a mission to transform the understanding and treatment of mental illnesses through basic and clinical research, paving the way for prevention, recovery, and cure. Applications considered for funding by the NIMH must fall within the areas of priority detailed in the NIMH Strategic Plan and the NIMH Strategic Research Priorities. Applicants are strongly encouraged to contact the person listed under Agency Contacts (Section VII) prior to submission. NIAMS supports research into the causes, treatment, and prevention of arthritis and musculoskeletal and skin diseases; the training of basic and clinical scientists to carry out this research; and the dissemination of information on research progress in these diseases. NIAMS also conducts and supports basic research on the normal structure and function of bones, joints, muscles, and skin. Basic research involves a wide variety of scientific disciplines, including immunology, genetics, molecular biology, structural biology, biochemistry, physiology, virology, and pharmacology. Clinical research includes rheumatology, orthopedics, dermatology, metabolic bone diseases, heritable disorders of bone and cartilage, inherited and inflammatory muscle diseases, and sports and rehabilitation medicine. NIAMS will accept applications for research projects in areas within the Institute's mission. Applications from institutions serving underrepresented groups and institutions with well-developed, documented programs promoting diversity in the biomedical, behavioral, and clinical research workforce are strongly encouraged to apply. The NIAMS website (<https://www.niams.nih.gov/>)

provides information about the institute mission and areas of research interest (<https://www.niams.nih.gov/about-niams/strategic-plan-fiscal-years-2020-2024>). For additional scientific program information and for pre-application guidance, potential applicants are encouraged to contact the NIAMS Extramural Research Program Staff whose portfolio covers the scientific topic of interest (<https://www.niams.nih.gov/grants-funding/funding-opportunities/supported-scientific-areas>). NIDDK conducts and supports medical research and research training and to disseminate science-based information on diabetes and other endocrine and metabolic diseases; digestive diseases, nutritional disorders, and obesity; and kidney, urologic, and hematologic diseases, to improve people's health and quality of life. Research projects considered for funding by NIDDK must fall within the scientific research mission of the Institute. Potential applicants are encouraged to contact the NIDDK Extramural Research Program Staff whose portfolio covers the scientific topic of interest. Specific information about our Research Programs & Contacts is available at <https://www.niddk.nih.gov/research-funding/research-programs>. NINR supports research that builds the scientific foundation for nursing practice and policy across clinical and community settings, and advances the prevention, detection, and management of disease and disability. Drawing on nursing's holistic perspective, NINR funds basic, clinical, population, and translational research that integrates factors at multiple levels to identify their role in health, health improvement and health inequities. NINR promotes research that improves the health of individuals, families, and populations in a variety of settings, translating science in order to maximize the impact of findings on practice and policy. Potential applicants are strongly encouraged to review the research supported by NINR and to discuss their research plans with the Program Staff in relevant areas. NIEHS supports a variety of scientific disciplines, including basic, mechanistic, clinical, epidemiological, computational, engineering, and/or health risk communication approaches, can be used to advance the NIEHS Strategic Plan. Applications submitted to this FOA must have a research focus on exposure-health related responses from environmental agents within the mission interest of the NIEHS (e.g., industrial chemicals or manufacturing byproducts, metals, pesticides, herbicides, air pollutants and other inhaled toxicants, particulates or fibers, fungal, and bacterial or biologically derived toxins). Agents that are considered within the primary mission responsibility of other NIH Institutes and Centers include, but are not limited to: alcohol; chemotherapeutic agents; radiation that is not a result of an ambient environmental exposure; smoking, except when considered as a secondary smoke exposure that is a component in the indoor environment (particularly in children); drugs of abuse; pharmaceuticals; dietary nutrients; and infectious or parasitic agents. Applications that focus entirely, or primarily, on these exposure factors will be not be considered for support by NIEHS. NEI supports research aimed at increasing our understanding of the eye, the visual system, and visual function in normal health and disease as well as the special problems and requirements of the blind. Applicants are strongly

advised to contact the NEI R15 Program Contact before submitting applications to this FOA for guidance about NEI's mission and interests as related to the R15 program. NCI considers meritorious R15 applications requesting support for cancer research-focused projects across the full spectrum of its mission, including projects focused on studies of cancer biology, etiology, prevention, detection, diagnosis, treatment, control, survivorship, and population sciences. The NCI R15 Program Contact person (indicated below) can be contacted for more information and guidance about NCI's mission, priorities, and interests as related to the R15 Program, this R15 funding opportunity announcement, and R15 applications. NINDS seeks fundamental knowledge about the brain and nervous system and to use that knowledge to reduce the burden of neurological disease. NINDS supports basic, translational and clinical research within specifically defined areas of neuroscience. Research projects considered for funding by NINDS must fall within the scientific research mission of the Institute. A key component of research projects submitted to NINDS in response to this FOA is to provide an outstanding opportunity for undergraduates to gain a solid understanding of rigorous scientific methodology within the particular field of study. NINDS also strongly urges PIs to engage students from diverse backgrounds and perspectives in their research project. It is critical that applicants with research interests relevant to the NINDS mission contact the person listed under Agency Contacts (Section VII) to confirm that the proposed clinical trial meets NINDS's requirements for this funding opportunity. In addition, applicants are encouraged to consult the Frequently Asked Questions website and the NIH Research Enhancement Award R15 website for more information about this program

See Section VIII. Other Information for award authorities and regulations.

Section II. Award Information

Funding Instrument Grant: A support mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity.

Application Types Allowed

Renewal

Resubmission

Revision

NewRenewalResubmissionRevision The OER Glossary and the SF424 (R&R) Application Guide provide details on these application types. Only those application types listed here are allowed for this FOA.

Clinical Trial? Not Allowed: Only accepting applications that do not propose clinical trials. Need help determining whether you are doing a clinical trial?

Funds Available and Anticipated Number of Awards The number of awards is contingent upon NIH appropriations and the submission of a sufficient number of meritorious applications.

Award Budget Applicants may request up to \$300,000 in direct costs for the entire project period of up to 3 years.

Award Project Period The scope of the proposed project should determine the project period. The maximum project period is 3 years.

NIH grants policies as described in the NIH Grants Policy Statement will apply to the applications submitted and awards made from 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)

In addition, all organizations must meet the following criteria at the time of application submission: 1. The applicant institution must be an accredited public or non-profit private school that grants baccalaureate degrees in biomedical sciences. This FOA does not provide support for research from Health Professional Schools and colleges and accredited institutions that provide education and training leading to a health professional degree, including but not limited to: BSN, MSN, DNP, MD, DDS, DO, PharmD, DVM, OD, DPT, DC, ND, DPM, MOT, OTD, DPT, , MS-SLP, CScD, SLPD, AuD, MSPO, MSAT, and MPH. The application must be submitted by the eligible undergraduate-focused organization with a unique entity identifier (such as DUNS) and a unique NIH eRA Institutional Profile File (IPF) number. 2. At the time of application submission, all of the non-health professional components of the institution combined must not have received support from the NIH totaling more than \$6 million per year (in both direct and F&A/indirect costs) in 4 of the last 7 years. A year is defined as a federal fiscal year: from October 1 through September 30. For institutions composed of multiple schools and colleges, the \$6 million funding limit is based on the amount of NIH funding received by all of the non-health professional schools and colleges within the institution as a whole. Note that all activity codes are included in this calculation except the following: C06, S10, and all activity codes starting with a G. For this FOA: An academic component is any school, college, center, or institute that is not a Health Professional School or College.

For this FOA: A qualifying academic component (school, college, center, or institute) within an institution (e.g. School of Arts and Sciences) has greater undergraduate student enrollment than graduate student enrollment.

For this FOA: All types of Health Professional Schools are not eligible to apply, and are not considered in this calculation.

Health Professional Schools and Colleges provide education and training leading to a health professional degree (including but not limited to: BSN, MSN, DNP, MD, DDS, DO, PharmD, DVM, OD, DPT, DC, ND, DPM, MOT, OTD, DPT, , MS-SLP, CScD, SLPD, AuD, MSPO, MSAT, and MPH).

Health Professional Schools and Colleges may include schools of medicine, dentistry, osteopathy, pharmacy, nursing, veterinary medicine, public health, optometry, allied health, chiropractic, naturopathy and podiatry.

For institutions with multiple campuses, eligibility can be considered for each individual campus (e.g. main, satellite, etc.) only if a unique identifier number and NIH IPF number are established for each campus. For institutions that use one identifier number or NIH IPF number for all campuses, eligibility is determined for all campuses (e.g. main, satellite, etc.) together. Additional Eligibility Guidance A signed letter is required from the Provost or similar official with institution-wide responsibility verifying the eligibility of the applicant institution at the time of application submission according to the eligibility criteria indicated above. See the application instructions for "Other Attachments" on the SF424(R&R) Other Project Information form in Section IV.2 Instructions for Application Submission. Final eligibility will be validated by NIH prior to award. To assist in determining eligibility, organizations are encouraged to use the NIH RePORT website under NIH Awards by Location & Organization. An AREA grant is permitted to have a subcontract to a non-AREA-eligible institution. However, applicants should keep the goals of the AREA program in mind when preparing the application, which include strengthening the research environment of eligible institutions and engaging students from eligible institutions in research. The majority of the research must be directed by the PD(s)/PI(s) at the grantee institution.

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 defined in the NIH Grants Policy Statement, are 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 NIH Policy on Late Submission of Grant Applications states that

failure to complete registrations in advance of a due date is not a valid reason for a late submission. Dun and Bradstreet Universal Numbering System (DUNS) - 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) - 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.

eRA Commons - Applicants must have an active DUNS number to register in eRA Commons. Organizations can register with the eRA Commons as they are working through their SAM or Grants.gov registration, but all registrations must be in place by time of submission. 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.

Grants.gov - 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 as the Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)) 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 Multiple Program Director/Principal Investigator Policy and submission details in the Senior/Key Person Profile (Expanded) Component of the SF424 (R&R) Application Guide.

To be eligible for an AREA grant, the PD(s)/PI(s) must meet the following additional criteria: Each PD(s)/PI(s) must have a primary appointment at a non-health professional school or college within the applicant institution, as defined in "Eligible Institutions," above. If proposing multiple PD(s)/PI(s), each PD/PI must be at an AREA-eligible institution.

Each PD(s)/PI(s) may not be the PD(s)/PI(s) of an active NIH research grant, including another R15 grant, at the time of award of an AREA grant, although he or she may be one of the Key Personnel for an active NIH grant held by another PD/PI.

Each PD(s)/PI(s) may not be awarded more than one R15 grant at a time, although he or she may hold successive New or Renewal grants.

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

Applicant organizations may submit more than one application, provided that each application is scientifically distinct. The NIH will not accept duplicate or highly overlapping applications under review at the same time. This means that the NIH will not accept: A new (A0) application that is submitted before issuance of the summary statement from the review of an overlapping new (A0) or resubmission (A1) application.

A resubmission (A1) application that is submitted before issuance of the summary statement from the review of the previous new (A0) application.

An application that has substantial overlap with another application pending appeal of initial peer review (see NOT-OD-11-101).

Section IV. Application and Submission Information

1. Requesting an Application Package The application forms package specific to this opportunity must be accessed through ASSIST, Grants.gov Workspace or an institutional system-to-system solution. Links to apply using ASSIST or

Grants.gov Workspace are available in Part 1 of this FOA. See your administrative office for instructions if you plan to use an institutional system-to-system solution.

2. Content and Form of Application Submission It is critical that applicants follow the instructions in the Research (R) Instructions in the SF424 (R&R) Application Guide 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.

Page Limitations

All page limitations described in the SF424 Application Guide and the Table of Page Limits must be followed.

Instructions for Application Submission

Note: Effective for due dates on or after January 25, 2023, the Data Management and Sharing (DMS) Plan will be attached in the Other Plan(s) attachment in FORMS-H and subsequent application forms packages. For due dates on or before January 24, 2023, the Data Sharing Plan and Genomic Data Sharing Plan (GDS) will continue to be attached in the Resource Sharing Plan attachment in FORMS-G application forms packages.

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

All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Project/Performance Site Locations

All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Other Project Information

All instructions in the SF424 (R&R) Application Guide must be followed.

Facilities & Other Resources: This attachment should include the following information: A profile of the students of the applicant institution and any information or estimate of the number who have obtained a baccalaureate degree and gone on to obtain an academic or professional doctoral degree in the health-related sciences during the last five years.

Description of plans to recruit well-qualified undergraduate students from diverse backgrounds, including those from groups underrepresented in the biomedical research workforce (See NOT-OD-20-031) to participate in the research project.

Description of the special characteristics of the applicant institution that make it appropriate for an AREA grant awarded through this FOA, where the goals of this FOA are to: (1) provide support for meritorious research at undergraduate-focused institution or institutional components; (2) strengthen the research environment at these institutions/components; and (3) give undergraduate students an opportunity to gain significant biomedical research experience through active involvement in the research.

Description of the likely impact of an AREA grant on the PD(s)/PI(s).

Description of the likely impact of an AREA grant on the research environment of the applicant institution.

Description of the likely impact of the AREA grant on the ability of undergraduate students at the institution to gain experience conducting biomedical research.

Provide a description of the resources of the grantee institution available for the proposed research (e.g., equipment, supplies, laboratory space, release time, matching funds, etc.).

Although the majority of the research must be directed by the PD(s)/PI(s) and conducted at the applicant institution, limited use of special facilities or equipment at another institution is permitted. For any proposed research sites other than the applicant institution, provide a brief description of the resources and access students will need and have to these resources. Other Attachments: The application must include a PDF-formatted letter named

"ProvostLetter.pdf" (without quotation marks). For MPI applications a signed Provost letter is required from each involved institution. The letter must be signed by the Provost or similar official with institution-wide responsibility attesting to the following information: The eligible academic component(s) (i.e., the college/school level) has more undergraduates than graduate students as of the date of submission.

All the non-health professional components of the institution together have received support from the NIH totaling no more than \$6 million per year (in both direct and F&A/indirect costs) in 4 of the last 7 years, as described in Section III, "Eligible Organization".

Validation that the PD(s)/PI(s) has (or in the case of a multiple PD/PI application that all PD(s)/PI(s) have) a primary appointment at the qualifying component (i.e., the college/school level). Applications that do not contain this signed letter will be withdrawn without review.

SF424(R&R) Senior/Key Person Profile

All instructions in the SF424 (R&R) Application Guide must be followed.

Biographical Sketch: The PD(s)/PI(s) should include a summary of his or her previous and/or current experience supervising undergraduate and/or graduate students in research in the Personal Statement. The PD(s)/PI(s) should indicate which peer-reviewed publications or other research products involved undergraduate and/or graduate students under his or her supervision.

R&R or Modular Budget All instructions in the SF424 (R&R) Application Guide must be followed.

The total budget for all years of the proposed project must be requested in Budget Period 1. Do not complete Budget Periods 2 or 3. They are not required and will not be accepted with the application.

Applicants submitting an application with direct costs of \$250,000 or less (total for all years, excluding consortium Facilities and Administrative [F&A] costs) must use the Modular Budget.

Applicants submitting an application with direct costs of \$250,001 - \$300,000 (total for all years, excluding

consortium Facilities and Administrative [F&A] costs) must use the R&R Budget.

Students must be compensated for their participation in the lab's research and in accord with institutional policies. Salaries can be requested for students in the R15 budget or other resources at the university can be used to pay them for their participation. Undergraduate students who are compensated from the R15 grant or other institutional funds should receive at least the national minimum wage. Compensation through course credit hours towards graduation is allowable, but must be justified. If universities/colleges provide room and board for summer research students, details must be provided in the application.

NIH does not fund stipends for undergraduates on R15 awards. Modular Budget (direct costs of \$250,000 or less) All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions: Budget Period 1: Direct Costs Direct Costs less Consortium F&A: Select the appropriate dollar amount from the drop-down list. This number must not exceed \$250,000 Budget Justification: Personnel Justification: Since a primary objective of the AREA program is to engage undergraduate students in meritorious research, the research team must be composed primarily of undergraduate students from the applicant institution/AREA-eligible component. Indicate aspects of the proposed research in which undergraduate students will participate. If participating students have not yet been individually identified, the number and academic level of those to be involved should be provided. If there are any Collaborators or Consultants for the project, provide their names, organizational affiliations, and the services they will perform. R&R Budget (direct costs of \$250,001 to \$300,000) All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions: Budget Period 1: Direct Costs Total Direct Costs less Consortium F&A: This number must not exceed \$300,000. Budget Justification: Personnel Justification: Since a primary objective of the AREA program is to engage undergraduate students to meritorious research, the research team must be composed primarily of undergraduate students from the applicant institution/AREA-eligible component. Indicate aspects of the proposed research in which undergraduate students will participate. If participating students have not yet been individually identified, the number and academic level of those to be involved should be provided. If there are any Collaborators or Consultants for the project, provide their names, organizational affiliations, and the services they will perform.

R&R Subaward Budget

All instructions in the SF424 (R&R) Application Guide must be followed.

PHS 398 Cover Page Supplement

All instructions in the SF424 (R&R) Application Guide must be followed.

PHS 398 Research Plan

Other Plan(s):

Note: Effective for due dates on or after January 25, 2023, the Data Management and Sharing Plan will be attached in the Other Plan(s) attachment in FORMS-H and subsequent application forms packages. For due dates on or before January 24, 2023, the Data Sharing Plan and Genomic Data Sharing Plan (GDS) will continue to be attached in the Resource Sharing Plan attachment in FORMS-G application forms packages.

All applicants planning research (funded or conducted in whole or in part by NIH) that results in the generation of scientific data are required to comply with the instructions for the Data Management and Sharing Plan. All applications, regardless of the amount of direct costs requested for any one year, must address a Data Management and Sharing Plan.

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions:

Research Strategy: Describe how the proposed plan can achieve the specific aims using a research team composed primarily of undergraduate students. Describe how undergraduate students will be engaged in and supervised in conducting hands-on, rigorous research. Describe how undergraduate students will participate in research activities such as planning, execution, and/or analysis of the research. Formal training plans (e.g., non-research activities, didactic training, seminars) should not be provided, although a brief description of activities related to enhancing students' research capabilities and progress (e.g., the use of individual development plans, etc.) is permitted.

Progress Report Publication List: For renewals, when listing publications, manuscripts accepted for publication, patents, and other printed materials that have resulted from the project, note which of these products have included the work of students conducting research supported by the AREA grant.

Resource Sharing Plan: Individuals are required to comply with the instructions for the Resource Sharing Plans as

provided in the SF424 (R&R) Application Guide.

Appendix:

Only limited Appendix materials are allowed. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

PHS Human Subjects and Clinical Trials Information

When involving human subjects research, clinical research, and/or NIH-defined clinical trials (and when applicable, clinical trials research experience) follow all instructions for the PHS Human Subjects and Clinical Trials Information form in the SF424 (R&R) Application Guide, with the following additional instructions: If you answered "Yes" to the question "Are Human Subjects Involved?" on the R&R Other Project Information form, you must include at least one human subjects study record using the Study Record: PHS Human Subjects and Clinical Trials Information form or Delayed Onset Study record. Study Record: PHS Human Subjects and Clinical Trials Information All instructions in the SF424 (R&R) Application Guide must be followed.

Delayed Onset Study Note: Delayed onset does NOT apply to a study that can be described but will not start immediately (i.e., delayed start). All instructions in the SF424 (R&R) Application Guide must be followed.

PHS Assignment Request Form

All instructions in the SF424 (R&R) Application Guide must be followed.

3. Unique Entity Identifier and System for Award Management (SAM) See Part 1. Section III.1 for information regarding the requirement for obtaining a unique entity identifier and for completing and maintaining active registrations in System for Award Management (SAM), NATO Commercial and Government Entity (NCAGE) Code (if applicable), eRA Commons, and Grants.gov.

4. Submission Dates and Times

Part I. Overview Information contains information about Key Dates and times. 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. When a submission date falls on a weekend or Federal holiday, the application deadline is automatically extended to the next business day. Organizations must submit applications to Grants.gov (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 eRA Commons, NIH's electronic system for grants administration. NIH and Grants.gov systems check the application against many of the application instructions upon submission. Errors must be corrected and a changed/corrected application must be submitted to Grants.gov on or before the application due date and time. If a Changed/Corrected application is submitted after the deadline, the application will be considered late. Applications that miss the due date and time are subjected to the NIH Policy on Late Application Submission. 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.

5. Intergovernmental Review (E.O. 12372) This initiative is not subject to intergovernmental review.

6. Funding Restrictions

All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement. Pre-award costs are allowable only as described in the NIH Grants Policy Statement.

7. 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 How to Apply Application Guide. If you encounter a system issue beyond your control that threatens your ability to complete the submission process on-time, you must follow the Dealing with System Issues guidance. For assistance with application submission, contact the Application Submission Contacts in Section VII. Important reminders: All PD(s)/PI(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/PI Commons ID in the credential field will prevent the successful submission of an electronic application to NIH. See Section III of this FOA for information on registration requirements. 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. 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 and compliance with application instructions by the Center for Scientific Review and the assigned Institute or Center. Applications that are incomplete or non-compliant will not be reviewed.

Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in the policy.

Section V. Application Review Information

1. Criteria Note: Effective for due dates on or after January 25, 2023, the Data Sharing Plan and Genomic Data Sharing Plan (GDS) as part of the Resource Sharing Plan will not be evaluated at time of review. Only the review criteria described below will be considered in the review process. Applications submitted to the NIH in support of the NIH mission are evaluated for scientific and technical merit through the NIH peer review system.

For this particular announcement, note the following: This FOA has three objectives: (1) provide support for meritorious research at undergraduate-focused institution or institutional components; (2) strengthen the research environment at these institutions/components; and (3) give undergraduate students an opportunity to gain significant biomedical research experience through active involvement in the research. For the purpose of this announcement, an undergraduate institution/component is one in which the undergraduate enrollment is greater than the graduate enrollment. Scientific foundation for the proposed research should be established using preliminary data (if available) and/or published data. Although preliminary data are not required for an R15 application, they may be included if available.

Overall Impact

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to make important scientific contributions to the research field(s) involved, to provide research opportunities to undergraduate students by engaging them in primary research activities, and to strengthen the research environment of the institution, 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 relation to the AREA program objectives and give a separate score for each. An application does not need to be strong in all categories to be judged as a high impact AREA application. For example, a solid and interesting scientific research project that is not by its nature innovative or paradigm-shifting, and includes a good plan to engage undergraduates in primary research may be considered a strong AREA application.

Significance Does the project address an important problem or a barrier to progress in the field? Is the prior research that serves as the key support for the proposed project rigorous? If the aims of the project are achieved, will the data be publishable, disseminated, and important to the field? If funded, will the AREA grant have a substantial effect on the applicant institution in terms of strengthening the research environment and exposing undergraduate students to research?

Investigator(s) Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project? If investigators are in the early stages of their careers, do they have appropriate scientific experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their scientific field(s)? Do the PD(s)/PI(s) have suitable experience in supervising and engaging undergraduate students in research? If the project is collaborative or multi-PD(s)/PI(s), do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

Innovation Does the application take advantage of, challenge or build on current research concepts and models or research techniques? Are innovative approaches to engaging undergraduate students in research proposed?

Approach Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Have the investigators included plans to address weaknesses in the rigor of prior research that serves as the key support for the proposed project? Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?

If the project involves human subjects and/or NIH-defined clinical research, are the plans to address 1) the protection of human subjects from research risks, and 2) inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion or exclusion of individuals of all ages (including children and older adults), justified in terms of the scientific goals and research strategy proposed?

Environment Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Does the application demonstrate the likely availability of well-qualified students to participate in the research project? Does the application demonstrate appropriate plans to recruit well-qualified undergraduate students from diverse backgrounds including those from groups underrepresented in the biomedical research workforce (See NOT-OD-20-031) to participate in the research project? Does the application provide sufficient evidence that students at the AREA-eligible institution/academic component have in the past and/or are likely in the future to pursue careers in the biomedical sciences? Does the PD/PI(s) have sufficient time and institutional support to conduct the proposed project?

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 For research that involves human subjects but does not involve one of the 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 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. For additional information on review of the Human Subjects section, please refer to the Guidelines for the Review of Human Subjects.

Inclusion of Women, Minorities, and Individuals Across the Lifespan When the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of individuals of all ages (including children and older adults) to determine if it is justified in terms of the scientific goals and research strategy proposed. For additional information on review of the Inclusion section, please refer to the Guidelines for the Review of Inclusion in Clinical Research.

Vertebrate Animals The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following criteria: (1) description of proposed procedures involving animals, including species, strains, ages, sex, and total number to be used; (2) justifications for the use of animals versus alternative models and for the appropriateness of the species proposed; (3) interventions to minimize discomfort, distress, pain and injury; and (4) justification for euthanasia method if NOT consistent with the AVMA Guidelines for the Euthanasia of Animals. Reviewers will assess the use of chimpanzees as they would any other application proposing the use of vertebrate animals. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section.

Biohazards 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.

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

For Renewals, the committee will consider the progress made in the last funding period as well as whether the application provides sufficient evidence that undergraduate students have been included in publications in the past.

Revisions

For Revisions, the committee will consider the appropriateness of the proposed expansion of the scope of the project. If the Revision application relates to a specific line of investigation presented in the original application that was not recommended for approval by the committee, then the committee will consider whether the responses to comments from the previous scientific review group are adequate and whether substantial changes are clearly evident.

Additional Review Considerations

Note: Effective for due dates on or after January 25, 2023, the Data Sharing Plan and Genomic Data Sharing Plan (GDS) as part of the Resource Sharing Plan will not be evaluated at time of review.

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.

Applications from Foreign Organizations

Not Applicable.

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).

Resource Sharing Plans

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) Genomic Data Sharing Plan (GDS).

Authentication of Key Biological and/or Chemical Resources: For projects involving key biological and/or chemical resources, reviewers will comment on the brief plans proposed for identifying and ensuring the validity of those resources.

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.

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 will receive a written critique.

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.

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. Applications will be assigned on the basis of established PHS referral guidelines to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications submitted in response to this FOA. Following initial peer review, recommended applications will receive a second level of review by the appropriate national Advisory Council or Board. The

following will be considered in making funding decisions:

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 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 eRA Commons . Refer to Part 1 for dates for peer review, advisory council review, and earliest start date. 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 NIH Grants Policy Statement. 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 recipient's business official. Awardees must comply with any funding restrictions described in Section IV.5. Funding Restrictions. 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 terms and conditions found on the Award Conditions and Information for NIH Grants website. This includes any recent legislation and policy applicable to awards that is highlighted on this website.

Institutional Review Board or Independent Ethics Committee Approval: Recipient institutions must ensure that protocols are reviewed by their IRB or IEC. To help ensure the safety of participants enrolled in NIH-funded studies, the awardee must provide NIH copies of documents related to all major changes in the status of ongoing protocols.

Cooperative Agreement Terms and Conditions of Award

Not Applicable

Data Management and Sharing Note: The NIH Policy for Data Management and Sharing is effective for due dates on or after January 25, 2023. Consistent with the NIH Policy for Data Management and Sharing, when data management and

sharing is applicable to the award, recipients will be required to adhere to the Data Management and Sharing requirements as outlined in the NIH Grants Policy Statement. Upon the approval of a Data Management and Sharing Plan, it is required for recipients to implement the plan as described. 3. Reporting Progress reports for multi-year funded awards are due annually on or before the anniversary of the budget/project period start date of award. The reporting period for multi-year funded award progress report is the calendar year preceding the anniversary date of the award. Information on the content of the progress report and instructions on how to submit the report using the RPPR are posted at <http://grants.nih.gov/grants/policy/myf.htm>

A final RPPR, invention statement, and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the NIH Grants Policy Statement. 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 www.fsrs.gov on all subawards over \$25,000. See the NIH Grants Policy Statement for additional information on this reporting requirement. In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts from all Federal awarding agencies with a cumulative total value greater than \$10,000,000 for any period of time during the period of performance of a Federal award, must report and maintain the currency of information reported in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently FAPIIS). This is a statutory requirement under section 872 of Public Law 110-417, as amended (41 U.S.C. 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available. Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75 "Award Term and Conditions for Recipient Integrity and Performance Matters.

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 Service Desk (Questions regarding ASSIST, eRA Commons, application errors and warnings, documenting system problems that threaten submission by the due date, and post-submission issues) Finding Help Online:
<http://grants.nih.gov/support/> (preferred method of contact)

Telephone: 301-402-7469 or 866-504-9552 (Toll Free) General Grants Information (Questions regarding application instructions, application processes, and NIH grant resources)

Email: GrantsInfo@nih.gov (preferred method of contact)

Telephone: 301-637-3015 Grants.gov Customer Support (Questions regarding Grants.gov registration and Workspace)

Contact Center Telephone: 800-518-4726

Email: support@grants.gov

Scientific/Research Contact(s)

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Eunice Kennedy Shriver National Institute Of Child Health & Human Development (NICHD)

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National Institute on Aging (NIA)

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National Institute of Nursing Research (NINR)

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Email: liz.perruccio@nih.gov Tina Gatlin, Ph.D.

National Institute Of Biomedical Imaging And Bioengineering (NIBIB)

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E-mail: christine.gatlin@nih.gov NIAID AI Training Help Desk

AITrainingHelpDesk@niaid.nih.gov Lanay M. Mudd, Ph.D., FACSM

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210.0015555556

National Institute of Mental Health (NIMH)

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National Institute On Alcohol Abuse And Alcoholism (NIAAA)

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E-mail: li.lin@nih.gov

Peer Review Contact(s)

Examine your eRA Commons account for review assignment and contact information (information appears two weeks after the submission due date). General R15-Related Review Questions: Svetlana E. Kotliarova, PhD

Center for Scientific Review (CSR)

Telephone: 301-594-7945

Email: kotiars@csr.nih.gov

Financial/Grants Management Contact(s)

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Section VIII. Other Information

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

Authority and Regulations

Reference

[Dyslexia in Context: Research, Policy and Practice \(Dyslexia Series \(Whurr\)\)](#)

[Health Care Informatics: An Interdisciplinary Approach \(Book + Web Course\)](#)