Part 1. Overview Information

Participating Organization(s)

National Institutes of Health (NIH (http://www.nih.gov))

Components of Participating Organizations

National Institute of Biomedical Imaging and Bioengineering (NIBIB (https://www.nibib.nih.gov/))

Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD (https://www.nichd.nih.gov/))

Funding Opportunity Title

Team-Based Design in Biomedical Engineering Education (R25 Clinical Trial Not Allowed)

Activity Code

R25 (https://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=r25) Education Projects

Announcement Type

Reissue of PAR-19-215 (https://grants.nih.gov/grants/guide/pa-files/PAR-19-215.html)

Related Notices

April 16, 2024 - Notice of Extension of the Expiration Date of PAR-22-000, "Team-Based Design in Biomedical Engineering Education (R25 Clinical Trial Not Allowed)". See Notice NOT-EB-24-008 (//grants.nih.gov/grants/guide/notice-files/NOT-EB-24-008.html)

NOT-OD-23-012 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-23-012.html) 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 (/grants/guide/notice-files/NOT-OD-22-190.html) - Adjustments to NIH and AHRQ Grant Application Due Dates Between September 22 and September 30, 2022

March 24, 2022 - Notice of NICHD Participation in PAR-22-000. See Notice NOT-HD-22-012 (https://grants.nih.gov/grants/guide/notice-files/NOT-HD-22-012.html).

July 22, 2019 - Requirement for ORCID iDs for Individuals Supported by Research Training, Fellowship, Research Education, and Career Development Awards Beginning in FY 2020. See Notice NOT-OD-19-109 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-109.html)

Funding Opportunity Announcement (FOA) Number

PAR-22-000

Companion Funding Opportunity

None

Number of Applications

Only one application per institution is allowed, as defined in Section III. 3. Additional Information on Eligibility.

Assistance Listing Number(s)

93.286, 93.865

Funding Opportunity Purpose

The NIH Research Education Program (R25) supports research education activities in the mission areas of the NIH. The overarching goal of this R25 program is to support educational activities that complement and/or enhance the training of a workforce to meet the nation's biomedical, behavioral and clinical research needs.

To accomplish the stated over-arching goal, this FOA will support creative educational activities with a primary focus on:

- ***Courses for Skills Development***

This FOA seeks to support programs that include innovative approaches to enhance biomedical engineering (BME) design education to ensure a future workforce that can meet the nation's needs in biomedical research and healthcare technologies.

Applications are encouraged from institutions that propose to establish new or to enhance existing team-based design courses or programs in undergraduate biomedical engineering departments or other degree-granting programs with biomedical engineering tracks/minors. This FOA targets the education of undergraduate biomedical engineering/bioengineering students in a team-based environment. Health equity and universal design topics must be integrated throughout the educational activities. While current best practices such as multidisciplinary/interdisciplinary education, introduction to the regulatory pathway and other issues related to the commercialization of medical devices, and clinical immersion remain encouraged components of a strong BME program, this FOA also challenges institutions to propose other novel, innovative and/or ground-breaking activities that can form the basis of the next generation of biomedical engineering design education.

Key Dates

Posted Date

February 23, 2022

Open Date (Earliest Submission Date)

April 30, 2022

Letter of Intent Due Date(s)

April 30, 2022; April 30, 2023; April 30, 2024

Dates in bold and italics reflect changes per NOT-EB-24-008 (//grants.nih.gov/grants/guide/notice-files/NOT-EB-24-008.html)

Application Due Dates			Review and Award Cycles		
New	Renewal / Resubmission / Revision (as allowed)	AIDS	Scientific Merit Review	Advisory Council Review	Earliest Start Date
May 30, 2022	May 30, 2022	Not Applicable	November 2022	January 2023	April 2023
May 30, 2023	May 30, 2023	Not Applicable	November 2023	January 2024	April 2024
May 30, 2024	May 30, 2024	Not Applicable	November 2024	January 2025	April 2025

Application Due Dates			Review and Award Cycles		
New	Renewal / Resubmission / Revision (as allowed)	AIDS	Scientific Merit Review	Advisory Council Review	Earliest Start Date
January 29, 2025	*January 29, 2025*	*Not Applicable*	*July 2025*	*October 2025*	*December 2025*

All applications are due 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.

Expiration Date

New Date January 30, 2025 (Original Date: May 31, 2024) per issuance of NOT-EB-24-008 (//grants.nih.gov/grants/guide/notice-files/NOT-EB-24-008.html)

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 (//grants.nih.gov/grants/guide/url_redirect.php?id=12000), except where instructed to do otherwise (in this FOA or in a Notice from NIH Guide for Grants and Contracts (//grants.nih.gov/grants/guide/)).

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.

There are several options available to submit your application through Grants.gov to NIH and Department of Health and Human Services partners. You **must** use one of these submission options to access the application forms for this opportunity.

1. Use the NIH ASSIST system to prepare, submit and track your application online.

   Apply Online Using ASSIST

2. Use an institutional system-to-system (S2S) solution to prepare and submit your application to Grants.gov and eRA Commons (https://public.era.nih.gov/commons/) to track your application. Check with your institutional officials regarding availability.

3. Use Grants.gov (https://grants.gov/search-grants?oppStatuses=closed|archived|posted|forecasted&fon=PAR-22-000) Workspace to prepare and submit your application and eRA Commons (http://public.era.nih.gov/commons/) to track your application.

Table of Contents

Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

The NIH Research Education Program (R25) supports research educational activities that complement other formal training programs in the mission areas of the NIH Institutes and Centers.

The overarching goal of this R25 program is to support educational activities that complement and/or enhance the training of a workforce to meet the nation's biomedical, behavioral and clinical research needs.

To accomplish the stated over-arching goal, this FOA will support creative educational activities with a primary focus on:

- **Courses for Skills Development:** For example, courses and programs that use a team-based design approach which incorporates health equity, universal design (the purposeful design of products and environments to be useable by people of varying abilities and characteristics), design concepts early in educational activities, interaction between design students at different career/education levels, and state-of-the-art best practices (such as multidisciplinary/interdisciplinary education, the regulatory pathway and other issues related to the commercialization of medical devices), and further enhances these with novel creative and/or ground-breaking approaches and activities which will be implemented and evaluated with the goal of disseminating the outcomes for the benefit of the larger biomedical engineering education community. Programs may also include a clinical immersion experience that enhances skills and experiences in needs finding, communication across disciplines (including with healthcare providers, patients, caregivers, and/or communities), ideation coupled with frequent clinical/user feedback, and/or small projects to address minor, immediately solvable needs.
- **NIBIB Statement of Interest:** NIBIB interests include the development and integration of advanced bioengineering, sensing, imaging, and computational technologies for the improvement of human health and medical care. With this FOA, in addition to the goals described above NIBIB especially encourages courses and programs that incorporate the following topics: 1) Expanding the design perspective by designing for low resource settings; 2) Expanding the clinical immersion perspective by incorporating community-based engagement or emphasizing problem driven solutions; and, 3) Expanding the team perspective by including students from disciplines such as nursing, computer engineering, data science, and/or public health, as well as different education levels.

Research education programs may complement ongoing research training and education occurring at the applicant institution, but the proposed educational experiences must be distinct from those training and education programs currently receiving Federal support. R25 programs may augment institutional research training programs (e.g., T32, T90) but cannot be used to replace or circumvent Ruth L. Kirschstein National Research Service Award (NRSA) programs.

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

New
Renewal
Resubmission
The OER Glossary (//grants.nih.gov/grants/guide/url_redirect.php?id=11116) 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 trial(s).

Need help determining whether you are doing a clinical trial? (https://grants.nih.gov/grants/guide/url_redirect.php?id=82370)

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.

Only one active grant will be supported at any institution at any one time

Award Budget

Direct costs of up to $20,000 per year may be requested. Programs that include a clinical immersion program outside the academic year and lasting 6 to 10 weeks (at least 30 hours per week) may request an additional $20,000 to cover participant costs (see Participant Costs section below), yielding a total of $40,000 in direct costs.

Award Project Period

Project durations of up to five years may be requested.

Other Award Budget Information

rsonnel Costs

dividuals designing, directing, and implementing the research education program may request salary and fringe benefits appropriate for e person months devoted to the program. Salaries requested may not exceed the levels commensurate with the institution's policy for milar positions and may not exceed the congressionally mandated cap. (If mentoring interactions and other activities with participants are onsidered a regular part of an individual's academic duties, then any costs associated with the mentoring and other interactions with articipants are not allowable costs from grant funds).

s the activities associated with this FOA are considered a regular part of an academician's activities, faculty salary for the academic year is ot allowed. Up to $5,000 may be requested as summer salary for PD/PI(s) that engage in activities that are not a part of their regular cademic duties, such as coordinating a clinical immersion program or conducting workshops to discuss clinical immersion observations for eeds identification and project development. Whether funds are requested for a single PD/PI or multiple PD/PIs, the total faculty salary equest for the program cannot exceed $5,000 annually.

p to $5,000 may also be requested for: a) technical staff who directly support students in their design projects; and/or, b) administrators who rectly support a given aspect of the design or implementation of the course such as the restructuring of an existing course to enable terdisciplinary participation in the course, or working with clinical departments to establish and run a clinical immersion program.

otal salary costs requested may not exceed $10,000 annually ($5,000 for faculty summer salary and $5,000 for the technical staff and/or dministrators).

rticipant Costs

dividuals selected for participation in this program must be undergraduate students majoring or minoring in biomedical ngineering/bioengineering. Allowable participant costs for this funding opportunity are limited salary provided to students engaging in a full- ne (at least 30 hours per week), 6 to 10-week clinical immersion period outside of the academic year. Up to $20,000 may be requested nnually. The participant salary requested should not exceed $12 per hour or, if the state-mandated minimum wage is higher, the minimum ourly wage specified by the state. Participant costs are capped at $4,000 per participant per year. Expenses for foreign travel are not allowe articipant costs must be itemized in the Participant/Trainee Section of the budget and justified in the budget justification

her Program-Related Expenses

onsultant costs, equipment, supplies, travel for key persons, and other program-related expenses may be included in the proposed budg hese expenses must be justified as specifically required by the proposed program and must not duplicate items generally available at the pplicant institution.

he budgets for applications to this FOA can include support for, but are not limited to, the following items:

Purchase of necessary supplies and parts. -Hiring of machine shop/prototyping services.

Support for guest lecturers from academia or industry with direct experience in design planning, translation, or commercialization.

Support for web-based resources for patent searches, regulatory procedures, and business plans.

Support for PD(s)/PI(s) or mentor(s) of the program to attend scientific meetings specifically to present activities and outcomes of the ourse/program supported by this FOA.

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direct Costs

direct Costs (also known as Facilities & Administrative [F&A] Costs) are reimbursed at 8% of modified total direct costs (exclusive of tuition nd fees, expenditures for equipment and consortium costs in excess of $25,000), rather than on the basis of a negotiated rate agreement.

grants policies as described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?id=11120) will apply to the cations submitted and awards made from this FOA.

ction III. Eligibility Information

ligible Applicants

ible Organizations

er 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 Highe 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)

U.S. Territory or Possession

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

utions with existing Ruth L. Kirschstein National Research Service Award (NRSA) institutional training grants (e.g., T32) or other Federall ed training programs may apply for a research education grant provided that the proposed educational experiences are distinct from those ng programs receiving federal support. In many cases, it is anticipated that the proposed research education program will complement ing research training occurring at the applicant institution.

eign Institutions

domestic (non-U.S.) Entities (Foreign Institutions) **are not** eligible to apply

domestic (non-U.S.) components of U.S. Organizations **are not** eligible to apply.

gn components, as defined in the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.php?id=11118), **are not** allowed

uired Registrations

icant organizations

cant organizations must complete and maintain the following registrations as described in the SF 424 (R&R) Application Guide to be eligible for or receive an award. All registrations must be completed prior to the application being submitted. Registration can take 6 weeks or more cants should begin the registration process as soon as possible. The NIH Policy on Late Submission of Grant Applications nts.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html) states that failure to complete registrations in advance of a due date is not a vali on for a late submission.

System for Award Management (SAM) (https://www.sam.gov/portal/public/SAM/) Applicants must complete and maintain an active registra **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 (//grants.nih.gov/grants/guide/url_redirect.php?id=11176) Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.

Unique Entity Identifier (UEI)- A UEI is issued as part of the SAM.gov registration process. SAM registrations prior to fall 2021 were update include a UEI. For applications due on or after January 25, 2022, the UEI must be provided on the application forms (e.g., FORMS-G); the same UEI must be used for all registrations, as well as on the grant application.

Dun and Bradstreet Universal Numbering System (DUNS) (http://fedgov.dnb.com/webform) Organization registrations prior to April 2022 require applicants to obtain a DUNS prior to registering in SAM. By April 2022, the federal government will stop using the DUNS number a entity identifier and will transition to the Unique Entity Identifier (UEI) issued by SAM. Prior to April 2022, 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 o grant application.

eRA Commons (https://era.nih.gov/) - Once the unique organization identifier (DUNS prior to April 2022; UEI after April 2022) is establishe organizations can register with eRA Commons in tandem with completing their full SAM and Grants.gov registrations; all registrations mus in place by time of submission. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Progra Director/Principal Investigator (PD/PI) account in order to submit an application.

Grants.gov (//grants.nih.gov/grants/guide/url_redirect.php?id=82300) Applicants must have an active SAM registration in order to complete Grants.gov registration.

ram Directors/Principal Investigators (PD(s)/PI(s))

D(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 te their existing account with the applicant organization in eRA Commons. If the PD/PI is also the organizational Signing Official, they must l listinct eRA Commons accounts, one for each role. Obtaining an eRA Commons account can take up to 2 weeks.

ible Individuals (Program Director/Principal Investigator)

ndividual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Program Director(s)/Principal tigator(s) (PD(s)/PI(s)) is invited to work with his/her organization to develop an application for support. Individuals from diverse background ding underrepresented racial and ethnic groups, individuals with disabilities, and women are always encouraged to apply for NIH support. Se nder: Notice of NIH's Encouragement of Applications Supporting Individuals from Underrepresented Ethnic and Racial Groups as well as iduals with Disabilities, NOT-OD-22-019.

nstitutions/organizations proposing multiple PDs/PIs, visit the Multiple Program Director/Principal Investigator Policy and submission details enior/Key Person Profile (Expanded) Component of the SF424 (R&R) Application Guide.

PD/PI should be an established investigator in the scientific area in which the application is targeted and capable of providing both administr scientific leadership to the development and implementation of the proposed program. The PD/PI will be expected to monitor and assess the am and submit all documents and reports as required.

ost Sharing

FOA does not require cost sharing as defined in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?id=1112

dditional Information on Eligibility

nber of Applications

one application per institution (normally identified by having a unique DUNS number or NIH IPF number) is allowed.

gram Faculty

archers from diverse backgrounds, including racial and ethnic minorities, persons with disabilities, and women are encouraged to participate ptors/mentors. Mentors should have research, teaching, or industry experience relevant to the proposed program. Mentors must be commit ntinue their involvement throughout the total period of the mentee's participation in this award.

icipants

iduals selected for participation in this program must be undergraduate students majoring or minoring in biomedical engineering/bioengineer e only formally designated participants may receive support during a clinical immersion period, students pursuing studies in departments and olines relevant to medical device design and translation are encouraged to participate in courses or in team design projects where the teams ly consist of biomedical engineering/ bioengineering students.

ction IV. Application and Submission Information

equesting an Application Package

application forms package specific to this opportunity must be accessed through ASSIST, Grants.gov Workspace or an institutional syster m solution. Links to apply using ASSIST or Grants.gov Workspace are available in Part 1 of this FOA. See your administrative office for uctions if you plan to use an institutional system-to-system solution.

ontent and Form of Application Submission

ritical that applicants follow the instructions in the Research (R) Instructions in the SF424 (R&R) Application Guide nts.nih.gov/grants/guide/url_redirect.php?id=12000) except where instructed in this funding opportunity announcement to do otherwise. ormance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these uctions will not be reviewed.

er of Intent

ugh 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 ains allows IC staff to estimate the potential review workload and plan the review.

e date listed in Part 1. Overview Information, prospective applicants are asked to submit a letter of intent that includes the following informat

- 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

etter of intent should be sent to:

Gutekunst, Ph.D.

hone: 301-402-5069

l: dave.gutekunst@nih.gov (mailto:dave.gutekunst@nih.gov)

e Limitations

age limitations described in the SF424 Application Guide and the Table of Page Limits (https://grants.nih.gov/grants/how-to-apply-applicat e/format-and-write/page-limits.htm#train) must be followed.

ructions for Application Submission

: Effective for due dates on or after January 25, 2023 a Data Management and Sharing Plan is not applicable for this FOA.

ollowing section supplements the instructions found in the SF424 (R&R) Application Guide and should be used for preparing an applicati FOA.

24(R&R) Cover

w all instructions provided in the SF424 (R&R) Application Guide.

24(R&R) Project/Performance Site Locations

w all instructions provided in the SF424 (R&R) Application Guide.

24(R&R) Other Project Information Component

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

acilities & Other Resources. Describe the educational environment, including the facilities, laboratories, participating departments, compu ervices, and any other resources to be used in the development and implementation of the proposed program. List all thematically related ources of support for research training and education following the format for Current and Pending Support.

Other Attachments.

An Advisory Committee is not a required component of a Research Education program. However, if an Advisory Committee is intended, prov a plan for the appointment of an Advisory Committee to monitor progress of the research education program. The composition, roles, esponsibilities, and desired expertise of committee members, frequency of committee meetings, and other relevant information should be ncluded. Describe how the Advisory Committee will evaluate the overall effectiveness of the program. Proposed Advisory Committee membe

should be named in the application if they have been invited to participate at the time the application is submitted. Renewal applications with Advisory Committees should include the names of all committee members during the past project period. Please name your file Advisory_Committee.pdf .

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

24(R&R) Senior/Key Person Profile Expanded

w all instructions provided in the SF424 (R&R) Application Guide.

R Budget

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

Include all personnel other than the PD(s)/PI(s) in the Other Personnel section, including clerical and administrative staff.

Use the section on Participant/Trainee Support Costs to to include any participant salary requested for the clinical immersion program, if applicable. Indicate the hourly rate requested, number of hours per week, duration of program, and the number of participants for whom sa is requested.

S 398 Cover Page Supplement

w all instructions provided in the SF424 (R&R) Application Guide.

S 398 Research Plan

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

Research Strategy

Research Strategy section must be used to upload the **Research Education Program Plan**, which must include the following components lescribed below:

- Proposed Research Education Program
- Program Director/Principal Investigator
- Program Faculty
- Program Participants
- Institutional Environment and Commitment
- Recruitment Plan to Enhance Diversity
- Plan for Instruction in the Responsible Conduct of Research
- Evaluation Plan
- Dissemination Plan

Research Education Program Plan

Proposed Research Education Program. While the proposed research education program may complement ongoing research training and education occurring at the applicant institution, the proposed educational experiences must be distinct from those research training and rese education programs currently receiving federal support. When research training programs are on-going in the same department, the applicar organization should clearly distinguish between the activities in the proposed research education program and the research training supporte he training program.

The information should include a description of the education and/or career levels of the planned participants. Provide programmatic detail o special activities proposed (e.g., courses, curricula, seminars, workshops). Provide a description of the design course(s), discussing didactic experiential components and, if possible, providing a syllabus. Discuss how, in addition to the design concepts, students will be introduced to egulatory, business, and ethical considerations involved in developing a design idea and translating it for clinical or patient use. Discuss how concepts of health equity will be integrated into and across educational activities. Discuss how concepts of universal design will be integrated nto and across educational activities. Institutions with existing design courses must describe the new and enhanced aspects of the proposed course(s). Discuss the innovative components of the program. Describe how student teams will be formed, how the teams will identify or be assigned a design project, and how faculty advisors will be assigned to the teams. Provide examples of current design projects and, if applic past design projects undertaken by course participants. Discuss the roles of clinical or industrial co-advisors, if applicable. Provide specifics o he interaction between students and advisors and course leader(s), and how student and team progress will be evaluated. If a clinical imme period is proposed, describe the organization of the program and provide an overview of the activities and deliverables of the proposed mmersion period. Discuss how students in either the hospital or community-based setting will receive structured engagement and mentorshi Discuss how this period will inform or be incorporated into the activities undertaken in the design course/program. Describe the breadth of cli experiences offered and how these experiences result in a rich and state-of-the-art design experience for trainees.

Program Director/Principal Investigator. Describe arrangements for administration of the program. Provide evidence that the Program Director/Principal Investigator is actively engaged in research and/or teaching in an area related to the mission of NIH, and can organize, administer, monitor, and evaluate the research education program. For programs proposing multiple PDs/PIs, describe the complementary a integrated expertise of the PDs/PIs, their leadership approach, and governance appropriate for the planned project.

The PD/PI(s) should ensure their biosketches reflect their experience in BME thoroughly. The PD/PI(s) must possess the scientific backgrou leadership and administrative capabilities required to coordinate, supervise, and direct the proposed design course(s). Describe any relevant experience in teaching design courses, supervising design teams, and designing and commercializing biomedical devices or technologies.

Program Faculty. Researchers from diverse backgrounds, including racial and ethnic minorities, persons with disabilities, and women are encouraged to participate as program faculty. Faculty should have research expertise and experience relevant to the proposed program and demonstrate a history of, or the potential for, their intended roles. The application must include information about the planned faculty and clin and/or industrial advisors available to provide design problems as well as guidance and expertise in addressing these problems. The advisor should have strong records as educators and researchers or a strong background in medical device development. Discuss relevant experien in biomedical device design and in leading student teams in design projects. Provide examples of the projects the specific advisors may offe course participants.

Program Participants. Applications must describe the intended participants, and the eligibility criteria and/or specific educational backgroun characteristics that are essential for participation in the proposed research education program. Identify the undergraduate career levels for w the proposed program and its components are planned. If a clinical immersion period is proposed, discuss the process for the recruitment an selection of participants for this portion of the program.

Institutional Environment and Commitment. Describe any additional aspects of the Institutional Environment and Commitment not addres under Facilities & Other Resources or the required Institutional Commitment Letter of Support, described below. Appropriate institutional commitment should include the provision of adequate staff, facilities, and educational resources that can contribute to the planned research education program. This section should not duplicate information provided elsewhere.

The administration of the applicant institution as well as all participating departments should document institutional support and commitment the goals of the design course/program. The application should include a description of support (financial and otherwise) to be provided to th proposed course(s). This could include, for example, space, shared laboratory facilities and equipment, funds for curriculum development, release time for the PD/PI and/or participating faculty, support for project related expenses or student salaries for activities outside of the academic year, or any other creative ways to support the establishment and growth of the course. Describe ongoing research and clinical programs at the home and any collaborating institution that may provide design projects for the course participants to undertake. The applica should provide evidence that research, laboratory, and prototyping facilities will provide trainees with the necessary experience to prepare th for future careers in biomedcial engineering.

uitment Plan to Enhance Diversity (NOT-OD-20-031 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html)**):**

applicant must provide a recruitment plan to enhance diversity. Include outreach strategies and activities designed to recruit prospective cipants from diverse backgrounds, e.g. those from groups described in the Notice of NIH's Interest in Diversity s://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html). Describe the specific efforts to be undertaken by the program and how the osed plan reflects past experiences in recruiting individuals from underrepresented groups.

Renewal applications must include a detailed account of experiences in recruiting individuals from underrepresented groups during the previ unding period, including successful and unsuccessful recruitment strategies. Information should be included on how the proposed plan refle he program's past experiences in recruiting individuals from underrepresented groups.

Applications lacking a diversity recruitment plan will not be reviewed.

Plan for Instruction in the Responsible Conduct of Research. All applications must include a plan to fulfill NIH requirements for instructio he Responsible Conduct of Research (RCR). The plan must address the five, required instructional components outlined in the NIH policy: 1 *Format* - the required format of instruction, i.e., face-to-face lectures, coursework, and/or real-time discussion groups (a plan with only on-line nstruction is not acceptable); 2) *Subject Matter* - the breadth of subject matter, e.g., conflict of interest, authorship, data management, huma subjects and animal use, laboratory safety, research misconduct, research ethics; 3) *Faculty Participation* - the role of the program faculty in nstruction; 4) *Duration of Instruction* - the number of contact hours of instruction, taking into consideration the duration of the program; and 5 *Frequency of Instruction* instruction must occur during each career stage and at least once every four years. See also NOT-OD-10-019 https://grants.nih.gov/grants/guide/notice-files/not-od-10-019.html). The plan should be appropriate and reasonable for the nature and durati of the proposed program. Renewal (Type 2) applications must, in addition, describe any changes in formal instruction over the past project p and plans to address any weaknesses in the current instruction plan. Renewal applications must clearly describe the components of the curr application that are different than the past program. All participating faculty who served as course directors, speakers, lecturers, and/or discussion leaders during the past project period must be named in the application.

Applications lacking a plan for instruction in responsible conduct of research will not be reviewed.

Evaluation Plan. Applications must include a plan for evaluating the activities supported by the award. The application must specify baseline metrics (e.g., numbers, educational levels, and demographic characteristics of participants), as well as measures to gauge the short or long-success of the research education award in achieving its objectives. Wherever appropriate, applicants are encouraged to obtain feedback fro participants to help identify weaknesses and to provide suggestions for improvements. Evaluation results should include, where possible, information on the subsequent activities and career paths of participants, especially those participating in the clinical immersion program, and included in future competing continuation (renewal) applications and as part of the Final Progress Report. Any patents obtained or other step taken to commercialize the student projects should be reported.

Dissemination Plan. A specific plan must be provided to disseminate nationally any findings resulting from or materials developed under the auspices of the research education program, e.g., sharing course curricula and related materials via web postings, presentations at scientific meetings, workshops.

Letters of Support

A letter of institutional commitment must be attached as part of Letters of Support (see section above: **Institutional Environment and Commitment."**)

If additional departments/colleges of the home institution or other institutions are participating, their commitment to the goals of the design course/program should be documented in letters of support.

Resource Sharing Plans

Individuals are required to comply with the instructions for the Resource Sharing Plans as provided in the SF424 (R&R) Application Guide.

The following modifications also apply: Programs proposing to share any curricula or other resources such as list of projects or catalogs of u clinical needs for student teams or other innovators to address, should describe these plans in this section.

When relevant, applications are expected to include a software dissemination plan if support for development, maintenance, or enhancemen software is requested in the application.There is no prescribed single license for software produced. However, the software dissemination pla should address, as appropriate, the following goals:

- Software source code should be freely available to biomedical researchers and educators in the non-profit sector, such as institu of education, research institutions, and government laboratories. Users should be permitted to modify the code and share their modifications with others.
- The terms of software availability should permit the commercialization of enhanced or customized versions of the software, or incorporation of the software or pieces of it into other software packages.
- To preserve utility to the community, the software should be transferable such that another individual or team can continue development in the event that the original investigators are unwilling or unable to do so.

Appendix

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

The following modifications also apply:

Sample syllabi for the course(s) proposed, examples of past projects undertaken by former participants of the course or projects envisioned the future may be included in the Appendix.

Only applications that do not propose clinical trial(s) will be accepted under this FOA.

Human Subjects and Clinical Trials Information

n involving human subjects research, clinical research, and/or NIH-defined clinical trials (and when applicable, clinical trials research rience) follow all instructions for the PHS Human Subjects and Clinical Trials Information form in the SF424 (R&R) Application Guide, with ving additional instructions:

u answered Yes to the question Are Human Subjects Involved? on the R&R Other Project Information form, you must include at least one an subjects study record using the **Study Record: PHS Human Subjects and Clinical Trials Information** form or **Delayed Onset Study** rd.

y Record: PHS Human Subjects and Clinical Trials Information

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

yed Onset Study

: Delayed onset (https://grants.nih.gov/grants/glossary.htm#DelayedOnsetStudy) does NOT apply to a study that can be described but will n immediately (i.e., delayed start). All instructions in the SF424 (R&R) Application Guide must be followed.

s Assignment Request Form

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

nique Entity Identifier and System for Award Management (SAM)

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

ubmission Dates and Times

I. Overview Information contains information about Key Dates and times. Applicants are encouraged to submit applications before the due d sure they have time to make any application corrections that might be necessary for successful submission. When a submission date falls o end or Federal holiday (https://www.opm.gov/policy-data-oversight/snow-dismissal-procedures/federal-holidays/), the cation deadline is automatically extended to the next business day.

nizations must submit applications to Grants.gov (//grants.nih.gov/grants/guide/url_redirect.php?id=11128) (the online portal to find and appl s across all Federal agencies). Applicants must then complete the submission process by tracking the status of the application in the eRA mons (//grants.nih.gov/grants/guide/url_redirect.php?id=11123), NIH's electronic system for grants administration. NIH and Grants.gov syste k the application against many of the application instructions upon submission. Errors must be corrected and a changed/corrected applicatio be submitted to Grants.gov on or before the application due date and time. If a Changed/Corrected application is submitted after the deadli pplication will be considered late. Applications that miss the due date and time are subjected to the NIH Policy on Late Application Submissi

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

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

ıtergovernmental Review (E.O. 12372)

initiative is not subject to intergovernmental review. (https://grants.nih.gov/grants/policy/nihgps/html5/section_10/10.10.1_executive_orders.h

unding Restrictions

IH awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statemer rants.nih.gov/grants/guide/url_redirect.php?id=11120).

award costs are allowable only as described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?id=11143)

ther Submission Requirements and Information

cations must be submitted electronically following the instructions described in the SF424 (R&R) Application Guide. Paper applications will r cepted.

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

ssistance with your electronic application or for more information on the electronic submission process, visit How to Apply Application Guide s://grants.nih.gov/grants/how-to-apply-application-guide.html). If you encounter a system issue beyond your control that threatens your abilit plete the submission process on-time, you must follow the Dealing with System Issues (https://grants.nih.gov/grants/how-to-apply-applicatior e/due-dates-and-submission-policies/dealing-with-system-issues.htm) guidance. For assistance with application submission, contact the cation Submission Contacts in Section VII.

mportant reminders:

All PD(s)/PI(s) must include their eRA Commons ID in the Credential fieldof the Senior/Key Person Profile form**.** 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 NIH.

The applicant organization must ensure that the unique entity identifier (DUNS number or UEI as required) provided 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

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

See more tips (//grants.nih.gov/grants/guide/url_redirect.php?id=11146) for avoiding common errors.
receipt, applications will be evaluated for completeness and compliance with application instructions by the Center for Scientific Review, NI
cations that are incomplete or non-compliant will not be reviewed.

cants are strongly encouraged to visit http://www.nibib.nih.gov/training-careers/undergraduate-graduate/team-based-design-biomedical-
neering-education-r25 (http://www.nibib.nih.gov/training-careers/undergraduate-graduate/team-based-design-biomedical-engineering-educat
before preparing their application for this FOA.

t Submission Materials

cants are required to follow the instructions for post-submission materials, as described in the policy
nts.nih.gov/grants/guide/url_redirect.php?id=82299). Any instructions provided here are in addition to the instructions in the policy.

ction V. Application Review Information

riteria

the review criteria described below will be considered in the review process. Applications submitted to the NIH in support of the NIH miss
nts.nih.gov/grants/guide/url_redirect.php?id=11149) are evaluated for scientific and technical merit through the NIH peer review system.

his particular announcement, note the following:

goal of this R25 program is to support educational activities that prepare a biomedical engineering workforce able to design and translate ne
es and technologies to improve human health and well-being. The FOA seeks to fund applications that propose to develop courses or progr
offer undergraduate students the opportunity to acquire valuable experience and skills in identifying and addressing open-ended problems a
t needs in biomedical engineering and design while working in a team environment. Innovative approaches that will be implemented and
ated during the support period such that outcomes and best practices can be disseminated to the biomedical engineering education commu
specially encouraged.

rall Impact

ewers will provide an overall impact score to reflect their assessment of the likelihood for the project to strongly advance research educati
lfilling the goal of this R25 Education Program, in consideration of the following review criteria and additional review criteria, as applicable
roject proposed.

red Review Criteria

ewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each. An applica
not need to be strong in all categories to be judged likely to have major scientific impact.

Significance

Does the proposed program address a key audience and an important aspect or important need in research education? Is there convincing
evidence in the application that the proposed program will significantly advance the stated goal of the program?

nvestigator(s)

s the PD/PI capable of providing both administrative and scientific leadership to the development and implementation of the proposed progr
s there evidence that an appropriate level of effort will be devoted by the program leadership to ensure the program's intended goal is
ccomplished? If applicable, is there evidence that the participating faculty have experience in mentoring students and teaching science? If
pplicable, are the faculty good role models for the participants by nature of their scientific accomplishments? If the project is collaborative o
nulti-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organization
tructure appropriate for the project?

Specific for this FOA: Do the PD/PI(s) have relevant experience in BME design and the teaching of BME design, especially with a team-base
pproach? For programs that include a clinical immersion period, are there adequate clinical collaborators to supervise and mentor students'

nnovation

aking into consideration the nature of the proposed research education program, does the applicant make a strong case for this program
effectively reaching an audience in need of the program's offerings? Where appropriate, is the proposed program developing or utilizing
nnovative approaches and latest best practices to improve the knowledge and/or skills of the intended audience?

Specific for this FOA: Does the proposed program include novel and/or ground-breaking approaches with the potential to significantly advanc he state of the art in biomedical design education?

Approach

Does the proposed program clearly state its goals and objectives, including the educational level of the audience to be reached, the content conveyed, and the intended outcome? Is there evidence that the program is based on a sound rationale, as well as sound educational conce and principles? Is the plan for evaluation sound and likely to provide information on the effectiveness of the program? If the proposed progra will recruit participants, are the planned recruitment, retention, and follow-up (if applicable) activities adequate to ensure a highly qualified participant pool?

Specific for this FOA: Does the proposed program clearly describe how concepts of health equity are considered in the educational activities Does the proposed program clearly describe how concepts of universal design are considered in the educational activities? Does the propos course/program include a strong didactic component addressing design concepts and business, regulation, and ethical aspects relevant to ta a design idea from the bench to bedside? Are the proposed activities of the program conducive to providing a rich and state-of-the-art desigr experience to the participants? Are the methods for student team formation, needs assessment and project development by the teams or the assigning of projects to the teams, and the assigning of faculty advisors to the teams clearly described and reasonable? Are there sufficient numbers of qualified faculty and clinical/industrial advisors to assist students in identifying unmet clinical needs or provide design problems to students and guide them in designing and building effective solutions to these unmet needs or problems? For programs proposing a clinical mmersion period, are the activities in this period well-structured and likely to contribute to program goals? Will there be a breadth of clinical experiences? How will students in either the hospital or community-based settings receive appropriate clinical and technical mentoring? If the clinical immersion experience is community-based, does the program clearly describe activities within the community? Are the recruitment ar selection of students to take part in this part of the program reasonable and well described? Are the activities and outcomes of this period we ntegrated with the main program? Are the evaluation and dissemination plans clearly described and effective?

Environment

Will the scientific and educational environment of the proposed program contribute to its intended goals? Is there a plan to take advantage of environment to enhance the educational value of the program? Is there tangible evidence of institutional commitment? Is there evidence that faculty have sufficient institutional support to create a sound educational environment for the participants? Where appropriate, is there evider of collaboration and buy-in among participating programs, departments, and institutions and community organizations?

Specific for this FOA: Are the research, laboratory and manufacturing facilities and environment conducive to providing trainees with appropr experience to prepare them to develop state-of-the-art solutions to similar projects in their future careers? For applications with a clinical mmersion program, is the clinical and/or community-based environment conducive to providing rich and well-rounded clinical exposure to th participants?

litional Review Criteria

pplicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, ar ding 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 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 CFI Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources materials. For additional information on review of the Human Subjects section, please refer to the Guidelines for the Review of Human Subje //grants.nih.gov/grants/guide/url_redirect.php?id=11175).

nclusion 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 nclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of individuals of a 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 //grants.nih.gov/grants/guide/url_redirect.php?id=11174).

/ertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following criteria: lescription of proposed procedures involving animals, including species, strains, ages, sex, and total number to be used; (2) justifications for ıse of animals versus alternative models and for the appropriateness of the species proposed; (3) interventions to minimize discomfort, distr ɔain and injury; and (4) justification for euthanasia method if NOT consistent with the AVMA Guidelines for the Euthanasia of Animals. Reviev will assess the use of chimpanzees as they would any other application proposing the use of vertebrate animals. For additional information o eview of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section //grants.nih.gov/grants/guide/url_redirect.php?id=11150).

Biohazards

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, a ıeeded, 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 ɔrevious scientific review group and changes made to the project.

isions

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

ewals

For Renewals, the committee will consider the progress made in the last funding period, and the success of the program in attracting individu rom diverse populations, including populations underrepresented in biomedical, behavioral and clinical research on a national basis.

litional Review Considerations

: Effective for due dates on or after January 25, 2023, the Data Sharing Plan and Genomic Data Sharing Plan (GDS) as part of the Resou ing Plan will not be evaluated at time of review, and a Data Management and Sharing Plan is not applicable for this FOA.

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

ruitment Plan to Enhance Diversity

Peer reviewers will separately evaluate the recruitment plan to enhance diversity after the overall score has been determined. Reviewers will examine the strategies to be used in the recruitment of prospective participants from underrepresented groups. The review panel's evaluatio ɔe included in the summary statement. Plans will be rated as **acceptable** or **unacceptable**, and the summary statement will provide the consensus of the review committee.

Training in the Responsible Conduct of Research

Taking into account the specific characteristics of the proposed research education program, the level of participant experience, the reviewer will evaluate the adequacy of the proposed RCR training in relation to the following five required components: 1) ***Format -*** the required forma ıstruction, i.e., face-to-face lectures, coursework, and/or real-time discussion groups (a plan with only on-line instruction is not acceptable); ***Subject Matter -*** the breadth of subject matter, e.g., conflict of interest, authorship, data management, human subjects and animal use, aboratory safety, research misconduct, research ethics; 3) ***Faculty Participation -*** the role of the program faculty in the instruction; 4) ***Durat of Instruction -*** the number of contact hours of instruction, taking into consideration the duration of the program; and 5) ***Frequency of nstruction*** instruction must occur during each career stage and at least once every four years. See also: NOT-OD-10-019 http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-10-019.html). The review panel's evaluation will be included in the summary stateme Plans will be rated as **acceptable** or **unacceptable**, and the summary statement will provide the consensus of the review committee.

Applications from Foreign Organizations

Not Applicable.

Select Agent Research

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

Resource Sharing Plans

Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, a easonable (//grants.nih.gov/grants/guide/url_redirect.php?id=11153): 1) Data Sharing Plan (//grants.nih.gov/grants/guide/url_redirect.php?d=11151); 2) Sharing Model Organisms (https://grants.nih.gov/grants/policy/model_organism/); and 3) Genomic Data Sharing Plan https://osp.od.nih.gov/scientific-sharing/policies/).

f support for development, maintenance, or enhancement of software is requested in the application, the reviewers will comment on the roposed software dissemination plan.

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 esearch.

eview and Selection Process

cations will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s), in accordance with NIH peer revie y and procedures (//grants.nih.gov/grants/guide/url_redirect.php?id=11154), using the stated review criteria. Assignment to a Scientific Revie p will be shown in the eRA Commons.

art of the scientific peer review, all applications will receive a written critique.

cations may undergo a selection process in which only those applications deemed to have the highest scientific and technical merit (genera op half of applications under review) will be discussed and assigned an overall impact score.

cations will be assigned on the basis of established PHS referral guidelines to the appropriate NIH Institute or Center. Applications will comp vailable funds with all other recommended applications. Following initial peer review, recommended applications will receive a second level w by the appropriate national Advisory Council or Board. 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.

nticipated Announcement and Award Dates

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 mons (//grants.nih.gov/grants/guide/url_redirect.php?id=11123). Refer to Part 1 for dates for peer review, advisory council review, and earlies date.

nation regarding the disposition of applications is available in the NIH Grants Policy Statement (https://grants.nih.gov/policy/nihgps/index.ht

ction VI. Award Administration Information

ward Notices

application is under consideration for funding, NIH will request "just-in-time" information from the applicant as described in the NIH Grants y Statement (//grants.nih.gov/grants/guide/url_redirect.php?id=11157).

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

ients must comply with any funding restrictions described in Section IV.6. Funding Restrictions. Selection of an application for award is not orization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be reimbursed only xtent considered allowable pre-award costs.

application awarded in response to this FOA will be subject to terms and conditions found on the Award Conditions and Information for NIH ts (https://grants.nih.gov/grants/policy/nihgps/HTML5/part_ii_subpart_b.htm) website. This includes any recent legislation and policy applica ards that is highlighted on this website.

utional Review Board or Independent Ethics Committee Approval: Recipient institutions must ensure that protocols are reviewed by their IRE To help ensure the safety of participants enrolled in NIH-funded studies, the recipient must provide NIH copies of documents related to all m ges in the status of ongoing protocols.

dministrative and National Policy Requirements

IH grant and cooperative agreement awards include the NIH Grants Policy Statement as part of the NoA. For these terms of award, see the ts Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General and Part II: Terms and Conditions of NIH Grant ds, Subpart B: Terms and Conditions for Specific Types of Grants, Recipients, and Activities, including of note, but not limited to:

Federalwide Research Terms and Conditions (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_3/3.1_federalwide_standard_terms_and_conditions_for_research_grants.htm)
Prohibition on Certain Telecommunications and Video Surveillance Services or Equipment (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-041.html)
Acknowledgment of Federal Funding (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.2.1_acknowledgement_of_federal_funding.htm)

ecipient is successful and receives a Notice of Award, in accepting the award, the recipient agrees that any activities under the award are su provisions currently in effect or implemented during the period of the award, other Department regulations and policies in effect at the time o ward, and applicable statutory provisions.

ld the applicant organization successfully compete for an award, recipients of federal financial assistance (FFA) from HHS must administer t ams in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age and, in s mstances, religion, conscience, and sex (including gender identify, sexual orientation, and pregnancy). This includes ensuring programs are ssible to persons with limited English proficiency and persons with disabilities. The HHS Office for Civil Rights provides guidance on complyi civil rights laws enforced by HHS. Please see https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html s://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html) and https://www.hhs.gov/civil-rights/for-duals/nondiscrimination/index.html (https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html)

recognizes that research projects are often limited in scope for many reasons that are nondiscriminatory, such as the principal investigator's tific interest, funding limitations, recruitment requirements, and other considerations. Thus, criteria in research protocols that target or exclu in populations are warranted where nondiscriminatory justifications establish that such criteria are appropriate with respect to the health or y of the subjects, the scientific study design, or the purpose of the research. For additional guidance regarding how the provisions apply to N programs, please contact the Scientific/Research Contact that is identified in Section VII under Agency Contacts of this FOA.

Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html (https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html)and https://www.lep.gov (https://www.lep.gov/).

For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including reasonable accommodations and making services accessible to them, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html (http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html).

HHS funded health and education programs must be administered in an environment free of sexual harassment, see https://www.hhs.gov/ rights/for-individuals/sex-discrimination/index.html (https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html). For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, an what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm (https://grants.nih.gov/grants/policy/harassment.htm).

For guidance on administering programs in compliance with applicable federal conscience protection and associated anti-discrimination la see https://www.hhs.gov/conscience/conscience-protections/index.html (https://www.hhs.gov/conscience/conscience-protections/index.htr and https://www.hhs.gov/conscience/religious-freedom/index.html (https://www.hhs.gov/conscience/religious-freedom/index.html).

se contact the HHS Office for Civil Rights for more information about obligations and prohibitions under federal civil rights laws at ://www.hhs.gov/ocr/about-us/contact-us/index.html (https://www.hhs.gov/ocr/about-us/contact-us/index.html) or call 1-800-368-1019 or TDD 537-7697.

cordance with the statutory provisions contained in Section 872 of the Duncan Hunter National Defense Authorization Act of Fiscal Year 200 lic Law 110-417), NIH awards will be subject to the Federal Awardee Performance and Integrity Information System (FAPIIS) requirements. IS requires Federal award making officials to review and consider information about an applicant in the designated integrity and performanc

m (currently FAPIIS) prior to making an award. An applicant, at its option, may review information in the designated integrity and performanc ms accessible through FAPIIS and comment on any information about itself that a Federal agency previously entered and is currently in FAI Federal awarding agency will consider any comments by the applicant, in addition to other information in FAPIIS, in making a judgement abc pplicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicant ribed in 45 CFR Part 75.205 and 2 CFR Part 200.206 Federal awarding agency review of risk posed by applicants. This provision will apply grants and cooperative agreements except fellowships.

eporting

n multiple years are involved, recipients will be required to submit the Research Performance Progress Report (RPPR) nts.nih.gov/grants/rppr/index.htm) annually. Continuation support will not be provided until the required forms are submitted and accepted.

rams that involve participants associated with a clinical immersion program should report on education in the responsible conduct of researc complete a Trainee Diversity Report (//grants.nih.gov/grants/guide/url_redirect.php?id=61198), in accordance with the RPPR Instruction Guic nts.nih.gov/grants/rppr/rppr_instruction_guide.pdf).

FOAs outline intended research goals

objectives. Post award, NIH will review and measure performance based on the details and outcomes that are shared within the RPPR, as ribed at 45 CFR Part 75.301 and 2 CFR 200.301.

Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for awardees of Federal grants to t information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All recipien cable NIH grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at fsrs.gov (//grants.nih.gov/grants/guide/url_redirect.php?id=11170) on all subawards over the threshold. See the *NIH Grants Policy Statemer* s://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.1.8_federal_funding_accountability_and_transparency_act__ffata_.htm) for additi nation on this reporting requirement.

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

cordance with the regulatory requirements 45 CFR Part 75 and 2 CFR Part 200 and Appendix XII to 45 CFR Part 75.113 and 2 CFR Part 113, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts from all Federal awarding cies with a cumulative total value greater than $10,000,000 for any period of time during the period of performance of a Federal award, mus t and maintain the currency of information reported in the System for Award Management (SAM) about civil, criminal, and administrative eedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year perioc ecipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the nated integrity and performance system (currently FAPIIS). This is a statutory requirement under section 872 of Public Law 110-417, as nded (41 U.S.C. 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performanc m on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available. Full ting requirements and procedures are found in Appendix XII to 45 CFR Part 75 and 2 CFR Part 200 Award Term and Condition for Recipien rity and Performance Matters.

al RPPR and the expenditure data portion of the Federal Financial Report are required for closeout of an award as described in the *NIH ts Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?id=11161)*.

valuation

rrying out its stewardship of human resource-related programs, the NIH or its Institutes and Centers will periodically evaluate their R25 arch education programs, employing the measures identified below. In assessing the effectiveness of its research education investments, request information from databases, PD/PIs, and from participants themselves. Where necessary, PD/PIs and participants may be contac the completion of a research education experience for periodic updates on participants subsequent educational or employment history ar ssional activities.

the completion of a program evaluation, NIH and its ICs will determine whether to (a) continue a program as currently configured, (b) nue a program with modifications, or (c) discontinue a program.

aluating this research education program NIBIB expects to use the following evaluation measures:

Courses for Skills Development:

- Aggregate number and demographic characteristics of participants
- Educational level of participants
- Content

Participants feedback on the program
New knowledge or skills acquired
Where possible, information on students' entrepreneurial activities in the medical device area resulting from the projects undertaken in the program.
Scholarly articles or abstracts discussing the program and its outcomes
Curricula or other resources shared with the biomedical engineering education community.

ction VII. Agency Contacts

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

lication Submission Contacts

Service Desk (Questions regarding ASSIST, eRA Commons, application errors and warnings, documenting system problems that threaten ission by the due date, and post-submission issues)

ng Help Online: http://http://grants.nih.gov/support/ (http://http://grants.nih.gov/support/) (preferred method of contact)
hone: 301-402-7469 or 866-504-9552 (Toll Free)

eral Grants Information (Questions regarding application instructions, application processes, and NIH grant resources)
l: GrantsInfo@nih.gov (mailto:GrantsInfo@nih.gov) (preferred method of contact)
hone: 301-480-7075

ts.gov Customer Support (Questions regarding Grants.gov registration and Workspace)
act Center Telephone: 800-518-4726
l: support@grants.gov (mailto:support@grants.gov)

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ction VIII. Other Information

ntly issued trans-NIH policy notices (//grants.nih.gov/grants/guide/url_redirect.php?id=11163) may affect your application submission. A f policy notices published by NIH is provided in the NIH Guide for Grants and Contracts (//grants.nih.gov/grants/guide/url_redirect.php?164). All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy ment (//grants.nih.gov/grants/guide/url_redirect.php?id=11120).

hority and Regulations

ds are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and unde ral Regulations 42 CFR Part 52 and 45 CFR Part 75 and 2 CFR Part 200.

Weekly TOC for this Announcement (/grants/guide/WeeklyIndex.cfm?02-25-22)
NIH Funding Opportunities and Notices (/grants/guide/index.html)

Note: For help accessing PDF, RTF, MS Word, Excel, PowerPoint, Audio or Video files, see Help Downloading Files (/grants/edocs.htm).