Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)

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

Components of Participating Organizations

Office of Strategic Coordination (Common Fund (https://commonfund.nih.gov/))

This Funding Opportunity Announcement (FOA) is developed as a Common Fund initiative (https://commonfund.nih.gov/ (https://commonfund.nih.gov/)) through the Office of the NIH Director, Office of Strategic Coordination. All NIH Institutes and Centers participate in Common Fund initiatives. The FOA will be administered by a trans-NIH team, which will be led by the National Cancer Institute (NCI (https://www.cancer.gov/)) on behalf of the NIH.

Funding Opportunity Title

NIH Faculty Institutional Recruitment for Sustainable Transformation (FIRST) Program: FIRST Cohort (U54 Clinical Trial Optional)

Activity Code

U54 (https://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=U54&Search.x=0&Search.y=0&Search_Type=Activity) Specialized Center--Cooperative Agreements

Announcement Type

Reissue of RFA-RM-20-022 (https://grants.nih.gov/grants/guide/rfa-files/RFA-RM-20-022.html)

Related Notices

July 29, 2020 - Notice of Intent to Publish a Funding Opportunity Announcement for NIH Faculty Institutional Recruitment for Sustainable Transformation (FIRST) Program: FIRST Cohort (U54 Clinical Trial Not Allowed). See Notice NOT-RM-20-023 (https://grants.nih.gov/grants/guide/notice-files/NOT-RM-20-023.html).

July 29, 2020 - Notice of Intent to Publish a Funding Opportunity Announcement for NIH Faculty Institutional Recruitment for Sustainable Transformation (FIRST) Program: FIRST Coordination and Evaluation Center (U54 Clinical Trial Not Allowed). See Notice NOT-RM-20-022 (https://grants.nih.gov/grants/guide/notice-files/NOT-RM-20-022.html).

February 24, 2021 - Notice of Expiration of RFA-RM-20-023 "NIH Faculty Institutional Recruitment for Sustainable Transformation (FIRST) Program: FIRST Coordination and Evaluation Center (U24 Clinical Trial Not Allowed)." See Notice NOT-RM-21-018 (https://grants.nih.gov/grants/guide/notice-files/NOT-RM-21-018.html).

Funding Opportunity Announcement (FOA) Number

RFA-RM-21-025

Companion Funding Opportunity

None

Number of Applications

See Section III. 3. Additional Information on Eligibility.

Assistance Listing Number(s)

93.310

Funding Opportunity Purpose

The purpose of the FIRST Cohort is to transform culture at NIH-funded extramural institutions by building a self-reinforcing community of scientists committed to diversity and inclusive excellence (defined below). Implementing and sustaining cultures of inclusive excellence within the program has the potential to be transformational for biomedical research at the awardee institutions and beyond. This community will be built through recruitment of faculty who are competitive for an advertised research tenure-track or equivalent faculty position (positions must be at the Assistant Professor (or equivalent) level), have not held a position at this level, and have demonstrated strong commitment to promoting diversity and inclusive excellence.

Key Dates

Posted Date

July 12, 2021

Open Date (Earliest Submission Date)

August 24, 2021

Letter of Intent Due Date(s)

30 days prior to the application due date

Application Due Dates			Review and Award Cycles		
New	Renewal / Resubmission / Revision (as allowed)	AIDS	Scientific Merit Review	Advisory Council Review	Earliest Start Date
September 24, 2021	Not Applicable	Not Applicable	February 2022	May 2022	July 2022

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.
No late applications will be accepted for this Funding Opportunity Announcement.

Expiration Date

September 25, 2021

Due Dates for E.O. 12372

Not Applicable

Required Application Instructions

It is critical that applicants follow the Multi-Project (M) Instructions in the SF424 (R&R) Application Guide (//grants.nih.gov/grants/guide/url_redirect.htm?id=12000), except where instructed to do otherwise (in this FOA or in a Notice from the *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 (http://public.era.nih.gov/commons/) to track your application. Check with your institutional officials regarding availability.

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Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

Purpose:

The purpose of the FIRST Cohort is to transform culture at NIH-funded extramural institutions by building a self-reinforcing community of scientists committed to diversity and inclusive excellence (defined below). Implementing and sustaining cultures of inclusive excellence within the program has the potential to be transformational for biomedical research at the awardee institutions and beyond. This community will be built through recruitment of a diverse group of faculty who are competitive for an advertised research tenure-track or equivalent faculty position (positions must be at the Assistant Professor (or equivalent) level), have not held a position at this level, and have demonstrated strong commitment to promoting diversity and inclusive excellence.

Background:

NIH institutes and centers remain committed to increasing and sustaining the diversity of the biomedical research workforce.

NIH's commitment (https://extramural-diversity.nih.gov/building-participation/commitment-across-nih) has been informed by an extensive body of research supporting the argument that scientific workforce diversity is essential to accomplish the NIH's mission of discovery and innovation toward improving human health (Nielsen et al., 2017 (https://www.pnas.org/content/114/8/1740); Valantine and Collins, 2015 (https://www.pnas.org/content/112/40/12240)). Despite recognizing the pressing need to enhance diversity in NIH-funded institutions across the U.S., progress in accomplishing this goal has been seen mostly with trainee populations, leaving biomedical research faculty diversity as an ongoing, recalcitrant challenge (Gibbs et al., 2016 (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5153246/)). Starkly, extrapolation of current trends suggests that without new and effective strategies, it will take nearly 50 years for women to reach parity among full professors (Valantine et al., 2014 (https://www.ncbi.nlm.nih.gov/pubmed/?term=valantine+pizzo); National Science Foundation, 2019 (https://www.nsf.gov/statistics/wmpd)) and centuries for underrepresented racial/ethnic groups to reach parity among medical school faculty with the current recruitment pool (U.S. Medical School Faculty Trends: Percentages (https://www.aamc.org/data-reports/faculty-institutions/interactive-data/us-medical-school-faculty-trends-percentages)). This representation gap is driven in large part by institutional cultures lacking necessary elements of inclusion and equity and sending a message to certain groups that they do not belong in science (Price EG et al., 2009 (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2824594/); Pololi LH et al., 2013 (https://www.ncbi.nlm.nih.gov/pubmed/23887015)). Because U.S. biomedical research is largely driven by NIH-funded faculty in academic institutions, there is an urgency for NIH to encourage institutions to develop and implement broadly effective strategies to cultivate institutional culture change (Krupat E et al., 2013 (https://pubmed.ncbi.nlm.nih.gov/23887002/)), with the goal of enhancing biomedical research workforce diversity at the faculty level. The ultimate goal of the FIRST program is to utilize a faculty cohort model to foster cultures of inclusive excellence (scientific environments that can cultivate and benefit from a full range of talents) at NIH-funded institutions with a sustained commitment to diversity and inclusion in biomedical research. This effort aligns with the recent NIH UNITE initiative (https://www.nih.gov/ending-structural-racism/unite), which aims to establish an equitable and civil culture within the biomedical research enterprise and reduce barriers to racial equity in the biomedical research workforce. In addition, to address long-standing health disparities and promote health equity, UNITE will seek to improve transparency, accountability, and sustainability in support for research on health disparities, minority health, and health equity.

The FIRST program will test the primary hypothesis that a cohort model of faculty hiring, sponsorship, continual mentoring, and support for professional development, embedded within an institution implementing evidence-based practices to create academic cultures of inclusive excellence, will achieve significant improvements in metrics of institutional culture and biomedical research workforce diversity. Evidence supports the hypothesis that diversity positively impacts scientific discovery through improved problem-solving, innovation, prediction, evaluation, and verification (Page SE, 2017 (https://press.princeton.edu/books/hardcover/9780691176888/the-diversity-bonus); Page SE, 2007). Implementing and sustaining cultures of inclusive excellence within the program has the potential to be transformational for biomedical research at the awardee institutions and beyond. Implementing and sustaining cultures of inclusive excellence at a range of academic institutions has the potential to be transformational for the biomedical research workforce.

Needs, Gaps, Opportunities:

Establishing and maintaining scientific environments that can cultivate and benefit from a full range of talents is not only essential for the quality and impact of science, but it is also a matter of good stewardship of federal funds to ensure that the most talented researchers are recruited, supported, and advanced to become competitive research investigators. This initiative defines inclusive excellence consistent with the work of Williams et al., (2005) (http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.129.2597&rep=rep1&type=pdf) as the act of establishing hallmarks of excellence and organizational effectiveness; operationalizing inclusion across organizational functions; and creating education and professional development processes that have diversity, equity, and inclusion at their core. Achieving inclusive excellence at the national level must be preceded by transformation at the institutional level, through broad adoption of enhanced diversity of faculty and culture change, creating a welcoming environment to recruit and retain scientific talent. Thus, inclusive excellence hinges on both enhancing diversity and inclusion, as well as institutional culture change.

Underrepresented racial/ethnic groups comprise 34% of the US population, but publicly available data indicate that only 15% of the PhD recipient pool (NSF SED, 2018; DoctorateRecipients from U.S. Universities 2018 | NSF - National Science Foundation (https://ncses.nsf.gov/pubs/nsf20301/data-tables/)), 12% of medical school graduates (AAMC Data and Reports (https://www.aamc.org/data-reports)), 9% of current assistant professors, and 4% of tenured faculty (Faculty Roster: U.S. Medical School Faculty | AAMC (https://www.aamc.org/data-reports/faculty-institutions/report/faculty-roster-us-medical-school-faculty)). Recent 10-year trend data, 2010-2020, show a dismal 0.2% increase in the percentage of URM faculty at US medical schools. Reaching parity in the number of URM faculty with the PhD recipient pool is estimated to require centuries, assuming that institutions do not transform their current recruitment practices and work environments to attract and sustain diverse cohorts of faculty. The low diversity of faculty compared to the available talent pool is attributed in part to the disproportionately

high attrition of academic researchers from historically underrepresented racial and ethnic groups during the transition from training status into faculty-level research careers (Gibbs et al., 2016 (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5153246/); and Valantine, Lund & Gammie, CBE-Life Sciences Education, 2016 (https://www.lifescied.org/doi/pdf/10.1187/cbe.16-03-0138)). By contrast, women in science and medicine have made substantial progress in workforce participation.

Women comprise more than 50% of PhD graduates in NIH research-relevant disciplines, over 50% of U.S. medical school graduates, but only 40.6% of U.S. biomedical tenure-track faculty, 27% of tenured faculty (AAMC faculty roster, 2018 (https://www.aamc.org/data/facultyroster/reports/494946/usmsf18.html)), and about one-third of principal investigators (PIs) on NIH-funded research (R01-equivalent) grants (Plank-Bazinet, et al., 2017 (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5446606/),Hechtman et al., 2018 (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6077749/)). Furthermore, there is a lack of representation of women in leadership positions that also needs to be addressed. In addition, literature shows that women from underrepresented backgrounds face particular challenges at the graduate level and beyond in scientific fields (Ong M, et al., 2011 (https://pdfs.semanticscholar.org/6f39/c23d05cf0b16efc96448b2062f9f45181b12.pdf)).

Because progress has been seen mostly with trainee populations, diversifying the professoriate is the next logical, and achievable, step for an NIH-funded extramural investment. The FIRST program aims to not only provide support for diverse cohorts of new faculty, but to create systemic change at institutions. Reports on faculty cluster hiring at academic institutions suggest that the cohort model might be an effective strategy for enhancing diversity (Sgoutas-Emch S et al., 2016 (https://eric.ed.gov/?id=EJ1115566); Lord S, et al., 2015 (https://ieeexplore.ieee.org/stamp/stamp.jsp?tp=&arnumber=7344181); Faculty Cluster Hiring for Diversity And Institutional Climate Change, 2015 (http://urbanuniversitiesforhealth.org/media/documents/Faculty_Cluster_Hiring_Report.pdf)). The approach has been tested in undergraduate environments such as the successful Meyerhoff Scholars Program at the University of Maryland, Baltimore County (for example, Sto Domingo, et al., 2019 (http://www.sciencemag.org/cgi/pmidlookup?view=long&pmid=31023915)). However, little is known about the multi-level barriers and challenges encountered and overcome by institutions and faculty cohorts where efforts toward inclusive excellence have already been initiated. There is, therefore, a profound knowledge gap regarding integrated strategies to address diversity and inclusion, the impact of faculty cohort hiring in higher education, and institutional change models that achieve the goal of inclusive excellence.

The Faculty Institutional Recruitment for Sustainable Transformation (FIRST) program (consisting of two components: the FIRST Cohort and the FIRST Coordination and Evaluation Center (CEC)) has been developed to determine if a systematic approach that integrates multiple evidence-based strategies including the hiring of faculty cohorts with demonstrated commitments to inclusion and diversity will accelerate inclusive excellence, as measured by clearly defined metrics of institutional culture change, diversity, and inclusion. The FIRST program goals are to: (1) foster sustainable institutional culture change; (2) promote institutional inclusive excellence by hiring a diverse cohort of new faculty at the Assistant Professor (or equivalent) level; and (3) support faculty development, mentoring, sponsorship, and promotion.

Funding for the FIRST program will come from the NIH Common Fund, which supports cross-cutting programs expected to have exceptionally high impact. All Common Fund initiatives invite investigators to develop bold, innovative, and often risky approaches to address problems that may seem intractable or to seize new opportunities that offer the potential for rapid progress.

Objectives:

Faculty Institutional Recruitment for Sustainable Transformation (FIRST) Cohort Award.

The FIRST Cohort program aims to transform culture at two types of NIH-funded extramural institutions by building a self-reinforcing community of scientists committed to inclusive excellence, through recruitment of a diverse group of faculty who are competitive for an advertised research tenure-track or equivalent faculty position (positions must be at the Assistant Professor (or equivalent) level), have not held a position at this level, and have demonstrated strong commitment to promoting diversity and inclusive excellence. Any individual who is competitive for a research tenure-track or equivalent faculty position at the Assistant Professor (or equivalent) level, has not held a position at this level, and has demonstrated a strong commitment to promoting diversity and inclusive excellence is eligible to be hired for FIRST faculty positions.

The overall goals and specific measurable objectives that the program expects FIRST Cohort awardees to accomplish are:

Goal 1: Demonstrate institutional support and develop or modify a strategic plan with specific goals and strategies, interventions, and organizational policies that will be implemented to achieve significant systemic and sustainable institutional culture change over baseline toward inclusive excellence (at the faculty, department, and institution level). FIRST Cohort awardees are also expected to develop an evaluation plan to assess the impact on their institution of action taken toward FIRST program goals.

Goal 2: Conduct recruitment activities for new faculty, outline institutional commitment,and develop recruitment committees based on past interests and commitments to diversity, equity, and inclusion. FIRST Cohort awardees are also expected to establish a supportive environment for new faculty.

Goal 3: Develop strategies to establish individual research and career development plans and mentorship and sponsorship plans for all new faculty hired under this award. The applicants must describe how the program will reduce isolation, increase community building, foster career development, and ensure retention of the new faculty.

Applicant institutions must be conducting research in any NIH mission area. This funding opportunity will accept applications from eligible Highly Resourced Institutions (HRI), Limited-Resourced Institutions (LRI), or Partnerships (any composition of HRI and/or LRI) to develop faculty cohort models. All eligible institutions are categorized into these two types to encourage inclusion and broaden participation.

For this funding announcement, to qualify as an LRI (https://commonfund.nih.gov/sites/default/files/Flow_Chart_FIRST_508.pdf) , institutions must:

- have received less than $50 million average in annual NIH funds within the three years prior to the time of application, and
- offer doctorate degrees in the health professions or in a health-related science, and
- have a historical and current commitment to educating underrepresented students, and,
- if institutions provide clinical health care services, those services must be provided to medically underserved communities.

These criteria are similar to the Research Centers in Minority Institutions criteria (https://grants.nih.gov/grants/guide/rfa-files/RFA-MD-20-006.html), an independent program.

HRIs are institutions that do not meet the LRI criteria. Both LRIs and HRIs must provide evidence of their commitment to diversity and inclusion.

All institutions supported in the FIRST Cohort program, regardless of their configuration, must also adhere to the program goal of inclusive excellence. For HRIs, the faculty cohort must be comprised of no fewer than 10 scientists and for LRIs, no fewer than 6 scientists. Both HRI and LRI institutions can apply to form mutually beneficial partnerships. The number of scientists supported in a partnership must be based on prior planning and what was proposed and justified in the application. If a partnership includes an HRI, it must hire no fewer than 10 scientists. If a partnership includes only LRIs, it must hire no fewer than 6 scientists.

The new faculty comprising a FIRST Cohort must be at the Assistant Professor (or equivalent) level, and if there is a tenure track at the awardee institution, these individuals must be hired on the tenure track. The new faculty are expected to be organized into research clusters, and for the purposes of this RFA a “cluster” is defined as no fewer than three new faculty in a related biomedical research area. All biomedical research areas within the NIH mission are included in this funding announcement. For example, an institutional cohort might be comprised of multiple smaller research clusters of scientists within various scientific disciplines, such as (but not limited to) neuroscience, cardiovascular disease, cancer, minority health, health disparities, community-based participatory research, behavioral, social, population science, or any NIH mission area. By incentivizing hiring of a co-localized cohort, this initiative offers an added benefit of engaging both university-level and departmental leadership and leveraging departmental faculty to form an extended network for the cohort to access. Although institutional capacity will shape the size of each cohort and the design of any research cluster, each cohort must be large enough to create an interactive group and include collaborations among relevant departments, divisions, and institutions to help achieve this goal. Professional and research development, mentoring, and sponsorship are integral elements of the cohort model design, and the program must include activities and resources to reduce isolation, increase community building and networking, and foster career, research, and professional advancement. Sponsorship refers to a person in a senior position within the institution who serves as an advocate to assist the faculty member with networking, career opportunities, and strategic identification of individualized professional milestones that ensure success. A sponsor provides an in-depth commitment and possesses the power and influence to substantively support the faculty member. The sponsor’s role extends beyond that of a mentor with respect to advocacy, active tracking, and proactive outreach to those who can impact the career success of the faculty member and includes the gravitas that may not necessarily be characteristic of a mentor. Faculty must be appointed with 75% protected research time averaged across the 12 months of the year and for the length of the award for future transition to competitive research awards. In addition to creating a self-reinforcing community of scientists committed to inclusive excellence, hiring a diverse cohort of new faculty could create a critical mass of scientists within the microcultures in which they work.

All future FIRST faculty candidates will be required to submit a statement to the grantee institution describing their commitment to promoting diversity and inclusive excellence. Institutions will decide how to evaluate this commitment, but some tangible examples include active participation in diversity efforts, mentoring individuals from underrepresented backgrounds, volunteer activities in an underserved community, outreach activities, teaching diversity-related courses, the area of a candidate's research e.g., research in topic areas such as health disparities and workforce diversity, other inclusive excellence activities, etc. This statement would also describe the candidate's personal trajectory to a scientific research career and philosophy and/or approach to inclusive excellence and diversity.

In addition, NIH will encourage FIRST Cohort awardees to enhance the diversity of the FIRST Cohort by actively recruiting candidates from groups identified as underrepresented in the biomedical, clinical, behavioral, and social sciences, some of which are described in NOT-OD-20-031 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html), such as racial and ethnic minorities, those from socioeconomically disadvantaged backgrounds, individuals with disabilities, and women. Institutional search processes must mitigate implicit bias in hiring through education modules, tools, and assessments.

Faculty in the FIRST Cohort must participate in multilevel mentoring, sponsorship, and professional and research development trainings embedded within institutions that are actively implementing integrated, systems-level approaches for sustainable culture change.

Each FIRST Cohort awardee will be responsible for evaluating its own FIRST program. Each FIRST Cohort awardee will be responsible for collecting quantitative and qualitative data (e.g., focus group data, observations of processes data, and survey data) and sharing the required data with the FIRST Coordination and Evaluation Center (CEC). The FIRST CEC will conduct a comprehensive evaluation of the program and coordinate with FIRST Cohort awardees to collect the necessary data. The FIRST CEC, in collaboration with the FIRST Cohort awardees, will identify and harmonize a minimum set of common data elements to be used by each of the FIRST Cohort awardees to evaluate the faculty and the institutional culture. While FIRST Cohort awardees must implement the set of common data elements identified by the FIRST CEC, they may also add measures of interest to their research team and institution. The FIRST CEC will lead the development of the final FIRST Data Sharing Plan to be developed in conjunction with FIRST Cohort awardees post award.

All FIRST Cohort programs will operationalize through three cores—Administrative, Faculty Development, and Evaluation.

Applications Not Responsive to this FOA

Applications nonresponsive to terms of this FOA will not be reviewed. The following components must be included to be deemed responsive:

- Applications must describe development of institutional/organizational policies, practices, and plans that focus on the identification and elimination of organizational barriers that impede the full participation and advancement of faculty from diverse backgrounds in academia.
- Applications must include a written "Institutional Commitment Letter" from the institution leadership and, if a partnership application, from the leaderships of each of the partnering institutions.
- Applications must include three cores—Administrative, Faculty Development, and Evaluation. Justification for all costs associated with all cores must be provided.
- For HRIs, the faculty cohort must be comprised of no fewer than 10 scientists; for LRIs, no fewer than 6 scientists; and for partnerships, the number of scientists supported must be based on prior planning and what was proposed and justified in the application (must define institutional type in the application). If a partnership includes an HRI, it must hire no fewer than 10 scientists. If a partnership includes LRIs, it must hire no fewer than 6 scientists. Each cohort (LRI, HRI, or Partnership) must be large enough to create an interactive community and include collaborations between relevant departments, divisions, and institutions to help achieve FIRST program goals.

Prospective applicants are encouraged to visit the Common Fund website (https://commonfund.nih.gov/first (https://commonfund.nih.gov/first)) to access additional information, including the Technical Assistance Webinar recording and the helpful and continually updated Frequently Asked Questions.

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

Section II. Award Information

Funding Instrument

Cooperative Agreement: A support mechanism used when there will be substantial Federal scientific or programmatic involvement. Substantial involvement means that, after award, NIH scientific or program staff will assist, guide, coordinate, or

participate in project activities. See Section VI.2 for additional information about the substantial involvement for this FOA.

Application Types Allowed

New
The OER Glossary (//grants.nih.gov/grants/guide/url_redirect.htm?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?

Optional: Accepting applications that either propose or do not propose clinical trial(s).

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

Funds Available and Anticipated Number of Awards

The NIH intends to commit up to a total of $70.5M total costs over five years to fund up to four awards starting in fiscal year 2022.

These awards are contingent upon NIH appropriations and the submission of a sufficient number of meritorious applications. Future year amounts will depend on annual appropriations.

Award Budget

Application budgets per award are limited to $300,000 direct costs for all cores combined in year one; $3,275,000 direct costs each year in years 2-4; and $120,000 direct costs for all cores combined in year 5 and need to reflect the actual needs of the proposed project.

These awards are contingent upon NIH appropriations and the submission of a sufficient number of meritorious applications. Future year amounts will depend on annual appropriations.

Application budgets are limited and need to reflect the actual needs of the proposed project. Budgets should only reflect the costs the applicant institution(s) are requesting from NIH.

See Budget (Overall) section for full budget details.

Award Project Period

The maximum project period may not exceed five years.

NIH grants policies as described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11120) 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)

Nonprofits Other Than Institutions of Higher Education

- Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)

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* (//grants.nih.gov/grants/guide/url_redirect.htm?id=11118), **are not** allowed.

Required Registrations

Applicant organizations

Applicant organizations must complete and maintain the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. All registrations must be completed prior to the application being submitted. Registration can take 6 weeks or more, so applicants should begin the registration process as soon as possible. The NIH Policy on Late Submission of Grant Applications (//grants.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 valid reason for a late submission.

- Dun and Bradstreet Universal Numbering System (DUNS) (http://fedgov.dnb.com/webform) - 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) (https://www.sam.gov/portal/public/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 (//grants.nih.gov/grants/guide/url_redirect.htm?id=11176) – Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
- eRA Commons (//grants.nih.gov/grants/guide/url_redirect.htm?id=11123) - 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.

2. Cost Sharing

This FOA does not require cost sharing as defined in the NIH Grants Policy Statement. (//grants.nih.gov/grants/guide/url_redirect.htm?id=11126)

3. Additional Information on Eligibility

Number of Applications

Only one application per institution, normally identified by having a unique DUNS number or NIH IPF number, is allowed. This funding opportunity will accept applications from eligible Highly Resourced Institutions (HRI), Limited-Resourced Institutions (LRI), or Partnerships (any composition of HRI and/or LRI) to develop faculty cohort models. All eligible institutions are categorized into these two types to encourage inclusion and broaden participation. If an institution is applying as an LRI, the institution must include a statement demonstrating that it meets the LRI criteria. See Institutional Support section.

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 (//grants.nih.gov/grants/guide/notice-files/NOT-OD-11-101.html)).

Section IV. Application and Submission Information

1. Requesting an Application Package

The application forms package specific to this opportunity must be accessed through ASSIST or an institutional system-to-system solution. A button to apply using ASSIST is 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 Multi-Project (M) Instructions in the SF424 (R&R) Application Guide (//grants.nih.gov/grants/guide/url_redirect.htm?id=12000), except where instructed in this funding opportunity announcement to do otherwise and where instructions in the Application Guide are directly related to the Grants.gov downloadable forms currently used with most NIH opportunities. 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.

Letter of Intent

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

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

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

The letter of intent should be sent to:

Sanya A. Springfield, Ph.D.
National Cancer Institute (NCI)
Email: FIRSTNIH@nih.gov (mailto:FIRSTNIH@nih.gov)

Page Limitations

All page limitations described in the SF424 Application Guide and the Table of Page Limits (//grants.nih.gov/grants/guide/url_redirect.htm?id=11133) must be followed.

Component	Component Type for Submission	Page Limit	Required/Optional	Minimum	Maximu
Overall	Overall	12	Required	1	1
Administrative Core	Admin Core	12	Required	1	1
Faculty Development Core	Faculty Development	12	Required	1	1
Evaluation Core	Evaluation	12	Required	1	1

Instructions for the Submission of Multi-Component Applications

The following section supplements the instructions found in the SF424 (R&R) Application Guide, and should be used for preparing a multi-component application.

Overall Component

When preparing your application, use Component Type 'Overall'.

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

SF424(R&R) Cover (Overall)

Complete entire form.

PHS 398 Cover Page Supplement (Overall)

Note: Human Embryonic Stem Cell lines from other components should be repeated in cell line table in Overall component.

Research & Related Other Project Information (Overall)

Follow standard instructions.

Project/Performance Site Locations (Overall)

Enter primary site only.

A summary of Project/Performance Sites in the Overall section of the assembled application image in eRA Commons compiled from data collected in the other components will be generated upon submission.

Research and Related Senior/Key Person Profile (Overall)

Include only the Project Director/Principal Investigator (PD/PI) and any multi-PDs/PIs (if applicable to this FOA) for the entire application.

A summary of Senior/Key Persons followed by their Biographical Sketches in the Overall section of the assembled application image in eRA Commons will be generated upon submission.

Budget (Overall)

The only budget information included in the Overall component is the Estimated Project Funding section of the SF424 (R&R) Cover.

Budgets should only reflect the costs the applicant institution(s) are requesting from NIH. Application budgets for all cores combined are limited to the following and need to reflect the actual needs of the proposed project:

Year 1: Budget limit $300,000 direct costs **for all cores combined**.

Years 2-4: Budget limit $3,275,000 direct costs each year (more details on years 2-4 below).

Year 5: Budget limit $120,000 direct costs **for all cores combined**.

- In years 2-4, the Administrative Core, which contains the faculty start-up costs, is limited to $2,995,000 direct costs per year, consisting of a limit of $140,000 direct costs for administrative management and a limit of $2,855,000 direct costs for faculty start-up. These faculty start-up funds should be budgeted in three annual allocations (again, maximum $2,855,000/year). These funds can support both faculty salary and research project start-up costs. All faculty should be hired by the end of year 3 of an awarded grant. Each FIRST Cohort awardee institution will determine how to allocate the faculty start-up funds.
- In years 2-4, the Faculty Development Core budget is limited to $140,000 direct costs per year.
- In years 2-4, the Evaluation Core budget is limited to $140,000 direct costs per year.

A budget summary in the Overall section of the assembled application image in eRA Commons compiled from detailed budget data collected in the other components will be generated upon submission.

PHS 398 Research Plan (Overall)

Specific Aims: Outline the rationale for and specific aims of the program and explain how it strategically fits into the organizing framework and will achieve the goals of the FIRST Cohort program.

Research Strategy: Describe how the program will plan, implement, and sustain the overall goals and specific measurable objectives that the FIRST Cohort program expects in the areas of:

***Goal 1: Fostering Sustainable Institutional Culture Change*:**

- Describe potential strategies that would explicitly guide the institution's specific setting toward inclusive excellence, where scientific environments and cultures are established by design and maintained to cultivate and benefit from a full range of talent. Applications must demonstrate institutional support and describe development of institutional/organizational policies and practices that focus on the identification and elimination of organizational barriers that impede the full participation and advancement of faculty from diverse backgrounds in academia.

***Goal 2: Hiring a Diverse Cohort of New Faculty*:**

- Describe the recruitment search protocol, highlighting evidence-based strategies for reducing implicit bias. Describe the rubric for interviewing processes that are institution wide and characteristic of inclusive excellence goals. Given that search committees recommend individuals for interviews and selection for faculty positions, education about equity and inclusion will be an integral part of the success of this initiative (NIH Scientific Workforce Recruitment Toolkit (https://diversity.nih.gov/programs-partnerships/recruitment-search-protocol)). Therefore, describe how search committees for new faculty and collaborative efforts across departments and institutions to hire new faculty will be established and their commitments to diversity, equity, and inclusion. Other activities may include hiring/search committee practices; recruitment and outreach to applicants; allocation of resources and support available to faculty; salary structure and benefits; and the promotion and tenure process.

***Goal 3: Faculty Development, Retention, Progression, and Promotion*:**

- Describe how the program will reduce isolation, increase community building, and foster career development for the new faculty. Describe the strategy for the institution to develop personalized faculty career and research development plans for each faculty hired under this award. Describe the structure for mentoring (committee, peer, research sponsorship, career) and identify courses for skill development, workshops/courses/seminars around topics such as grant writing, manuscript preparation, enhancing laboratory management, staff supervision, budgeting, academic advancement, leadership skills, and balancing teaching, research, and service. FIRST Cohort awardee institutions will be expected to collect annual data on number and diversity of faculty, recruitment, retention, promotion, tenure, attainment of research grants, research productivity, development of new research programs, new collaborations, and other metrics of success. FIRST Cohort awardees will collect outcome measures and submit to the FIRST CEC, as needed. Ensure retention of the new faculty.

Specifically describe and address the following:

Leadership and Key Personnel

- Describe the experiences and expertise of the leadership and key personnel that are relevant to the proposed activities, especially in diversity and inclusion.
- Specify the roles and responsibilities of key leadership including detailing the experience and expertise needed to lead and guide the FIRST Cohort program. Leadership roles with respect to initiating, facilitating, and implementing the successful completion of the program goals must be described.

- Describe the succession planning that will take place to sustain FIRST Cohort award activities in the event of transitions of FIRST Cohort leadership.

Management

- Describe the overall governance structure with leadership, administrative, fiscal, and scientific functions outlined with levels of authority for each.
- Explain how the FIRST Cohort cores will interact and integrate with communication and evaluation activities, including plans for working with FIRST CEC to provide necessary data for overall program evaluation.

Institutional Culture and Environment

- Specify the types and numbers of strategies, interventions, policies, evidence-based practices, and other activities that will be implemented to achieve significant systemic and sustainable institutional change over baseline (at cohort/faculty, institution, and department/college institution level).
- Explain how implementing and sustaining cultures of inclusive excellence within the program has the potential to be transformational for biomedical research at the FIRST Cohort awardee institution(s) and beyond.
- Describe how the program will provide an environment that will reduce isolation/discrimination/implicit bias for the new faculty.
- Describe how institutional culture change will be implemented at each participating institution.

Strategy and Methodology

- Detail how the program goals/aims will be aligned with yearly milestones and metrics in collaboration with the FIRST CEC, including launch year and baseline metrics and milestones and other yearly evaluation metrics and reporting.
- Specify how the program will test the primary hypothesis that a cohort and cluster design model of faculty hiring, sponsorship, continual mentoring, and professional development, embedded within an institution implementing evidence-based practices to create academic cultures of inclusive excellence, will achieve significant improvements in metrics of institutional culture.
- In addition, a timeline (or Gantt chart) including milestones is required for all applications. Milestones are intermediate steps toward the completion of concrete goals. They must include clear and quantitative criteria for success. During the award period, yearly quantitative milestones are required in order to provide clear indicators of a project's continued success or emergent difficulties and will be used to evaluate the application not only in peer review but also in consideration of the awarded project for funding of non-competing award years. The application must include clearly specified, well-defined milestones, quantitative go/no-go decision points, and timelines for assessing progress.
- Identify anticipated barriers and describe possible solutions.

Professional Development and Progression

- Describe the overall strategies proposed for faculty development, promotion and retention, including the use of mentors and sponsors.
- Explain the overall strategy for the faculty cohort hires to be supported and integrated during the FIRST Cohort award and sustained if an independent R-type award or equivalent is not attained.
- Specify target expectations for faculty achieving competitive grant applications (i.e., independent R-type awards or equivalents).
- Describe the commitment from the leaderships of each partnering institution toward diversity and inclusion.
- Explain the planning and priority-setting processes. In chronological order, present each process used in planning and setting the priorities and objectives for this application. Briefly describe the nature of each planning activity completed (e.g., meetings of higher institutional officials, planning committees, steering committees in areas of common interest, workshops, retreats, surveys of faculty), its purpose, the individuals that participated from both institutions, and any conclusions. Describe the outcomes of the planning process that are particularly relevant to the partnership proposed in this application.

Institutional Support: An Institutional Letter of Commitment must be included in the Appendix (see below).

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.

All applications, regardless of the amount of direct costs requested for any one year, must address a Data Sharing Plan. The FIRST CEC will lead the development of the final FIRST Data Sharing Plan to be developed in conjunction with FIRST Cohort awardees post award.

Appendix:

Only limited items are allowed in the Appendix. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide; any instructions provided here are in addition to the SF424 (R&R) Application Guide instructions.

Applications must include a written "Institutional Commitment Letter" in the Appendix. This letter should be from the institution leadership and, if a partnership application, from the leaderships of each of the partnering institutions (e.g., President, Dean) to show institutional commitment to the FIRST Cohort program. This is likely to include commitment of additional resources necessary to ensure that the program will have the maximum success and sustainability. Specifically, institutional leaders must provide detailed statements of both short- and long-term commitment and list the specific resources being provided, including supplemental funding to start-up packages and professional development, laboratory and administrative space, protected time for research independent of grant funding, and access to core resources within the institution. These statements must also identify the specific number of faculty hires expected and commitment to sustainable institutional culture change. The letter must clearly explain how the institution(s) would monitor these efforts and specific steps and procedures to ensure the institution(s) achieve the planned goals and objectives. If an institution is applying as an LRI, statement demonstrating that the institution meets the LRI criteria.

The letter must include:
• Statement detailing the effort of commitment of the designated PD(s)/PI(s).
• Statement of the activities that each faculty listed as Key Personnel is being released from (e.g., teaching, mentor, sponsor, clinical, administrative duties), including a statement as to whether the costs of this “released time” are shared or not between partnering institutions.
• Statement that details provisions for recruitment of new faculty, including supplemental funds for startup and professional development and expected number of faculty to be hired.
• Statement that identifies the potential research clusters of scientists in various scientific disciplines within the NIH mission.
• Statement that details provisions to leverage funds for long-term sustainability of FIRST Cohort-supported activities.
• Statement indicating the application type: HRI, LRI or Partnership.
• If this is a Partnership application, statement listing the partnering institutions.

Letters of Support: "Other Letters of Support" should be included in the Appendix.

PHS Human Subjects and Clinical Trials Information (Overall)

When involving human subjects research, clinical research, and/or NIH-defined clinical trials 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, there must be at least one human subjects study record using the **Study Record: PHS Human Subjects and Clinical Trials Information** form or a **Delayed Onset Study** record within the application. The study record(s) must be included in the component(s) where the work is being done, unless the same study spans multiple components. To avoid the creation of duplicate study records, a single study record with sufficient information for all involved components must be included in the Overall component when the same study spans multiple components.

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.

If the applicant institution envisions hiring faculty that may conduct research with Human Subjects or may conduct Clinical Trials, but the details are unknown at the time of application, a Delayed Onset Study applies.

Vertebrate Animals: If the applicant institution envisions hiring faculty with this award, and those faculty may use vertebrate animals, but the details are unknown at the time of application, a Delayed Onset Study applies.

PHS Assignment Request Form (Overall)

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

Administrative Core

When preparing your application, use Component Type 'Administrative Core.'

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

SF424 (R&R) Cover (Administrative Core)

Complete only the following fields:

- Applicant Information
- Type of Applicant (HRI, LRI, or Partnership)
- Descriptive Title of Applicant's Project
- Proposed Project Start/Ending Dates

PHS 398 Cover Page Supplement (Administrative Core)

Enter Human Embryonic Stem Cells in each relevant component.

Research & Related Other Project Information (Administrative Core)

Human Subjects: Answer only the 'Are Human Subjects Involved?' and 'Is the Project Exempt from Federal regulations?' questions.

Vertebrate Animals: Answer only the 'Are Vertebrate Animals Used?' question.

Project Narrative: Do not complete. Note: ASSIST screens will show an asterisk for this attachment indicating it is required. However, eRA systems only enforce this requirement in the Overall component and applications will not receive an error if omitted in other components.

Project /Performance Site Location(s) (Administrative Core)

List all performance sites that apply to the specific component.

Note: The Project Performance Site form allows up to 300 sites, prior to using additional attachment for additional entries.

Research & Related Senior/Key Person Profile (Administrative Core)

- In the Project Director/Principal Investigator section of the form, use Project Role of 'Other' with Category of 'Project Lead' and provide a valid eRA Commons ID in the Credential field.
- In the additional Senior/Key Profiles section, list Senior/Key persons that are working in the component.
- Include a single Biographical Sketch for each Senior/Key person listed in the application regardless of the number of components in which they participate. When a Senior/Key person is listed in multiple components, the Biographical Sketch can be included in any one component.
- If more than 100 Senior/Key persons are included in a component, the Additional Senior Key Person attachments should be used.

Budget (Administrative Core)

Budget forms appropriate for the specific component will be included in the application package.

The Administrative Core includes the faculty start-up (salary and research project start-up) and all administrative management funds. Administrative management costs may be higher in the early years of the program and lower in the later stages for managing the planning efforts, such as salaries for Administrative Core key personnel, travel for key personnel, publications, equipment, and supplies to support the administrative structure. In years 2-4, administrative management costs are limited to $140,000 direct costs per year.

Effort Commitments: For effective leadership, individuals designated as PD(s)/PI(s) must be meaningfully committed to the program. Specifically, for a single-PI application, a minimum of 20% or 2.4 person months of effort per year is expected for the PD/PI, with a maximum of three person months effort per year. For a multi-PI application, at least one PI must commit a minimum of 10%, and the total PI salary costs supported by this award cannot exceed 25%. Travel costs for attending any in-person meetings and FIRST Executive Steering Committee (FESC) meetings must be included.

Budget Justification: Justification for all costs associated with this core must be provided. The faculty start-up funds will support both salary and research project start-up costs. Administrative management funds support the salaries for PD(s)/PI(s) and for key personnel such as Program Managers (i.e., key personnel that assist the PD(s)/PI(s) in

coordinating and organizing day-to-day activities of the program; travel for key personnel; publications; equipment; and supplies to support the administrative structure).

Note: The R&R Budget form included in many of the component types allows for up to 100 Senior/Key Persons in section A and 100 Equipment Items in section C prior to using attachments for additional entries. All other SF424 (R&R) instructions apply.

PHS 398 Research Plan (Administrative Core)

Specific Aims: Succinctly list and describe the aims for achieving the specific goals and objectives of the Administrative Core, which will support and manage the FIRST Cohort program.

Research Strategy: For each of the below areas, describe the role the core plays and how the core will plan, implement, and/or sustain its objectives through the activities described.

Leadership and Key Personnel

- Specify the roles and responsibilities of leadership and key personnel, including detailing the experience and expertise needed to lead and manage the core. Leadership roles with respect to initiating, facilitating, and implementing the successful completion of the core goals must be described.

Management

- Describe the core governance structure with leadership, administration, fiscal, and scientific functions outlined, with levels of authority for each.
- Describe how the Administrative Core will develop and manage internal and external communications.
- Include the process to be used to allocate and prioritize fiscal and other core resources.
- Detail the composition and roles of committees that will help manage or oversee FIRST Cohort program activities, including how it will interact with the required FIRST Executive Steering Committee (FESC).
- Explain how the core will interact and integrate with other cores.

Culture and Environment

- Describe the institutional diversity and inclusion strategic plan for inclusive excellence and climate data collection —necessary institutional data to indicate changes to culture of inclusive excellence at the faculty, department, and institution level.

Strategy and Methodology

- Describe the recruitment search protocol, highlighting evidence-based strategies for reducing implicit bias. Describe the rubric for interviewing processes that are institution wide and characteristic of inclusive excellence goals. Describe how search committees and collaborative efforts across departments and institutions to hire and retain new faculty will be established.
- Demonstrate that the new faculty will be conducting research in an area supported by the NIH and will complement and enhance the breadth of existing institutional strengths.
- Demonstrate that new faculty will receive a faculty appointment(s) within an academic unit that is part of the *Hiring Unit (the department or center in which the new faculty reside)* and will be appointed within the institution providing the required 75% protected research time across the 12 months of the year and for the length of the award for future transition to competitive research awards (i.e., independent R-type awards or equivalents).
- Demonstrate that the new faculty will receive salary and start-up package or other institutional support equitable to that given to other faculty recently hired into research tenure-track or equivalent faculty positions (at the Assistant Professor (or equivalent) level), which can include supplies, equipment, and support for technical personnel.
- Specify the strategies, interventions, and organizational policies and practices for hiring and search committees, including recruitment and outreach activities planned for prospective applicants.
- Include a plan for sustaining institutional commitment, policies, practices, and culture changes system-wide aimed toward inclusive excellence after the FIRST award ends.

Professional Development and Progression

- Describe the expectations for new faculty for tenure and promotion, as well as the plan for how the start-up packages and other resources for professional development and progression will be equitable for all faculty in the appropriate area of research.
- Explain the expectations for the retention of the new faculty.

Partnership applications must also address the following (Administrative Core):

- The general rationale for and the mutual benefits that the partnership institutions expect to derive from the partnership, including the ways in which both institutions believe they can help each other to achieve the core goals and objectives.
- The Administrative Core co-leadership roles and responsibilities.
- The roles and decision-making responsibilities of fiscal and administrative leadership between the partnering institutions.
- The partnership co-location and integration activities.

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, with the following modification:
All applications, regardless of the amount of direct costs requested for any one year, must address a Data Sharing Plan. The FIRST CEC will lead the development of the final FIRST Data Sharing Plan to be developed in conjunction with FIRST Cohort awardees post award.

Appendix:

Only limited items are allowed in the Appendix. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide; any instructions provided here are in addition to the SF424 (R&R) Application Guide instructions.

PHS Human Subjects and Clinical Trials Information (Administrative Core)

When involving human subjects research, clinical research, and/or NIH-defined clinical trials 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 a **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 (https://grants.nih.gov/grants/glossary.htm#DelayedOnsetHumanSubjectStudy) 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.

Faculty Development Core

When preparing your application, use Component Type ‘Faculty Development Core.’

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

SF424 (R&R) Cover (Faculty Development Core)

Complete only the following fields:

- Applicant Information
- Type of Applicant (HRI, LRI, or Partnership)
- Descriptive Title of Applicant’s Project
- Proposed Project Start/Ending Dates

PHS 398 Cover Page Supplement (Faculty Development Core)

Enter Human Embryonic Stem Cells in each relevant component.

Research & Related Other Project Information (Faculty Development Core)

Human Subjects: Answer only the 'Are Human Subjects Involved?' and 'Is the Project Exempt from Federal regulations?' questions.

Vertebrate Animals: Answer only the 'Are Vertebrate Animals Used?' question.

Project Narrative: Do not complete. Note: ASSIST screens will show an asterisk for this attachment indicating it is required. However, eRA systems only enforce this requirement in the Overall component and applications will not receive an error if omitted in other components.

Project /Performance Site Location(s) (Faculty Development Core)

List all performance sites that apply to the specific component.

Note: The Project Performance Site form allows up to 300 sites, prior to using additional attachment for additional entries.

Research & Related Senior/Key Person Profile (Faculty Development Core)

- In the Project Director/Principal Investigator section of the form, use Project Role of 'Other' with Category of 'Project Lead' and provide a valid eRA Commons ID in the Credential field.
- In the additional Senior/Key Profiles section, list Senior/Key persons that are working in the component.
- Include a single Biographical Sketch for each Senior/Key person listed in the application regardless of the number of components in which they participate. When a Senior/Key person is listed in multiple components, the Biographical Sketch can be included in any one component.
- If more than 100 Senior/Key persons are included in a component, the Additional Senior Key Person attachments should be used.

Budget (Faculty Development Core)

Budget forms appropriate for the specific component will be included in the application package.

Faculty development costs may be higher in the early years of the program and lower in the later stages for managing the efforts, such as salaries for Faculty Development Core key personnel, travel for key personnel, equipment, and supplies to support the faculty success and retention.

Note: The R&R Budget form included in many of the component types allows for up to 100 Senior/Key Persons in section A and 100 Equipment Items in section C prior to using attachments for additional entries. All other SF424 (R&R) instructions apply.

PHS 398 Research Plan (Faculty Development Core)

Specific Aims: Succinctly list and describe the aims for achieving the specific goals and objectives of the Faculty Development Core, which will support and manage faculty development activities in the FIRST Cohort program.

Research Strategy: For each of the below areas, describe the role the core plays and how the core will plan, implement, and/or sustain its objectives through the activities described.

Leadership and Key Personnel

- Specify the roles and responsibilities of leadership and key personnel, including detailing the experience and expertise needed to lead and manage the core. Leadership roles with respect to initiating, facilitating, and implementing the successful completion of the core goals must be described.

Management

- Describe the core governance structure with leadership, administrative fiscal, and scientific functions outlined with levels of authority for each.
- Explain how the core will interact and integrate with other cores.

Culture and Environment

- Describe the plans and programs to enhance inclusive excellence, reduce isolation, increase community building, and provide support for new faculty to overcome institutional or structural challenges associated with academic advancements.
- Identify the types of practices to address isolation and racial/ethnic, gender, or other types of discrimination, implicit bias, or injustices, such as the disproportionate assignment of committee work or other administrative tasks to URM faculty members.

Strategy and Methodology

- Detail the efforts for new faculty promotion, tenure, and academic advancements within the cohort model, including how new faculty will receive credit in the tenure and promotion process for any collaborative work they perform as research clusters.
- Describe the institution's promotion process and how unique aspects of certain fields of study are considered in tenure-related decisions.
- Explain the plans for organizational integration and networking of the new faculty into their cohort and research cluster, as well as into the fabric of the Hiring Unit and across the departments/institution(s)/organization(s).

Professional Development and Progression

- Outline the strategies for developing individual research development plans, career development approaches, and professional development activities planned for all FIRST faculty and how they will be implemented throughout the award period. Plans must include how new faculty will be establishing independent research careers leading to independent R-type awards or equivalents.
- Describe the mentoring and sponsorship programs planned or already in place, including how these efforts collectively will be aimed at eventually securing competitively funded extramural research awards. Specify target expectations for faculty achieving competitive grant applications (i.e., independent R-type awards or equivalents). The diversity of the mentors, how mentoring committee(s) will be constituted and tailored based on the individual needs of the faculty, and how the mentoring plans will include dedicated senior mentors, sponsors, and small peer/near-peer group mentoring must be addressed.
- Describe the proposed courses for skills development, including workshops/courses/seminars around topics such as grant writing, manuscript preparation, enhancing laboratory management, budgeting, academic advancement, and balancing teaching, research, and service.
- Explain the types of opportunities to network among faculty at a similar career level and with senior faculty and administrative officials at the institution, as well as opportunities to establish relationships in the new faculty's scientific community. Explain the expectations for the retention of the new faculty.

Partnership applications must also address the following (Faculty Development Core):

- The general rationale for and the mutual benefits that the partnership institutions expect to derive from the partnership, including the ways in which both institutions believe they can help each other to achieve the core goals and objectives;
- Faculty Development Core co-leadership roles and responsibilities;
- The roles and decision-making responsibilities, core leadership, and dispute resolution process between the partnering institutions;
- The mentors, sponsors, and faculty development activity sharing;
- The partnership co-location and integration activities;
- The professional development opportunities offered and coordinated across partnering institutions.

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, with the following modification:

All applications, regardless of the amount of direct costs requested for any one year, must address a Data Sharing Plan. The FIRST CEC will lead the development of the final FIRST Data Sharing Plan to be developed in conjunction with FIRST Cohort awardees post award.

Appendix:

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

Application Guide; any instructions provided here are in addition to the SF424 (R&R) Application Guide instructions.

Evaluation Core

When preparing your application, use Component Type 'Evaluation Core.'

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

SF424 (R&R) Cover (Evaluation Core)

Complete only the following fields:

- Applicant Information
- Type of Applicant (HRI, LRI, or Partnership)
- Descriptive Title of Applicant's Project
- Proposed Project Start/Ending Dates

PHS 398 Cover Page Supplement (Evaluation Core)

Enter Human Embryonic Stem Cells in each relevant component.

Research & Related Other Project Information (Evaluation Core)

Human Subjects: Answer only the 'Are Human Subjects Involved?' and 'Is the Project Exempt from Federal regulations?' questions.

Vertebrate Animals: Answer only the 'Are Vertebrate Animals Used?' question.

Project Narrative: Do not complete. Note: ASSIST screens will show an asterisk for this attachment indicating it is required. However, eRA systems only enforce this requirement in the Overall component and applications will not receive an error if omitted in other components.

Project /Performance Site Location(s) (Evaluation Core)

List all performance sites that apply to the specific component.

Note: The Project Performance Site form allows up to 300 sites, prior to using additional attachment for additional entries.

Research & Related Senior/Key Person Profile (Evaluation Core)

- In the Project Director/Principal Investigator section of the form, use Project Role of 'Other' with Category of 'Project Lead' and provide a valid eRA Commons ID in the Credential field.
- In the additional Senior/Key Profiles section, list Senior/Key persons that are working in the component.
- Include a single Biographical Sketch for each Senior/Key person listed in the application regardless of the number of components in which they participate. When a Senior/Key person is listed in multiple components, the Biographical Sketch can be included in any one component.
- If more than 100 Senior/Key persons are included in a component, the Additional Senior Key Person attachments should be used.

Budget (Evaluation Core)

Budget forms appropriate for the specific component will be included in the application package.

Evaluation costs may be higher in the early years of the program and lower in the later stages for managing the planning efforts, such as salaries for Evaluation Core key personnel, travel for key personnel, equipment, and supplies to support the evaluation structure.

Budget costs for the Evaluation Core may include costs for internal evaluation activities.

Note: The R&R Budget form included in many of the component types allows for up to 100 Senior/Key Persons in section A and 100 Equipment Items in section C prior to using attachments for additional entries. All other SF424 (R&R) instructions apply.

PHS 398 Research Plan (Evaluation Core)

Specific Aims: Succinctly list and describe the aims for achieving the specific goals and objectives of the Evaluation Core,

which will support and evaluate the FIRST Cohort program at the applicant institution and collaboratively with the FIRST CEC. Applicants must incorporate aims that are appropriate to the strategies to ensure that planning, monitoring, evaluation, and tracking of program activities will be continuously ongoing, shared as negotiated, and reported to the FIRST CEC.

Research Strategy:

For each of the below areas, describe the role the core plays and how the core will plan, implement, and/or sustain its objectives through the activities described.

Leadership and Key Personnel

- Specify the roles and responsibilities of leadership and key personnel, including detailing the experience and expertise needed to lead and manage the core. Leadership roles with respect to initiating, facilitating, and implementing the successful completion of the core goals must be described.

Management

- Describe the core governance structure with leadership, administration, fiscal, and scientific functions outlined with levels of authority for each.
- Detail the strategies proposed to ensure that planning, monitoring, evaluation, and tracking of program activities will be continuously ongoing and reported to the FIRST CEC.
- Explain how the core will interact and integrate with other cores.
- Describe the resources that will be dedicated and the management strategies that will facilitate collaboration with the FIRST CEC to determine common data elements and collection and sharing of data.

Strategy and Methodology

- Outline the theoretical models and conceptual frameworks that will guide evaluation plan/activities for all FIRST program goals.
- Specify the types and numbers of strategies, interventions, institutional policies, evidence-based practices, and other activities that will be implemented to achieve significant systemic and sustainable institutional change over baseline (at faculty, department, and institution level).
- Specify how the program will test the primary hypothesis that a cohort and cluster design model of faculty hiring, sponsorship, continual mentoring, and professional development, embedded within an institution implementing evidence-based practices to create academic cultures of inclusive excellence, will achieve significant improvements in metrics of institutional culture and scientific discovery.
- Include the evaluation strategies for achieving the major milestones associated with hiring a diverse cohort and faculty development, progression, and retention.
- Identify any potential comparators, as needed, and methods to determine the efficacy of the interventions as related to the cohort model for diverse groups of faculty who are nationally underrepresented (NOT-OD-20-031 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html)) in biomedical research.
- Describe the approaches to analyze data to yield fundamental insights about factors that determine whether the new faculty, who are pursuing biomedical research careers in an inclusive scientific environment, are supported, retained, and ultimately excel in these careers.
- Detail the planned committees or workgroups to guide, support, or implement evaluation activities.
- Explain the tracking and assessment of the impact of the FIRST Cohort program's metrics from baseline through to the end of the award term.
- Describe how quantitative data will be collected.
- Describe what qualitative evaluations e.g., focus groups or observations of processes, will be conducted and what survey data will be collected.
- In conducting the institution evaluation, describe how focus groups or structured interviews will be transcribed and what program will be used to conduct the initial analysis.
- Describe how collaboration with the FIRST CEC will be facilitated to: develop program milestones and metrics; determine how faculty survey, minimum common data elements on faculty and institutional culture, and all other data will be entered, cleaned, and transferred to the FIRST CEC, in accordance with an established timeline; and to harmonize measures.
- Describe what additional measures the research team/institution will be interested in exploring, outside of the

minimum common data elements on faculty and institutional culture.

Partnership applications must also address the following (Evaluation Core):

- The general rationale for and the mutual benefits that the partnership institutions expect to derive from the partnership, including the ways in which both institutions believe they can help each other to achieve the core goals and objectives;
- The Evaluation Core co-leadership roles and responsibilities;
- The roles and decision-making responsibilities, core leadership, and dispute resolution process between the partnering institutions;
- How progress will be assessed for each partner, including progress toward FIRST program goals and the collection of data demonstrating progress beyond baseline.
- The partnership co-location and integration activities, and potential barriers and strategies for overcoming them.
- How collaboration with the FIRST CEC will be facilitated to develop program metrics and common data elements and determine how the data will be collected, shared, and submitted to FIRST CEC in accordance with an established timeline.

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, with the following modification:

All applications, regardless of the amount of direct costs requested for any one year, must address a Data Sharing Plan. The FIRST CEC will lead the development of the final FIRST Data Sharing Plan to be developed in conjunction with FIRST Cohort awardees post award.

Appendix:

Only limited items are allowed in the Appendix. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide; any instructions provided here are in addition to the SF424 (R&R) Application Guide instructions.

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 (https://grants.nih.gov/grants/guide/url_redirect.htm?id=82380), the application deadline is automatically extended to the next business day.

Organizations must submit applications to Grants.gov (//grants.nih.gov/grants/guide/url_redirect.htm?id=11128) (the online portal to find and apply for grants across all Federal agencies) using ASSIST or other electronic submission systems. Applicants must then complete the submission process by tracking the status of the application in the eRA Commons (//grants.nih.gov/grants/guide/url_redirect.htm?id=11123), 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. (//grants.nih.gov/grants/guide/url_redirect.htm?id=11142)

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* (//grants.nih.gov/grants/guide/url_redirect.htm?id=11120).

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

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.

For information on how your application will be automatically assembled for review and funding consideration after submission go to: http://grants.nih.gov/grants/ElectronicReceipt/files/Electronic_Multi-project_Application_Image_Assembly.pdf (//grants.nih.gov/grants/ElectronicReceipt/files/Electronic_Multi-project_Application_Image_Assembly.pdf).

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 (https://grants.nih.gov/grants/how-to-apply-application-guide.html). 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 (https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/dealing-with-system-issues.htm) guidance. For assistance with application submission, contact the Application Submission Contacts in Section VII.

Important reminders:

All PD(s)/PI(s) and component Project Leads 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.

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

See more tips (//grants.nih.gov/grants/guide/url_redirect.htm?id=11146) for avoiding common errors.

Upon receipt, applications will be evaluated for completeness and compliance with application instructions by the Center for Scientific Review, NIH. Applications that are incomplete or non-compliant will not be reviewed.

Upon receipt, applications will be evaluated for completeness and compliance with application instructions by the Center for Scientific Review and responsiveness by components of participating organizations, NIH. Applications that are incomplete, non-compliant and/or nonresponsive will not be reviewed.

Post Submission Materials

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

Section V. Application Review Information

1. Criteria

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

Scoring. Reviewers will provide an overall impact score for the entire U54 application (Overall). In addition, assigned reviewers will provide individual "criterion scores" for the Overall application but not for the other components.

Other components of the U54 application will be evaluated but each will receive only one overall impact score (not numerical) rating.

In addition, for applications involving clinical trials:

A proposed Clinical Trial application may include study design, methods, and intervention that are not by themselves innovative but address important questions or unmet needs. Additionally, the results of the clinical trial may indicate that further clinical development of the intervention is unwarranted or lead to new avenues of scientific investigation.

Overall Impact - Overall

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

Scored Review Criteria - Overall

Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance

Does the project address an important problem or a critical 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, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

In addition, for applications involving clinical trials:

Are the scientific rationale and need for a clinical trial to test the proposed hypothesis or intervention well supported by preliminary data, clinical and/or preclinical studies, or information in the literature or knowledge of biological mechanisms? For trials focusing on clinical or public health endpoints, is this clinical trial necessary for testing the safety, efficacy or effectiveness of an intervention that could lead to a change in clinical practice, community behaviors or health care policy? For trials focusing on mechanistic, behavioral, physiological, biochemical, or other biomedical endpoints, is this trial needed to advance scientific understanding?

Investigator(s)

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

In addition, for applications involving clinical trials:

With regard to the proposed leadership for the project, do the PD/PI(s) and key personnel have the expertise, experience, and ability to organize, manage and implement the proposed clinical trial and meet milestones and timelines? Do they have appropriate expertise in study coordination, data management and statistics? For a multicenter trial, is the organizational structure appropriate and does the application identify a core of potential center investigators and staffing for a coordinating center?

In addition, for this FOA:

Leadership and Key Personnel

- Are the experiences and expertise of the leadership and key personnel relevant to the proposed activities?
- Are the roles and responsibilities of key leadership, including detailing the experience and expertise needed to lead and guide the FIRST Cohort program, adequate? Are leadership roles with respect to initiating, facilitating, and implementing the successful completion of the program goals adequate?
- Are the details for succession planning to sustain FIRST Cohort award activities in the event of transitions of FIRST Cohort leadership adequate?
- Are details demonstrating institutional support adequate?

Management

- Is the overall governance structure with leadership, administration, fiscal, and scientific functions outlined with levels of authority for each appropriate?
- Are the core interactions and integration plans adequate?

Innovation

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel

theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

In addition, for applications involving clinical trials:

Does the design/research plan include innovative elements, as appropriate, that enhance its sensitivity, potential for information or potential to advance scientific knowledge or clinical practice?

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?

Are the Resource Sharing Plans, or the rationale for not sharing the following types of resources, appropriate and well justified: Data Sharing Plan (//grants.nih.gov/grants/guide/url_redirect.htm?id=11151)?

In addition, for applications involving clinical trials:

Does the application adequately address the following, if applicable:

Study Design

Is the study design justified and appropriate to address primary and secondary outcome variable(s)/endpoints that will be clear, informative and relevant to the hypothesis being tested? Is the scientific rationale/premise of the study based on previously well-designed preclinical and/or clinical research? Given the methods used to assign participants and deliver interventions, is the study design adequately powered to answer the research question(s), test the proposed hypothesis/hypotheses, and provide interpretable results? Is the trial appropriately designed to conduct the research efficiently? Are the study populations (size, gender, age, demographic group), proposed intervention arms/dose, and duration of the trial, appropriate and well justified?

Are potential ethical issues adequately addressed? Is the process for obtaining informed consent or assent appropriate? Is the eligible population available? Are the plans for recruitment outreach, enrollment, retention, handling dropouts, missed visits, and losses to follow-up appropriate to ensure robust data collection? Are the planned recruitment timelines feasible and is the plan to monitor accrual adequate? Has the need for randomization (or not), masking (if appropriate), controls, and inclusion/exclusion criteria been addressed? Are differences addressed, if applicable, in the intervention effect due to sex/gender and race/ethnicity?

Are the plans to standardize, assure quality of, and monitor adherence to, the trial protocol and data collection or distribution guidelines appropriate? Is there a plan to obtain required study agent(s)? Does the application propose to use existing available resources, as applicable?

Data Management and Statistical Analysis

Are planned analyses and statistical approach appropriate for the proposed study design and methods used to assign participants and deliver interventions? Are the procedures for data management and quality control of data adequate at clinical site(s) or at center laboratories, as applicable? Have the methods for standardization of procedures for data management to assess the effect of the intervention and quality control been addressed? Is there a plan to complete data analysis within the proposed period of the award?

In addition, for this FOA:

Strategy and Methodology

- Are details on how the program goals/aims will be aligned with yearly milestones and metrics in collaboration with the FIRST CEC, including launch year, baseline, and other yearly evaluation metrics adequate?
- Is the primary hypothesis that a cohort and cluster design model of faculty hiring, sponsorship, continual mentoring,

and professional development appropriate to achieve significant improvements in metrics of institutional culture clearly articulated and justified?
- Are anticipated potential barriers and possible solutions included?
- Are appropriate quantitative milestones provided and clearly defined? Do the applicants detail how many faculty will be recruited and hired, and on what timeline? Are these goals feasible and well developed on the timeline of the award?

Professional Development and Progression

- Are the overall strategies proposed for faculty development, promotion, and retention, including the use of mentors and sponsors, adequate?
- Is the overall strategy for the faculty cohort hires to be supported and integrated during the duration of the award and sustained if an independent R-type award or equivalent is not attained adequate?

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

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

In addition, for applications involving clinical trials:

If proposed, are the administrative, data coordinating, enrollment and laboratory/testing centers, appropriate for the trial proposed?

Does the application adequately address the capability and ability to conduct the trial at the proposed site(s) or centers? Are the plans to add or drop enrollment centers, as needed, appropriate?

If multi-sites/centers, is there evidence of the ability of the individual site or center to: (1) enroll the proposed numbers; (2) adhere to the protocol; (3) collect and transmit data in an accurate and timely fashion; and, (4) operate within the proposed organizational structure?

In addition, for this FOA:

Culture and Environment

- Are the types and numbers of strategies, interventions, policies, evidence-based practices, and other activities proposed for implementation adequate and feasible to achieve significant systemic and sustainable institutional change over baseline (at cohort/faculty, institution and department/college institution level)?
- Do the strategies for implementing and sustaining cultures of inclusive excellence within the program have the potential to be transformational for biomedical research at the FIRST Cohort awardee institution(s) and beyond?
- Will the program provide an environment that will reduce isolation/discrimination/implicit bias for the new faculty?

In addition, for partnership applications:

- Are the general rationale for and the mutual benefits that the partnership institutions expect to derive from the partnership outlined, including the ways in which both institutions believe they can help each other to achieve the program goals and objectives?
- Are the immediate priorities of the partnership, which must be derived from a careful planning process that considers mutual benefits, adequate?
- Are other areas of opportunity that the partnership will consider as the relationship evolves identified?
- Are strategies for promoting institutional culture change at each partnership institution adequate?
- Are the scientific co-leadership roles and decision-making responsibilities detailed?
- Are the partnership's overall goal and specific objectives and the projected timeline for achieving each objective adequate?
- Are the location, program, aim, and activities (where faculty will be hired, where professional development activities will take place, etc.) outlined?

- Is there an adequate plan for the integration of activities?
- Are joint partnership efforts aimed at eventually securing competitively funded extramural research awards adequate, including target expectations (i.e., independent R-type awards or equivalents)?
- Are the commitments from the leaderships of each partnering institution toward diversity and inclusion adequate?
- Are the planning and priority-setting processes detailed, including, in chronological order, each process used in planning and setting the priorities and objectives for this application? Have the nature of each planning activity completed (e.g., meetings of higher institutional officials, planning committees, steering committees in areas of common interest, workshops, retreats, surveys of faculty), its purpose, the individuals that participated from both institutions, and any conclusions been briefly described? Are the outcomes of the planning process that are particularly relevant to the partnership proposed in this application described?

Additional Review Criteria - Overall

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.

Study Timeline

Specific to applications involving clinical trials:

Is the study timeline described in detail, taking into account start-up activities, the anticipated rate of enrollment, and planned follow-up assessment? Is the projected timeline feasible and well justified? Does the project incorporate efficiencies and utilize existing resources (e.g., CTSAs, practice-based research networks, electronic medical records, administrative database, or patient registries) to increase the efficiency of participant enrollment and data collection, as appropriate?

Are potential challenges and corresponding solutions discussed (e.g., strategies that can be implemented in the event of enrollment shortfalls)?

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 (//grants.nih.gov/grants/guide/url_redirect.htm?id=11175).

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 (//grants.nih.gov/grants/guide/url_redirect.htm?id=11174).

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 (//grants.nih.gov/grants/guide/url_redirect.htm?id=11150).

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

Not Applicable

Renewals

Not Applicable

Revisions

Not Applicable.

Additional Review Considerations - Overall

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)) Sharing Model Organisms (//grants.nih.gov/grants/guide/url_redirect.htm?id=11152); and 2) Genomic Data Sharing Plan (//grants.nih.gov/grants/guide/notice-files/NOT-OD-14-124.html).

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.

Administrative Core

Reviewers will provide an overall merit descriptor score to reflect their assessment of the likelihood for the core to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

Leadership and Key Personnel

- To what extent do the leadership and key personnel for the Administrative Core possess the skills, knowledge, and expertise needed to achieve the specific aims of this core?
- Are the leadership and key personnel roles with respect to initiating, facilitating, and implementing the successful completion of the program goals detailed?

Management

- Are clear and logical administrative, organizational, and governance structures described, and are they likely to

accomplish the goals of the FIRST Cohort program?
- Is the process to be used to allocate and prioritize fiscal and other core resources adequate?
- Are management plans described for internal and external communication, including website development and management, for the duration of the program?
- Is an adequate infrastructure described to support evaluation and data coordination and reporting activities?
- Are the composition and roles of committees that will help manage or oversee FIRST Cohort program activities, including the required FESC, adequately described and appropriate?

Strategy and Methodology

- Are appropriate strategies, interventions, and organizational policies and practices proposed for search committees, recruitment, and hiring, including outreach activities planned for prospective applicants and collaborations with other departments or institutions?
- Is the rationale for the number of hires, demographics, and proposed position descriptions justified and appropriate, and does it demonstrate that the new faculty will be conducting research in areas supported by the NIH institutes and/or centers and will complement and enhance the breadth of existing institutional strengths?
- Is it evident that the faculty will receive a faculty appointment(s) within an academic unit that is part of the *Hiring Unit(the department or center in which the new faculty reside)* for future transition to competitive research awards?

Professional Development and Progression

- Are there appropriate expectations for new faculty for tenure and promotion?
- Is there an adequate plan for how the start-up packages and other resources for professional development and progression will be equitable for all faculty in the appropriate area of research?
- Are appropriate expectations described for the retention of the new faculty?

Culture and Environment

- Are the institutional diversity and inclusion strategic plan for inclusive excellence and climate data collection adequate?
- Are the activities to create cultures of inclusive excellence (scientific environments that cultivate and benefit from a full range of talents) with a sustained commitment to diversity and inclusion and biomedical research while employing a faculty cohort model appropriate?
- Are there adequate strategies to develop, implement, and cultivate meaningful change (from baseline) in the environment at the institutional and departmental level, with the goal of enhancing biomedical research workforce diversity and inclusion?

In addition, for partnership applications:

- Are the general rationale for and the mutual benefits that the partnership institutions expect to derive from the partnership outlined, including the ways in which both institutions believe they can help each other to achieve the core goals and objectives?
- Are the Administrative Core co-leadership roles and responsibilities detailed?
- Are the roles and decision-making responsibilities of fiscal and administrative leadership between the partnering institutions detailed?
- Is there an adequate plan for the partnership co-location and integration activities?

Faculty Development Core

Reviewers will provide an overall merit descriptor score to reflect their assessment of the likelihood for the core to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

Leadership and Key Personnel

- To what extent do the leadership and key personnel for the Faculty Development Core possess the skills, knowledge, and expertise needed to achieve the specific aims of this core?
- Are the leadership and key personnel roles with respect to initiating, facilitating, and implementing the successful completion of the program goals detailed?

Management

- Are clear and logical governance structures described, and are they likely to accomplish the goals of the core?
- Is the process to be used to allocate and prioritize core resources adequate?
- Are management plans described for internal and external communication?
- Is an adequate infrastructure described to support faculty development core?
- Are the composition and roles of committees that will help manage or oversee faculty development core activities adequately described and appropriate?

Strategy and Methodology

- To what extent does the applicant describe the efforts for new faculty promotion, tenure, and academic advancements within the cohort model, including how new faculty will receive credit in the tenure and promotion process for any collaborative work they perform as research clusters?
- To what extent does the application describe the institution's promotion process and how unique aspects of certain fields of study were considered in tenure-related decisions?
- Does the applicant adequately describe the metrics for assessing the success and the plans for integrating the new faculty into their cohort and for integrating the individual/research cluster into the fabric of the Hiring Unit and across the institution/organization?

Professional Development and Progression

- Are the individual research development plans, career development plans, and professional development plans proposed for all new faculty adequate, and do they demonstrate an effective implementation process for these plans during the award period?
- Does the applicant describe the individual mentorship and sponsorship plans and small peer/near-peer group mentoring activities for each new faculty hire? Do these plans provide the necessary description of mentoring support required and a sponsor for academic advancements?
- Does the applicant identify and provide adequate descriptions of courses for skills development, including workshops/courses/seminars around topics such as grant writing, manuscript preparation, enhancing laboratory management, budgeting, academic advancement, and balancing teaching, research, and service?

Culture and Environment

- Does the applicant adequately describe the plans to integrate new faculty into the organization and provide new faculty with networking opportunities, including networking among faculty at a similar career level and with senior faculty and administrative officials at the institution, as well as opportunities to establish relationships in the new faculty's scientific community?
- Are the plans and programs to enhance inclusive excellence, reduce isolation, increase community building detailed, and provide support for new faculty to overcome institutional or structural challenges associated with academic achievements appropriate? Is there an adequate explanation of how these efforts, collectively, will be aimed at eventually submitting and securing competitively funded extramural research awards (i.e., independent R-type awards or equivalents)?

In addition, for partnership applications:

- Are the general rationale for and the mutual benefits that the partnership institutions expect to derive from the partnership outlined, including the ways in which both institutions believe they can help each other to achieve the core goals and objectives?
- Are the Faculty Development Core co-leadership roles and responsibilities detailed?
- Are the roles and decision-making responsibilities, core leadership, and dispute resolution process between the partnering institutions detailed?
- Are the mentors, sponsors, and faculty development activity sharing detailed?
- Is there an adequate plan for the partnership co-location and integration activities?
- Are the professional development opportunities offered and coordinated across partnering institutions?

Evaluation Core

Reviewers will provide an overall merit descriptor score to reflect their assessment of the likelihood for the core to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

Leadership and Key Personnel

- To what extent do the leadership and key personnel for the Evaluation Core possess the skills, knowledge, and expertise needed to achieve the specific aims of this core?
- Are the leadership and key personnel roles with respect to initiating, facilitating, and implementing the successful completion of the program goals detailed?

Management

- Are clear governance structures described, and are they likely to accomplish the goals of the evaluation core?
- Is the process to be used to allocate and prioritize fiscal and other core resources adequate?
- Are management plans described for internal and external communication, including website development and management, for the duration of the program?
- Is an adequate infrastructure described to support evaluation and data coordination and reporting activities?
- Are the composition and roles of committees that will help manage or oversee core activities, including interacting with the required FESC, adequately described and appropriate?
- Are planned committees or workgroups involved in evaluation and data coordination activities appropriate?

Strategy and Methodology

- To what extent are the theoretical model or conceptual framework and associated evaluation activities appropriate for guiding evaluation of the impact and outcomes of the FIRST Cohort program? Do they provide adequate evidence that supports the use of the models and frameworks and their application to the FIRST Cohort program?
- Are the methods to be used to assess efficacy of individual FIRST Cohort awardee activities compelling?
- Are appropriate data analytic strategies being applied to understand factors associated with the key aspects of the FIRST program and its goals?
- Are the proposed evaluation activities likely to identify the unique impact of the FIRST Cohort program across and within multiple levels: all faculty, FIRST Cohort faculty, departments, and institution?
- Are there potential comparators, if proposed, and methods to determine the efficacy of the interventions as related to the cohort model for diverse groups of faculty who are nationally underrepresented (NOT-OD-20-031 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html)) in biomedical research?
- Are there appropriate measures of institutional culture and cohort type for successful biomedical researchers?
- Are there adequate approaches to analyze data to yield fundamental insights about factors that determine whether faculty from underrepresented groups in a cohort setting, who are pursuing biomedical research careers in an inclusive scientific environment, are supported, retained, and ultimately excel in these careers?
- Are the plans appropriate for the tracking and assessment of the impact of the FIRST Cohort from baseline through to the end of the award?
- Are the proposed collaboration efforts with the FIRST CEC and dedicated resources appropriate to develop program milestones and metrics and determine how faculty survey, minimum common data elements on faculty and institutional culture, and all other data will be entered, cleaned, and transferred to the FIRST CEC, in accordance with an established timeline; and to harmonize measures?
- Is there an adequate description of how quantitative data will be collected?
- Are the plans adequate for how qualitative evaluations e.g., focus groups or observations of processes, will be conducted and what survey data will be collected?
- Are the plans adequate for how, in conducting the institution evaluation, focus groups or structured interviews will be transcribed and what program will be used to conduct the initial analysis?
- Is there an appropriate description of what additional measures the research team/institution will be interested in exploring, outside of the minimum common data elements on faculty and institutional culture?

Institutional Commitment Letter

Is the level of authority of the officials committing to this effort adequate? Does the written “Institutional Commitment Letter” from the appropriate leadership (e.g., President, Dean) detail adequate support of the following:

- The overall program priorities and objectives proposed with assurances that the program will have the maximum success and sustainability?
- The plans for the commitment to the activities proposed in the program goals, and support for how these efforts will be monitored?
- The institutional investment/commitment to new faculty? Does it include adequate additional resources (e.g., discretionary resources, space, faculty positions, protected time for research, etc.) committed to the program?
- The effort of commitment of the designated PD(s)/PI(s) and other key personnel with respect to released time from

other institutional responsibilities (e.g., teaching, clinical, administrative duties), to whether the costs of this "released time" are shared or not between partnering institutions; the provisions for recruitment of new faculty, including supplemental funds for start-up and professional development; the provisions to leverage funds for long-term sustainability of FIRST Cohort-supported activities; and provisions to leverage funds for long-term support of the new faculty?

In addition, does the written "Institutional Commitment Letter" from the appropriate leadership (e.g., President, Dean):

- Indicate the application type: HRI, LRI, or Partnership?
- Identify the potential research clusters of scientists in various scientific disciplines within the NIH mission?

In addition, for partnership applications:

- Is there an adequate statement listing the partnering institutions?
- Are the general rationale for and the mutual benefits that the partnership institutions expect to derive from the partnership outlined, including the ways in which both institutions believe they can help each other to achieve the core goals and objectives?
- Are the Evaluation Core co-leadership roles and responsibilities detailed?
- Are the roles and decision-making responsibilities, core leadership, and dispute resolution process between the partnering institutions detailed?
- Are there adequate details on how progress will be assessed for each partnership, including progress toward FIRST program goals and the collection of data demonstrating progress beyond baseline?
- Is there an adequate plan for the partnership co-location and integration activities, and potential barriers and strategies for overcoming them?
- Are there adequate details on how collaboration with the FIRST CEC will be facilitated to develop program metrics and common data elements and determine how the data will be collected, shared, and submitted to FIRST CEC in accordance with an established timeline?

Additional Review Considerations - Overall

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).

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.

Additional Review Criteria - Cores

As applicable for the Cores, 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 (https://grants.nih.gov/grants/guide/url_redirect.htm?id=11175).

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 (https://grants.nih.gov/grants/guide/url_redirect.htm?id=11174).

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section (https://grants.nih.gov/grants/guide/url_redirect.htm?id=11150).

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

Not applicable

Renewals

Not applicable

Revisions

Not applicable

Additional Review Considerations - Cores

As applicable for the collaborative partnership 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).

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 Center for Scientific Review, in accordance with NIH peer review policy and procedures (//grants.nih.gov/grants/guide/url_redirect.htm?id=11154), 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.

Appeals (//grants.nih.gov/grants/guide/notice-files/NOT-OD-11-064.html) of initial peer review will not be accepted for applications submitted in response to this FOA.
Applications will be assigned to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications submitted in response to 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:

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

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 eRA Commons (//grants.nih.gov/grants/guide/url_redirect.htm?id=11123). 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 (//grants.nih.gov/grants/guide/url_redirect.htm?id=11156).

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 (//grants.nih.gov/grants/guide/url_redirect.htm?id=11157).
A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the grants management officer is the authorizing document and will be sent via email to the grantee's business official.

Awardees must comply with any funding restrictions described in 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 (//grants.nih.gov/grants/guide/url_redirect.htm?id=11158) website. This includes any recent legislation and policy applicable to awards that is highlighted on this website.

Individual awards are based on the application submitted to, and as approved by, the NIH and are subject to the IC-specific terms and conditions identified in the NoA.

ClinicalTrials.gov: If an award provides for one or more clinical trials. By law (Title VIII, Section 801 of Public Law 110-85), the "responsible party" must register and submit results information for certain "applicable clinical trials" on the ClinicalTrials.gov Protocol Registration and Results System Information Website (https://register.clinicaltrials.gov (https://register.clinicaltrials.gov/)). NIH expects registration and results reporting of all trials whether required under the law or not. For more information, see https://grants.nih.gov/policy/clinical-trials/reporting/index.htm (https://grants.nih.gov/policy/clinical-trials/reporting/index.htm)

Institutional Review Board or Independent Ethics Committee Approval: Grantee institutions must ensure that all 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.

Data and Safety Monitoring Requirements: The NIH policy for data and safety monitoring requires oversight and monitoring of all NIH-conducted or -supported human biomedical and behavioral intervention studies (clinical trials) to ensure the safety of participants and the validity and integrity of the data. Further information concerning these requirements is found at http://grants.nih.gov/grants/policy/hs/data_safety.htm and in the application instructions (SF424 (R&R) and PHS 398).

Investigational New Drug or Investigational Device Exemption Requirements: Consistent with federal regulations, clinical research projects involving the use of investigational therapeutics, vaccines, or other medical interventions (including licensed products and devices for a purpose other than that for which they were licensed) in humans under a research protocol must be performed under a Food and Drug Administration (FDA) investigational new drug (IND) or investigational device exemption (IDE).

2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.htm?id=11120) as part of the NoA. For these terms of award, see the *NIH Grants Policy Statement* Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General (//grants.nih.gov/grants/guide/url_redirect.htm?id=11157) and Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Grantees, and Activities (//grants.nih.gov/grants/guide/url_redirect.htm?id=11159). More information is provided at Award Conditions and Information for NIH Grants (//grants.nih.gov/grants/guide/url_redirect.htm?id=11158).

Recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age and, in some circumstances, religion, conscience, and sex. This includes ensuring programs are accessible to persons with limited English proficiency. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. Please see https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html (https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html) and http://www.hhs.gov/ocr/civilrights/understanding/section1557/index.html (http://www.hhs.gov/ocr/civilrights/understanding/section1557/index.html).

HHS recognizes that research projects are often limited in scope for many reasons that are nondiscriminatory, such as the principal investigator's scientific interest, funding limitations, recruitment requirements, and other considerations. Thus, criteria in research protocols that target or exclude certain populations are warranted where nondiscriminatory justifications establish that such criteria are appropriate with respect to the health or safety of the subjects, the scientific study design, or the purpose of the research. For additional guidance regarding how the provisions apply to NIH grant 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. HHS provides guidance to recipients of FFA on meeting their legal obligation to take reasonable steps to provide meaningful access to their programs by persons with limited English proficiency. Please 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 further guidance on providing culturally and linguistically appropriate services, recipients should review the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care at https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53 (https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53).
- Recipients of FFA also have specific legal obligations for serving qualified individuals with disabilities. Please 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. Please see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html (https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html); https://www2.ed.gov/about/offices/list/ocr/docs/shguide.html; and https://www.eeoc.gov/eeoc/publications/upload/fs-sex.pdf (https://www.eeoc.gov/eeoc/publications/upload/fs-sex.pdf). For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and 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).
- Recipients of FFA must also administer their programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws. Collectively, these laws

prohibit exclusion, adverse treatment, coercion, or other discrimination against persons or entities on the basis of their consciences, religious beliefs, or moral convictions. Please see https://www.hhs.gov/conscience/conscience-protections/index.html (https://www.hhs.gov/conscience/conscience-protections/index.html) and https://www.hhs.gov/conscience/religious-freedom/index.html (https://www.hhs.gov/conscience/religious-freedom/index.html).

Please contact the HHS Office for Civil Rights for more information about obligations and prohibitions under federal civil rights laws at https://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 1-800-537-7697.

In accordance with the statutory provisions contained in Section 872 of the Duncan Hunter National Defense Authorization Act of Fiscal Year 2009 (Public Law 110-417), NIH awards will be subject to the Federal Awardee Performance and Integrity Information System (FAPIIS) requirements. FAPIIS requires Federal award making officials to review and consider information about an applicant in the designated integrity and performance system (currently FAPIIS) prior to making an award. An applicant, at its option, may review information in the designated integrity and performance systems accessible through FAPIIS and comment on any information about itself that a Federal agency previously entered and is currently in FAPIIS. The Federal awarding agency will consider any comments by the applicant, in addition to other information in FAPIIS, in making a judgement about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in 45 CFR Part 75.205 "Federal awarding agency review of risk posed by applicants." This provision will apply to all NIH grants and cooperative agreements except fellowships.

Cooperative Agreement Terms and Conditions of Award

The following special terms of award are in addition to, and not in lieu of, otherwise applicable U.S. Office of Management and Budget (OMB) administrative guidelines, U.S. Department of Health and Human Services (DHHS) grant administration regulations at 45 CFR Part 75, and other HHS, PHS, and NIH grant administration policies.

The administrative and funding instrument used for this program will be the cooperative agreement, an "assistance" mechanism (rather than an "acquisition" mechanism), in which substantial NIH programmatic involvement with the recipients is anticipated during the performance of the activities. Under the cooperative agreement, the NIH purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role; it is not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the recipients for the project as a whole, although specific tasks and activities may be shared among the recipients and the NIH as defined below.

The PIs of the FIRST Cohort awards and FIRST CEC award and involved NIH staff acting as Program Officials (POs) and Project Scientists (PSs), and others as needed (ex-officio), will form a FIRST Executive Steering Committee (FESC) which will govern the activities of the FIRST program recipients. There will be a yearly rotating chair of the FESC who will be nominated and selected from among the PIs of the awards. NCI staff serving as POs will provide the normal scientific and programmatic stewardship of the FIRST Cohort awards and will be named in the award notices. The NIH will receive input from External Program Consultants (EPCs) who may attend recipient face-to-face or virtual meetings or provide guidance as needed. The FIRST CEC will organize FESC and recipient virtual or face-to-face meetings, but the NIH will organize meetings with EPCs, who will report only to the NIH.

The PSs, POs, Common Fund and multiple NIH ICOs' staff members will form an NIH FIRST Working Group, which will support the activities of the program of FIRST CEC and FIRST Cohort recipients. An NIH Project Team, consisting of NIH employees only, including the NCI POs and NIH PSs, will assist the POs with the normal scientific and programmatic stewardship of the awards. PSs may be named after awards are made and the scientific foci of any cohorts and research clusters are known.

- If metrics and milestones are not met, are inadequate, are not timely in order to meet the needs of the program, or do not conform with the requirements and restrictions specified in the FOA and NoA and with those described in the application, then the NIH will take the appropriate actions. These actions may include expanded reporting requirements, or more serious actions such as delayed or immediate reductions of funds, restrictions on use of funds, or an ordered phase-out of awards. For example, year 2 funds may be delayed or restricted pending satisfactory completion of any unmet year 1 milestones.
- If participation is not aligned with the activities specified in the RFA and described in the application, then the NIH will take the appropriate actions, such as delayed or immediate restrictions on use of funds or an ordered phase-out of awards.

The NIH Data sharing agreements must be met. If the NIH data sharing requirements are not met, then the NIH will take the

appropriate actions, such as delayed or immediate reductions of funds, restrictions on use of funds, or an ordered phase-out of awards.

Unspent funds from the award will be used to offset funds in the following year.

PI and Program Roles and Responsibilities are described under the terms of the Cooperative Agreement in the FOA.

The PD(s)/PI(s) will have the primary responsibility for:

- Recipients will retain custody of and have primary rights to the data and software developed under these awards, subject to Government rights of access consistent with current DHHS, PHS, and NIH policies.
- Determining cohort/research cluster hiring, professional and research development, institutional change approaches, and proposing project milestones.
- Participating in group activities, such as the FESC and subcommittees, as needed.
- Meeting, as needed, throughout the duration of the FIRST program, including either in-person, WebEx or teleconference meetings recommended by the FESC.
- Establishing data collection and reporting timelines in collaboration with FIRST CEC and providing periodic reports and data in a timely fashion and in standard format, as agreed upon by the FESC and NCI.
- Working with the FIRST CEC PIs to establish a data collection timeline and maintain quality control.
- Preparing abstracts, presentations, and publications and collaborating with all FIRST Cohort recipients on making the public and research and academic professionals aware of the program.
- Assessing and disseminating data, protocols, and methods developed for or derived from the FIRST program within and outside of the FIRST program.
- Adhering to policies regarding data sharing and publication established by the FESC to the extent consistent with the applicable NIH policies, laws, and regulations.
- Abiding by common definitions, timelines, and procedures, as established by the FESC, as appropriate.
- Submitting periodic progress reports in a standard format, in addition to the RPPR, as agreed upon by the FESC and NCI.
- Complying with governance processes of the FESC for issues affecting the program.
- Ensuring that resources (e.g. data sets; procedure manuals) developed during this program are made publicly available to the extent consistent with applicable NIH policies, laws, and regulations, and that results are published in a timely manner.
- Adhering to applicable NIH policies, laws, and regulations regarding intellectual property and data release, and to other FESC policies to the extent consistent with applicable NIH policies, laws, and regulations.
- Attending and participating in FESC meetings and accepting and implementing its decisions, as appropriate.
- Providing for secure, accurate, and timely data submission in collaboration with the FIRST CEC.
- Participating in presenting and publishing new processes and substantive findings.
- Assessing and disseminating FIRST data and resources.
- Participating in governance of the FIRST program as a member of the FESC.
- Interacting with other relevant NIH activities, as needed, to promote synergy and consistency among similar projects.

Minimal PD(s)/PI(s) Commitments. Recipients must be committed to making diversity of the research community a priority. The recipients must ensure a significant effort commitment of the program leadership. Specifically, for a single-PI application, a minimum of 20% or 2.4 person months of effort per year to the program activities is expected for the PD/PI, with a maximum of three person months effort per year. For a multi-PI application, at least one PI must commit a minimum of 10%, and the total PI salary costs supported by this award cannot exceed 25%.

Program Meetings. Each recipient must plan regular meetings (no less frequently than monthly) to discuss the progress and direction of its activities and to ensure that the necessary interactions are taking place. Recipients will be expected to participate in FIRST program-wide meetings. These meetings may be in the form of phone teleconferencing, videoconferencing, and/or web conferencing as well as face-to-face meetings. Unwillingness or a consistent inability of a PD/PI to attend may be the basis for administrative action including termination of the award.

Face-to-Face PI Meetings. The contact PD/PI and senior administrators for the program (e.g., Program Managers) must attend FIRST Program PI meetings for the purpose of sharing information and strategies.

Reports. Each recipient will submit annual progress reports to the NIH/NCI that describe activities and accomplishments during the previous funding period as part of the Research Performance Progress Report (RPPR).

Approval of Changes. If the institutional leadership changes during the award, new letters of commitment must be sent to

NIH/NCI no later than 90 days after the change. Documentation should include Institutional Commitment Letter and rationale for replacement.

Sharing Experiences. Successful programs are expected to participate in sharing their approaches and experiences with other FIRST recipients and the broader community.

Participation in External Program Evaluation Through FIRST CEC. All PD(s)/PI(s) of the FIRST Cohort awards are expected to participate and facilitate an evaluation of the program through the FIRST CEC. Conducting the national evaluation ensures objectivity and credibility of the evaluation findings and recommendations. However, NCI POs will remain responsible for the normal scientific and programmatic stewardship, annual progress report review of each FIRST Cohort award, and evaluation of the partnership program. The FIRST CEC, in collaboration with FIRST Cohort recipients, will identify and harmonize a minimum set of common data elements to be used by each of the FIRST Cohort recipients to evaluate the faculty and the institutional culture, as well as develop program-specific metrics and milestones which will include appropriate performance measures, program outputs, and outcomes which will be used to identify the core data elements required for monitoring and evaluating the program overall.

NIH staff have substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below:

- Work closely with individual U54 faculty, PIs and POs to facilitate collaborations.
- Assist the program efforts by facilitating access to fiscal and intellectual resources provided by NIH.
- Interact with each recipient, coordinate approaches, and contribute to the adjustment of projects/programs or approaches as warranted.
- Aid in reviewing and commenting on all major transitional changes.
- Coordinate activities with other ongoing programs supported by NIH.
- Facilitate the dissemination of experiences and approaches among recipients of the program as well as other NIH-supported networks.
- Help reprogram efforts within the peer-reviewed scope of work, including options to modify program goals and milestones when programs are not making headway relative to timelines for achieving the objectives of the FOA.
- If awards are collaborative between two or more institutions (a partnership award), NIH staff will evaluate the progress in the fulfillment of institutional commitment and resources available to the partners.
- Recommend the approval of new Contact PI, Co-leaders, and other key personnel to ensure that they have the appropriate expertise and experience to lead the effort.
- Participate in FIRST program activities.
- Participating with the other FESC members in addressing issues that arise with FIRST planning, operation, assessment, and data analysis. The Project Scientist(s) will assist and facilitate the group process and not direct it.
- Serving as a liaison, helping to coordinate activities, including acting as a liaison to other NIH Institutes/Centers, and as an information resource for the recipients. The Project Scientist(s) will also help coordinate the efforts of the FIRST program with other groups conducting similar efforts.
- Attending all FESC meetings as a voting member and assisting in developing standard operating procedures and consistent policies for dealing with situations that require coordinated action. The Project Scientist(s) will be responsible for working with the recipients, as needed, to help manage the logistic aspects of the FIRST program.
- Reporting periodically on FIRST progress to the NIH FIRST Working Group and, through it, to the NIH Common Fund.
- Serving on subcommittees of the FESC as appropriate.
- Assisting recipients in the development, if needed, of policies for dealing with situations that require coordinated action.
- Providing advice in the management and technical performance of the award.
- Assisting in promoting the availability of the data and related resources developed in the course of this program to the scientific community at large.

Additionally, NIH Program Official(s) will be responsible for the normal scientific and programmatic stewardship of the FIRST Cohort awards and the FIRST CEC award and will be named in the award notice. Prior to funding an application, the PO will contact the applicant to discuss the proposed milestones and any changes suggested by NIH staff or the NIH review panel. Milestones and metrics will be developed by each FIRST Cohort recipient, and each PI will work with PO and the Office of Grants Administration before the issuance of the Notice of Award (NoA). Milestones will be aligned with a timeframe in the NoA, and the recipient will need to meet milestones by the defined deadlines. Progress on milestones will be monitored annually by NIH staff and through regularly scheduled meetings. The NCI, in consultation with the NIH FIRST Working Group of NIH staff from different ICs, generally will work with or afford the recipients an opportunity, consistent with the terms of the Cooperative Agreement, to correct situations prior to restricting, reducing, or an ordered phase-out of FIRST Cohort awards.

The NCI Program Official(s), in consultation with the PSs and NIH FIRST Working Group, will determine if the recipient has met the milestones required for each year of funding.

The dominant role and prime responsibility for the activity resides with the recipients for the program, although specific tasks and activities in carrying out the programs will be shared among the recipients and the NIH PO/PS and/or NIH FIRST Working Group.

The NIH FIRST Working Group will participate and select program staff to review supplemental requests, extensions, and/or bridge funding requests.

In this case, an NCI Program Official will be responsible for the normal scientific and programmatic stewardship of the award and will be named in the award notice. The NCI PO and PS may not be the same person.

Areas of Joint Responsibility include:

Close interaction among the participating investigators will be required, as well as significant involvement from the NIH, to manage, assess, and disseminate the FIRST program. The recipients and the Project Scientist(s) will meet virtually or in person with the FESC at least once a year throughout the duration of the FIRST programs, and will meet on conference calls, as needed, to share information on methodologies, analytical tools, and preliminary results. PDs/PIs, key co-investigators and faculty hires, and mentors are eligible to attend these meetings.

The FESC will serve as the main governance body of the program. The FESC will be responsible for coordinating the activities being conducted by the program and is the Committee through which the NIH FIRST Working Group formally interact with the FIRST Cohort and FIRST CEC investigators. The FESC membership will include PD(s)/PI(s) of each FIRST Cohort award and the FIRST CEC award, other staff as needed (ex-officio), and the FIRST Cohort and FIRST CEC awards' PSs and POs. There will be a yearly rotating chair of the FESC who will be nominated from the PIs of the awarded sites. The FESC may add additional members, and other government staff may attend the FESC meetings as desired. Each award will have one vote, and the FIRST Cohort and FIRST CEC awards' Program Scientists (all Federal staff together) will have one vote. FESC decisions generally will be made by majority vote.

The FESC may establish subcommittees, as needed, to address issues. These subcommittees will include representatives from the program and the NIH and possibly other experts. The FESC will have the overall responsibility of assessing and prioritizing the progress of the various subcommittees.

The FIRST Cohort recipient agrees to work collaboratively to:

- Provide for secure, accurate, and timely data submission to the FIRST CEC.
- Participate in presenting and publishing new processes and substantive findings.
- Assess and disseminate FIRST data and resources.
- Participate in governance of the FIRST program as a member of the FESC.
- Interact with other relevant NIH activities or programs, as needed, to promote synergy and consistency among similar projects.

External Program Consultants

- The NIH will consult with experts, External Program Consultants (EPCs), to receive input as it supports and stimulates the recipient's activities in the program. These individual consultants may provide input with respect to all aspects of the program. All EPC opinions and advice will be given to the NIH as **individual** opinions; consensus opinions will not be requested or obtained, the group will never vote on issues. The NIH may use this consultant feedback in its review and evaluation of the program. The EPCs will be four to eight senior, non-federal experts who are not directly involved in the activities of the CEC program and who have relevant expertise. The FIRST Cohort and FIRST CEC awards' POs, PSs, NIH FIRST Working Group, and other NIH staff may attend the EPC meetings.
- NIH will seek input from individual EPCs on an as-needed basis. They will generally be asked to attend any face-to-face PI meetings of the FIRST Cohort recipients to gather information and meet with the NIH FIRST Working Group. EPCs may be consulted by phone or email at other times, as needed.
- Annually, the EPCs will provide their individual assessments (no consensus will be requested or obtained) to the NIH of the progress of the program and, as necessary, will present recommendations regarding any changes. The assessments and recommendations will be provided, through the NIH FIRST Working Group, to the Director of the Office of Strategic Coordination, NIH.

Dispute Resolution:

Any disagreements that may arise in scientific or programmatic matters (within the scope of the award) between award recipients and the NIH may be brought to Dispute Resolution. A Dispute Resolution Panel composed of three members will be convened. It will have three members: a designee of the FESC chosen without NIH staff voting, one NIH designee, and a third designee with expertise in the relevant area who is chosen by the other two; in the case of individual disagreement, the first member may be chosen by the individual awardee. This special dispute resolution procedure does not alter the awardee's right to appeal an adverse action that is otherwise appealable in accordance with PHS regulation 42 CFR Part 50, Subpart D and DHHS regulation 45 CFR Part 16.

3. Reporting

When multiple years are involved, awardees will be required to submit the Research Performance Progress Report (RPPR) (//grants.nih.gov/grants/rppr/index.htm) annually and financial statements as required in the NIH Grants Policy Statement. (//grants.nih.gov/grants/guide/url_redirect.htm?id=11161)

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* (//grants.nih.gov/grants/guide/url_redirect.htm?id=11161).

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 (//grants.nih.gov/grants/guide/url_redirect.htm?id=11170) on all subawards over $25,000. See the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.htm?id=11171) 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/ (//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 (mailto:GrantsInfo@nih.gov) (preferred method of contact)
Telephone: 301-945-7573

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

Scientific/Research Contact(s)

Sanya A. Springfield, Ph.D.
National Cancer Institute (NCI)

Telephone: 240-276-6170
Email: FIRSTNIH@nih.gov (mailto:FIRSTNIH@nih.gov)

Peer Review Contact(s)

Center for Scientific Review
Email: FOA_ReviewContact@csr.nih.gov (mailto:ReviewContact@csr.nih.gov)

Financial/Grants Management Contact(s)

Crystal Wolfrey
National Cancer Institute (NCI)
Telephone: 240-276-6277
Email: wolfreyc@mail.nih.gov (mailto:wolfreyc@mail.nih.gov)

Section VIII. Other Information

Recently issued trans-NIH policy notices (//grants.nih.gov/grants/guide/url_redirect.htm?id=11163) may affect your application submission. A full list of policy notices published by NIH is provided in the NIH Guide for Grants and Contracts (//grants.nih.gov/grants/guide/url_redirect.htm?id=11164). All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11120).

Authority and Regulations

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

Weekly TOC for this Announcement (/grants/guide/WeeklyIndex.cfm?07-16-21)
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).