

Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)

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

Components of Participating Organizations

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

This Funding Opportunity Announcement (FOA) is developed as a Common Fund initiative (<https://commonfund.nih.gov>) through the Office of the NIH Director, Office of Strategic Coordination (<https://dpcpsi.nih.gov> (<https://dpcpsi.nih.gov/>)). All NIH Institutes and Centers participate in Common Fund initiatives. Grants management of the awards will be administered by the National Institute of Dental and Craniofacial Research (<http://www.nidcr.nih.gov> (<http://www.nidcr.nih.gov/>)) on behalf of the NIH.

Funding Opportunity Title

NIH Director's Early Independence Awards (DP5 Clinical Trial Optional)

Activity Code

[DP5 \(//grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=dp5&Search_x=0&Search.y=0&Search_Type=Activity\)](https://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=dp5&Search_x=0&Search.y=0&Search_Type=Activity) Early Independence Award

Announcement Type

Reissue of [RFA-RM-20-014 \(https://grants.nih.gov/grants/guide/rfa-files/RFA-RM-20-014.html\)](https://grants.nih.gov/grants/guide/rfa-files/RFA-RM-20-014.html)

Related Notices

None

Funding Opportunity Announcement (FOA) Number

RFA-RM-21-018

Companion Funding Opportunity

None

Number of Applications

Only up to two applications per institution are allowed as defined in [Section III. 3. Additional Information on Eligibility](#).

Assistance Listing Number(s)

93.310

Funding Opportunity Purpose

The [NIH Director's Early Independence Award \(https://commonfund.nih.gov/earlyindependence\)](https://commonfund.nih.gov/earlyindependence) supports exceptional junior investigators who wish to pursue independent research soon after completion of their terminal doctoral degree or post-graduate clinical training, thereby forgoing the traditional post-doctoral training period and accelerating their entry into an independent research career. For the program to support the best possible researchers and research, applications are sought which reflect the full diversity of the research workforce. Individuals from diverse backgrounds, including those from underrepresented groups and from the full spectrum of eligible institutions in all geographic locations, are strongly encouraged to apply to this Funding Opportunity Announcement. In addition, applications in all topics relevant to the broad mission of NIH are welcome, including, but not limited to, topics in the behavioral, social,

biomedical, applied, and formal sciences and topics that may involve basic, translational, or clinical research. The NIH Director's Early Independence Award is a component of the [High-Risk, High-Reward Research program \(https://commonfund.nih.gov/highrisk\)](https://commonfund.nih.gov/highrisk) of the [NIH Common Fund \(https://commonfund.nih.gov/\)](https://commonfund.nih.gov/).

Key Dates

Posted Date

April 26, 2021

Open Date (Earliest Submission Date)

August 03, 2021

Letter of Intent Due Date(s)

August 3, 2021

Application Due Dates			Review and Award Cycles		
New	Renewal / Resubmission / Revision (as allowed)	AIDS	Scientific Merit Review	Advisory Council Review	Earliest Start Date
September 03, 2021	Not Applicable	September 03, 2021	March 2022	May 2022	September 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 04, 2021

Due Dates for E.O. 12372

Not Applicable

Required Application Instructions

It is critical that applicants follow the instructions in the Research (R) Instructions in the [SF424 \(R&R\) Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=12000\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=12000), except where instructed to do otherwise (in this FOA or in a Notice from [NIH Guide for Grants and Contracts \(https://grants.nih.gov/grants/guide/\)](https://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.

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/) (<http://public.era.nih.gov/commons/>) to track your application. Check with your institutional officials regarding availability.
3. Use [Grants.gov](https://www.grants.gov/web/grants/applicants/download-application-package.html#search=true&oppNum=RFA-RM-21-018) (<https://www.grants.gov/web/grants/applicants/download-application-package.html#search=true&oppNum=RFA-RM-21-018>) Workspace to prepare and submit your application and [eRA Commons](http://public.era.nih.gov/commons/) (<http://public.era.nih.gov/commons/>) to track your application.

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Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

The [NIH Director's Early Independence Award](https://commonfund.nih.gov/earlyindependence) (<https://commonfund.nih.gov/earlyindependence>) provides an opportunity for exceptional junior scientists to accelerate their entry into an independent research career by forgoing the traditional post-doctoral training period. Though most newly graduated doctoral-level researchers would benefit from post-doctoral training, a small number of outstanding junior investigators are capable of launching directly into an independent research career. The Early Independence Award is intended for these select junior investigators who have already established a record of scientific innovation and research productivity and have demonstrated unusual scientific vision and maturity; typical post-doctoral training would unnecessarily delay their entry into independent research. The NIH Director's Early Independence Award also provides an opportunity for institutions to invigorate their research programs by bringing in fresh scientific perspectives of the awardees they host.

To be eligible, investigators, at the time of application, must have received their most recent doctoral degree or completed clinical training within the previous fifteen months or expect to do so within the following twelve months. To be consistent with the updated [NIH definition of Early Stage Investigators](https://grants.nih.gov/policy/early-investigators/index.htm) (<https://grants.nih.gov/policy/early-investigators/index.htm>), eligible clinical training includes clinical residency and clinical fellowship. For full eligibility requirements, see [Section III. Eligibility Information](#) (<file:///R:/Research%20Teams%20of%20the%20Future/High-Risk%20Research/Early%20Independence%20Prog/ENS/2020/RFA-RM-19-008%20Early%20Independence%20Award.docx>).

NIH staff will conduct a site visit to assess the PD/PI's progress and to ensure that s/he is receiving the institutional resources and support outlined in the application. By the end of the award period, Early Independence Award investigators are expected to be competitive for continued funding of their research program through other NIH funding activities and for permanent research-oriented positions.

In order to support the most innovative and impactful research, the NIH recognizes the need to foster a diverse research workforce across the nation. Applications to this award program should reflect the full diversity of potential PDs/PIs, applicant institutions, and research areas relevant to the broad mission of NIH. Talented researchers from diverse backgrounds (see [NOT-OD-20-031](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031) (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html>)), including individuals from underrepresented racial and ethnic groups, individuals with disabilities, individuals from disadvantaged backgrounds, and women, are strongly encouraged to work with their institutions to develop applications for this Funding Opportunity Announcement. As outstanding research is conducted at a broad spectrum of institutions, it benefits the national scientific enterprise for NIH to support exceptionally innovative and impactful science that represents this breadth. Therefore, this Funding Opportunity Announcement encourages applications from the full range of eligible institutions, including those serving primarily underserved groups, those that may be less research-intensive, and from all domestic

geographic locations. Applications are welcome in all research areas broadly relevant to the mission of NIH. These areas include, but are not limited to, the behavioral, medical, natural, social, applied, and formal sciences. Research may be basic, translational, or clinical. The primary requirements are that the research be highly innovative and have the potential for unusually broad impact.

The NIH Director's Early Independence Award is part of the [High-Risk, High-Reward Research program](https://commonfund.nih.gov/highrisk) (<https://commonfund.nih.gov/highrisk>) funded through the [NIH Common Fund](https://commonfund.nih.gov/) (<https://commonfund.nih.gov/>), which supports cross-cutting programs that are 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.

See [Section VIII. Other Information](#) for award authorities and regulations.

Section II. Award Information

Funding Instrument

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

Application Types Allowed

New

The [OER Glossary](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11116) (https://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) (https://grants.nih.gov/grants/guide/url_redirect.htm?id=82370)

Funds Available and Anticipated Number of Awards

The NIH Common Fund intends to commit approximately \$4 million to support approximately 10 awards in FY 2022. The number of awards is contingent upon availability of funds and receipt of a sufficient number of meritorious applications. Future year amounts will depend on annual appropriations and satisfactory progress.

Award Budget

Awards will be for up to \$250,000 in direct costs per year, plus applicable Facilities and Administrative (F&A) costs.

Award Project Period

The project period is limited to five years.

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

For-Profit Organizations

- Small Businesses
- For-Profit Organizations (Other than Small Businesses)

Local Governments

- State Governments
- County Governments
- City or Township Governments
- Special District Governments
- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized)

Federal Governments

- Eligible Agencies of the Federal Government, including the NIH Intramural Program
- U.S. Territory or Possession

Other

- Independent School Districts
- Public Housing Authorities/Indian Housing Authorities
- Native American Tribal Organizations (other than Federally recognized tribal governments)
- Faith-based or Community-based Organizations
- Regional Organizations

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 \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11118\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11118), **are** allowed.

Required Registrations

Applicant organizations

Applicant organizations must complete and maintain the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. All registrations must be completed prior to the application being submitted. Registration can take 6 weeks or more, so applicants should begin the registration process as soon as possible. The [NIH Policy on Late Submission of Grant Applications \(//grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html\)](https://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 \(DUNS\) \(http://fedgov.dnb.com/webform\)](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 \(SAM\) \(https://www.sam.gov/portal/public/SAM/\)](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 \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11176\)](https://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 \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11123\)](https://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.

Applications with multiple PDs/Pis will not be accepted. Only single PD/PI applications are allowed. Only the PD/PI may be listed as a Senior/Key Person and provide a Biographical Sketch.

U.S. citizenship is not required for PDs/Pis. For applications submitted on behalf of non-U.S. citizens with temporary U.S. visas, visa status must allow the PD/PI to conduct the proposed research at the applicant institution. The applicant institution is responsible for determining if and documenting that the PD's/PI's visa will allow the PD/PI to remain in the U.S. for the duration of the award.

Time window for eligibility: Given the focus on early research independence, the receipt date of the terminal doctoral degree or end of post-graduate clinical training of the PD/PI must be between June 1, 2020 and September 30, 2022. The degree receipt date is that which appears on the official transcript for the degree. The end of post-graduate clinical training includes residency and fellowship periods. The PD/PI must not have served as a post-doctoral fellow for more than twelve months before June 1, 2020.

At the time of award, either 1) the Early Independence investigator must have received a PhD, MD, DO, DC, DDS, DVM, OD, DPM, ScD, EngD, DrPH, DNSc, ND (Doctor of Naturopathy), PharmD, DSW, PsyD, or equivalent doctoral degree from an accredited domestic or foreign institution (it is the responsibility of the sponsoring institution to determine if a foreign doctoral degree is equivalent), or 2) an authorized official of the degree-granting or training institution must certify that all degree requirements have been met and that the receipt date of the degree (as will appear on the transcript) will be before September 30, 2022. An authorized official of the host institution must certify that the PD/PI will be able to conduct independent research at the institution at the time of the project start date.

Level of effort: Individuals must commit at least 9.6 person-months each year (i.e., 80% effort of a 12-month appointment) to the Early Independence Award project in years 1-2 of the project period. In years 3-5, awardees may reduce effort towards the Early Independence Award project but must commit at least 9.6 person-months each year (i.e., 80% effort of a 12-month appointment) to independent research in general.

Research independence at time of application: Individuals are eligible only if they, at the time of application submission, do not have research independence. Lack of research independence is defined functionally rather than by position title. Eligible individuals must have all the following characteristics:

- The PD/PI's current research agenda is set through concurrence with mentors.
- The PD/PI's research is funded primarily through support to other investigators (mentored fellowships such as NIH F31 or F32 Fellowships or NSF Graduate Research Fellowships do not preclude eligibility).
- The PD/PI does not have any space assigned directly by the institution for the conduct of his/her research.
- The PD/PI, according to institutional policy, cannot apply for an NIH R01 grant without special waiver or exemption from the institution.

Though PDs/Pis must not be functionally independent at the time of application submission, they may become functionally independent prior to time of award and still retain eligibility for the award.

Prospective PDs/Pis should contact appropriate institutional leaders to seek an appointment in an independent research position. Alternatively, institutions may actively recruit eligible junior scientists to apply for support through this program. In either case, the institution is expected to provide substantial support for the junior scientist, as detailed below. To foster independence, PDs/Pis may benefit from being hosted by an institution at which they have not previously studied or trained.

PD/Pis may apply for a research career development (K) award and DP5 at the same time, but [NIH policy \(https://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-029.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-029.html) prohibits scientific and commitment overlap. A PD/PI may not hold a DP5 and career development (K) award concurrently. If the PD/PI receives a career development (K) award, the career development (K) award must be relinquished to receive the DP5.

2. Cost Sharing

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

3. Additional Information on Eligibility

Number of Applications

Each institution, as defined by having a unique DUNS number or NIH IPF number, may submit only up to two applications to this FOA.

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](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-101.html) ([//grants.nih.gov/grants/guide/notice-files/NOT-OD-11-101.html](https://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, Grants.gov Workspace or an institutional system-to-system solution. Links to apply using ASSIST or Grants.gov Workspace are available in [Part 1](#) of this FOA. See your administrative office for instructions if you plan to use an institutional system-to-system solution.

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the Research (R) Instructions in the [SF424 \(R&R\) Application Guide](https://grants.nih.gov/grants/guide/url_redirect.htm?id=12000) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=12000](https://grants.nih.gov/grants/guide/url_redirect.htm?id=12000)) except where instructed in this funding opportunity announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

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)
- Participating institution
- Names of other key personnel
- Number and title of this funding opportunity
- The letter of intent should be sent to:

Becky Miller, Ph.D.
Office of Strategic Coordination
Office of the Director
6001 Executive Blvd, Room 8190F
Rockville, MD 20854
Telephone: 301-594-9979
Fax: 301-435-7268
Email: earlyindependence@od.nih.gov (<mailto:earlyindependence@od.nih.gov>)

Page Limitations

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

Instructions for Application Submission

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

SF424(R&R) Cover

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

Cover Letter Attachment: The cover letter must include the names and institutions of those writing letters of reference for the PD/PI and key project personnel (e.g., collaborators and contractors).

SF424(R&R) Project/Performance Site Locations

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

SF424(R&R) Other Project Information

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

Facilities & Other Resources: A major consideration of this program is the institution's commitment to providing an environment in which the investigator would thrive as an independent researcher. **Applicant institution officials must address all the following items.** Be sure to use the corresponding subheading and numbering in the response. No page limits apply; responses should be concise, yet complete.

Candidate Selection Process

1. Describe the process and criteria used to select the Early Independence investigator.

Position Details

During the award period, the Early Independence investigator must be scientifically independent and administratively independent. The appointment need not be permanent or tenure-track and may be contingent upon receipt of the Early Independence Award. Describe in detail the position to which the Early Independence investigator will be appointed and how independence will be ensured during the award.

1. What is the title of the position?
2. Is the position permanent or tenure-track?
3. Is the position contingent upon receipt of the Early Independence Award?
4. Describe the position in detail.
5. How will the PD/PI's independence be ensured during the award?
6. Describe plans for maintaining protected time for the Early Independence investigator so that s/he can commit at least 9.6 person-months each year (i.e., 80% effort of a 12-month appointment) to the Early Independence Award project in years 1-2 of the project period. In years 3-5, the investigator may reduce effort towards the Early Independence Award project but must commit at least 9.6 person-months each year (i.e., 80% effort of a 12-month appointment) towards independent research in general. Clinicians should be permitted to perform clinical duties to the extent necessary to maintain credentials.
7. Describe the institutional organizational structure within which the Early Independence PD/PI's position will be administered (school, department, etc.).
8. Explain how this administrative structure will best meet the goal of supporting the success of the Early Independence PD/PI. Include details of responsibilities for integrating the Early Independence investigator and his/her scientific project into the institutional culture and the faculty community.
9. Describe management plans for potential problematic situations.
10. Describe institutional expectations related to the retention or transfer of the PD/PI at the end of the funding period.
11. Affirm that the PD/PI will be able to begin independent research by the project start date.

Institutional Resources Commitment

1. If the candidate is not a U.S. citizen or permanent resident, the sponsoring institution must include information about the candidate's visa status and assurance that the candidate's visa provides sufficient time to complete the award at a U.S. institution.
2. Describe details of the laboratory space to be provided to the Early Independence investigator, including physical structure and space layout.
3. Describe support staff and systems available to the Early Independence investigator, including, but not limited to, human resources, supply and equipment ordering systems, and administrative assistance.
4. Describe the institutional financial commitment to the Early Independence investigator. Matching funds are not required; however, an appropriate level of institutional support is expected. Institutional commitment to the development of the PD/PI as a successful and independent research scientist will be given considerable attention during the review and selection process.
5. If the Early Independence investigator already has a commitment of funding for independent research (such as through another independent research program or institutional start-up funds), describe how the Early Independence Award will affect the other funding.

Institutional Career Development Commitment

1. Describe plans for assuring scientific independence. Particularly if the Early Independence investigator is staying at the same institution at which s/he trained, indicate how independence from degree/fellowship mentors will be established and maintained.
2. Describe plans for integrating the Early Independence investigator into institutional scientific and administrative activities at the institution. Describe the scientific collaborative activities (attendance at faculty meetings, laboratory meetings, participation in institutional scientific retreats, etc.) and career development resources (courses in laboratory management and grant writing, etc.) that will be available to ensure the Early Independence investigator is successful.
3. Describe the mentoring structure, including membership, meeting frequency, and meeting format. Though the Early Independence investigator must be scientifically independent, it is important that senior colleagues are available as resources and periodically meet with the investigator.
4. The primary goal for an Early Independence investigator is to establish an independent scientific research program. However, if an Early Independence investigator has an interest in (limited) teaching, describe what opportunities will be available.
5. Describe expectations and opportunities for the Early Independence investigator to establish a record of independent funding by submitting and accepting grants from sources other than the Early Independence Award.

SF424(R&R) Senior/Key Person Profile

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

Only the PD/PI may be listed as a Senior/Key person and provide a Biographical Sketch.

Modular Budget

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

R&R Subaward Budget

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

PHS 398 Cover Page Supplement

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

PHS 398 Research Plan

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

Specific Aims:

The specific aims page must contain three sections with the following headings: "Research Objectives," "Institutional Support," and "Early Independence Rationale". These three sections should contain the information described below.

Research Objectives: State your research topic and overall approach. Why is this area of research significant? If you have an overarching hypothesis, what is it? What impact will your research have if successful? What are the major conceptual or technical innovations you are introducing into this research area?

Institutional Support: How will the institutional support, including the assurance of research independence, facilitate the accomplishment of your research objectives?

Early Independence Rationale: How will your scientific and technical background, research accomplishments, leadership/mentorship attributes, and scientific vision be leveraged to accomplish the research objectives?

Research Strategy:

Organize the Research Strategy using the instructions provided below. Start each section of the document with the appropriate section heading.

1. Rationale for omitting or abbreviating the typical post-doctoral phase: Why would omitting or abbreviating the typical post-doctoral fellowship benefit your long-term scientific career? What is driving your desire to pursue an independent research career at an earlier than usual stage?
2. Evidence of transition to an independent position: Provide evidence using all the characteristics described in Section III.1. Eligible Individuals (Program Director/Principal Investigator) that at the time of application submission, you do not have research independence. Also, describe any arrangements you may have made to assume an independent research position that would begin prior to award.
3. Personal/career development plan: What particular strengths and weaknesses do you have for launching a productive independent research career? How would you use this award period to build on your strengths and address your weaknesses? How would receipt of this award accelerate your establishment of an independent research career (especially if you already have made an agreement for a functionally independent position)? What will your planned career path be if an Early Independence Award is not provided?

4. Evidence of training ability and leadership: What activities have prepared you to lead a laboratory, train laboratory staff, and perhaps mentor students and post-doctoral fellows? (Note this information may reference but should not duplicate information submitted on the Biosketch.)
5. Host institution interactions: What arrangements have you made with your host institution to provide you with the support and feedback necessary to establish your research program while maintaining your intellectual independence? How will you try to integrate yourself as an active member in your institution's scientific community?
6. Research challenge: What is the scientific challenge that you wish to address in your research? What is the premise of the project, including strengths and weaknesses of prevailing theories? Why is this challenge significant to the biomedical/behavioral research community? What is the expected impact of your research on this challenge? Why did you choose this particular challenge to begin your independent research career?
7. Approach: What is your experimental approach in addressing your research challenge? The description of the approach should convey that you have thought deeply about your project, identified the major potential pitfalls, and considered alternative approaches. Address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects. Preliminary data are not required but will be evaluated in the review process if provided. You may wish to indicate prominently that substantial preliminary data are not being provided per the guidance in the FOA. Collaborative elements of the research may also be described here.
8. Innovation: What are the particularly innovative aspects of your proposed research?
9. Relationship to previous work: How is the proposed research related to your research as a student/trainee? How does it differ? How will this be accomplished independently from your previous mentors?
10. Timeline: What is the timeline for accomplishing intermediate steps in your award period? This should include steps in establishing a functioning laboratory, meeting career development objectives, as well as achieving your scientific objectives. State that you will commit at least 9.6 person-months each year (i.e., 80% effort of a 12-month appointment) towards your Early Independence Award project in years 1-2. In years 3-5, you may reduce effort towards the Early Independence Award project but must commit at least 9.6 person-months each year (i.e., 80% effort of a 12-month appointment) to independent research in general.

Letters of Support: Collaborators and consultants should provide letters of support that concisely describe their commitment to the research project and the role they will play in conducting the research.

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

Appendix:

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

PHS Human Subjects and Clinical Trials Information

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

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

Study Record: PHS Human Subjects and Clinical Trials Information

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

Delayed Onset Study

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

PHS Assignment Request Form

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

with the modification that since all applications are received as "Office of the Director" applications and are reviewed by a single Special Emphasis Panel, applicants should not request assignment to a particular Institute/Center or review panel. Names and affiliations of significant collaborators should be listed as individuals who should not review the application to help exclude conflicts during reviewer assignment.

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

Organizations must submit applications to [Grants.gov \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11128\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11128) (the online portal to find and apply for grants across all Federal agencies). Applicants must then complete the submission process by tracking the status of the application in the [eRA Commons \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11123\)](https://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 \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11142\)](https://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 \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11120\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11120).

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

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 \(https://grants.nih.gov/grants/how-to-apply-application-guide.html\)](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 \(https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/dealing-with-system-issues.htm\)](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) must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile Component of the SF424(R&R) Application Package. Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to NIH. See [Section III](#) of this FOA for information on registration requirements.

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

See [more tips \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11146\)](https://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 and responsiveness by [components of participating organizations](#), NIH. Applications that are incomplete, non-compliant and/or nonresponsive will not be reviewed.

Applications Involving the NIH Intramural Research Program

Requests by NIH intramural scientists will be limited to the incremental costs required for participation. As such, these requests will not include any salary and related fringe benefits for career, career conditional or other Federal employees (civilian or uniformed service)

with permanent appointments under existing position ceilings or any costs related to administrative or facilities support (equivalent to Facilities and Administrative or F&A costs). Allowable costs may include salary for staff to be specifically hired under a temporary appointment for the project, consultant costs, equipment, supplies, travel, and other items typically listed under Other Expenses. Applicants should indicate the number of person-months devoted to the project, even if no funds are requested for salary and fringe benefits.

If selected, funding will be provided by the NIH Common Fund through the NIH Intramural Program. NIH intramural scientists will participate in this program as PD/PIs in accordance with the Terms and Conditions provided in this FOA. Intellectual property will be managed in accord with established policy of the NIH in compliance with Executive Order 10096, as amended, 45 CFR Part 7; patent rights for inventions developed in NIH facilities are NIH property unless NIH waives its rights.

Should an extramural application include collaboration with an intramural scientist, no funds for the support of the intramural scientist may be requested in the application. The intramural scientist may submit a separate request for intramural funding as described above in the NIH Intramural Source Book.

Letters of Reference

Letters of reference are an important element of the Early Independence Award application. Applicants must arrange to have at least three and no more than five letters of reference submitted on their behalf. Applications that are missing letters of reference will be considered incomplete and will not be reviewed. Late letters will not be accepted. Applicants are responsible for monitoring the submission of letters to ensure that three letters have been submitted prior to the submission deadline. Applicants are encouraged to check the status of their letters in their Commons accounts.

Letters may be submitted beginning August 3, 2021, and must be submitted no later than 5:00 p.m. (local time) September 3, 2021.

Referees will need the following information to submit a letter:

- Funding Opportunity Number (FOA) for this announcement: RM-21-018
- The applicant's Commons User Name (Note: Referees do not need to be registered in the Commons and do not need their own Commons User Name – only the Commons User Name of the applicant is required)
- The applicant's first and last name (note – the name must match exactly the applicant's name in the Commons)
- The URL to the letter submission page (<https://public.era.nih.gov/commons/public/reference/submitReferenceLetter.do?mode=new> (<https://public.era.nih.gov/commons/public/reference/submitReferenceLetter.do?mode=new>))

Letters of reference are confidential; applicants will not have access to the letters. Confirmed receipt of letters of reference will be sent via email to both the applicant and the referee. The confirmation sent to the applicant will include the referee's name and the date and time the letter was submitted. The confirmation sent to the referee will include the referee and applicant's names, a confirmation number, and the date and time the letter was submitted.

Note: Since email can be unreliable, it is the applicant's responsibility to check the status of his/her letters of reference periodically in the Commons.

Applicants are strongly encouraged to send the following to their referees or to send their referees the following link to this information: <https://commonfund.nih.gov/earlyindependenceawards/reference-letters> (<https://commonfund.nih.gov/earlyindependenceawards/reference-letters>).

Instructions to Referees:

Letters must be submitted electronically using the letter submission URL above – paper copies or emails will not be accepted.

The applicant's name should be placed at the top of the letter. Although signatures are not required, the letter must include a signature block with the referee's full name, title, institution, and contact information.

In two pages or less, describe the applicant's qualities that support the applicant's claim to possess the scientific, leadership, mentorship, and management skills necessary to conduct successful, completely independent research. When possible, give specific examples that illustrate these qualities.

Note: The letter submission page can be accessed without signing into the Commons, and referees do not need to be registered in the Commons. Referees must provide the applicant's Commons User Name (User ID) and the other information below:

Referee Information (the individual providing the letter of reference):

- Referee's First and Last Name (Required)
- Referee's Middle Initial (MI) (Not Required)
- Referee's Email Address (Required)
- Referee's Institution/Affiliation (Required)
- Referee's Department (Required)

Applicant Information (applicants must send this information to their referees):

- Applicant's Commons User Name (User ID), (Required) (Important – this must be the applicant's, not the referee's, Commons User Name (User ID). The letter will not be linked to the appropriate application if the Applicant's User Name is not entered here.)
- Applicant's Last Name (Required). (Note: must match exactly the applicant's name in Commons)
- Funding Opportunity Number (FOA) of this announcement: RM-21-018 (Required)
- Confirmation Number (Required only when resubmitting a letter, that is, when submitting a revised or changed/corrected letter for the current FOA.)

Email confirmations will be sent to both the applicant and the referee following submission of the letter. The email confirmation will include a Confirmation Number that will be required only when submitting a revised or changed/corrected letter. Please print the confirmation email for your records.

Please see the detailed instructions [submitting letters of reference \(https://commonfund.nih.gov/earlyindependenceawards/reference-letters\)](https://commonfund.nih.gov/earlyindependenceawards/reference-letters) and [Frequently Asked Questions \(https://commonfund.nih.gov/earlyindependence/faq\)](https://commonfund.nih.gov/earlyindependence/faq) on the Early Independence Award website. Send question to [EarlyIndependence@od.nih.gov \(mailto:EarlyIndependence@od.nih.gov\)](mailto:EarlyIndependence@od.nih.gov).

Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in [the policy \(//grants.nih.gov/grants/guide/url_redirect.htm?id=82299\)](https://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. #160;Applications submitted to the NIH in support of the [NIH mission \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11149\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11149) are evaluated for scientific and technical merit through the NIH peer review system.

For this particular announcement, note the following:

The NIH Director's Early Independence Award is designed to accelerate the entry of exceptional junior investigators into positions of independent research by providing support to individuals whose terminal doctoral degree receipt date or end of post-graduate clinical training is between June 1, 2020 and September 30, 2022, thereby omitting the traditional post-doctoral training period. Accordingly, though all review criteria described below will be used, the emphases will be on the qualities of the investigator and on the environment provided by the host institution. Substantial preliminary data are not expected; rather, the approach should be made compelling primarily by the logic of the arguments presented.

Informed by the comments provided by Mail Reviewers, a subset of applications will be selected by the Review Panel (excluding Mail Reviewers) for discussion and numerical scoring. The same review criteria will be used by the Review Panel as was used by the Mail Reviewers.

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

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

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?

Is the PD's/PI's self-appraisal/rationale for early independence convincing? Is the investigator well suited to the project? Has the investigator demonstrated appropriate experience, training, and skills to conduct highly innovative research? Has the investigator demonstrated the leadership, mentorship, and management abilities necessary to successfully conduct completely independent research? Do the letters of reference indicate that the investigator is ready to embark upon an independent research career?

Is the Early Independence investigator at a juncture in his/her career at which the Early Independence Award would substantially accelerate establishment of his/her independent research career? Would the Early Independence investigator's scientific productivity and long-term career benefit from this acceleration?

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?

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?

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?

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?

Environment

Will the Early Independence investigator be given appropriate access to facilities and resources (shared or otherwise)? Are the plans for institutional support, equipment, staffing, and other physical resources available to the Early Independence investigator adequate? Will the scientific environment and collaborative arrangements contribute to the probability of success of the Early Independence investigator? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements? Is there evidence that the Early Independence investigator will have the necessary institutional commitment to conduct full-time, independent research for the duration of this award at the level of effort required? Will the research activities and resources provided to the Early Independence investigator assist in the development and strengthening of his/her development and career? Will the situation of the Early Independence investigator provide sufficient separation from previous mentors to promote true intellectual independence? Are the plans for appointing and integrating the Early Independence investigator into the institutional scientific culture adequate and appropriate? Are the strategies for addressing potential problems adequate? Are plans and criteria to monitor the immediate and long-term success of the Early Independence investigator adequate?

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 international site(s) is/are proposed, does the application adequately address the complexity of executing the clinical trial?

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?

Additional Review Criteria

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

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., CTSA, 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 \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11175\)](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 \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11174\)](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 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 \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11150\)](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

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

Applications from Foreign Organizations

Not Applicable.

Select Agent Research

Reviewers will assess the information provided in this section of the application, including 1) the Select Agent(s) to be used in the proposed research, 2) the registration status of all entities where Select Agent(s) will be used, 3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

Resource Sharing Plans

Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: (1) [Data Sharing Plan \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11151\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11151); (2) [Sharing Model Organisms \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11152\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11152); and (3) [Genomic Data Sharing Plan \(GDS\) \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11153\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11153).

Authentication of Key Biological and/or Chemical Resources:

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

Budget and Period of Support

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s) convened by the Center for Scientific Review, in accordance with [NIH peer review policy and procedures](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11154) (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11154), using the stated [review criteria](file:///C:/Users/mckenziene/AppData/Local/Microsoft/Windows/INetCache/Content.Outlook/13V4QPZR/Research%20Draft.doc#_1_.Criteria) (file:///C:/Users/mckenziene/AppData/Local/Microsoft/Windows/INetCache/Content.Outlook/13V4QPZR/Research%20Draft.doc#_1_.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](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-064.html) (<http://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 remain in the Office of the Director with the National Institute of Dental and Craniofacial Research performing grants management. 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 Council of Councils. 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, including
 - The potential for the PD/PI to lead a vigorous independent research program.
 - Unusually cross-cutting or underrepresented science.
 - Scientific balance in the portfolio of Early Independence Award-supported research.
 - Potential to invigorate exceptionally innovative and impactful science broadly across the nation.

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](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11123) (http://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](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11156) (http://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](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11157) (http://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 recipient's business official.

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

Any application awarded in response to this FOA will be subject to terms and conditions found on the [Award Conditions and Information for NIH Grants](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11158) (http://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: Recipient 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* (https://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* (https://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, Recipients, and Activities* (https://grants.nih.gov/grants/guide/url_redirect.htm?id=11159). More information is provided at *Award Conditions and Information for NIH Grants* (https://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

Not Applicable

3. Reporting

When multiple years are involved, awardees will be required to submit the [Research Performance Progress Report \(RPPR\)](https://grants.nih.gov/grants/rppr/index.htm) (<https://grants.nih.gov/grants/rppr/index.htm>) annually and financial statements as required in the [NIH Grants Policy Statement](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=11161). (https://grants.nih.gov/grants/guide/uri_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](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=11161) (https://grants.nih.gov/grants/guide/uri_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 (https://grants.nih.gov/grants/guide/uri_redirect.htm?id=11170) on all subawards over \$25,000. See the [NIH Grants Policy Statement](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=11171) (https://grants.nih.gov/grants/guide/uri_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/> (<http://grants.nih.gov/support/>) (preferred method of contact)

Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

General Grants Information (Questions regarding application instructions, application processes, and NIH grant resources)

Email: GrantsInfo@nih.gov (<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)

Becky Miller, Ph.D.

Office of the Director (OD)

Telephone: 301-594-9979

Email: earlyindependence@od.nih.gov (<mailto:earlyindependence@od.nih.gov>)

Peer Review Contact(s)

Suzanne Ryan, Ph.D.

Center for Scientific Review (CSR)

Telephone: 301-435-1712

Email: ryansj@csr.nih.gov (<mailto:ryansj@csr.nih.gov>)

Financial/Grants Management Contact(s)

Dede Rutberg

National Institute of Dental and Craniofacial Research (NIDCR)

Telephone: 301-594-4798

Email: rutbergd@mail.nih.gov (<mailto:rutbergd@mail.nih.gov>)

Section VIII. Other Information

Recently issued trans-NIH [policy notices](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11163) (http://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](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11164) (http://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](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11120) (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11120).

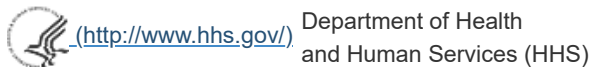
Authority and Regulations

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](http://grants/guide/WeeklyIndex.cfm?04-30-21) (<http://grants/guide/WeeklyIndex.cfm?04-30-21>)

[NIH Funding Opportunities and Notices](http://grants/guide/index.html) (<http://grants/guide/index.html>)

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