

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
National Institute of Arthritis and Musculoskeletal and Skin Diseases ([NIAMS \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=82475\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=82475))

All applications to this funding opportunity announcement should fall within the mission of the Institutes/Centers. The following NIH Offices may co-fund applications assigned to those Institutes/Centers.

Office of Research on Women's Health ([ORWH \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=82500\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=82500))

Note: Not all NIH Institutes, Centers, and Offices (ICOs) participate in Announcements. Applicants should carefully note which ICOs participate in this announcement and view their respective areas of research interest at the [ICO-Specific Scientific Interests website \(https://grants.nih.gov/funding/find-a-fit-for-your-research/nih-institutes-centers-offices\)](https://grants.nih.gov/funding/find-a-fit-for-your-research/nih-institutes-centers-offices). ICOs that do not participate in this announcement will not consider applications for funding.

Funding Opportunity Title
NIAMS P30 Centers Program (P30 - Clinical Trial Not Allowed)

Activity Code
[P30 \(http://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=p30&Search.x=0&Search.y=0&Search_Type=Activity\)](http://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=p30&Search.x=0&Search.y=0&Search_Type=Activity) Center Core Grants

Announcement Type
Reissue of RFA-AR-23-002
Reissue of RFA-AR-24-001
Reissue of RFA-AR-24-002
Reissue of RFA-AR-24-003

Related Notices

- Check for any recent [Notices of NIH Policy Changes \(https://grants.nih.gov/grants/guide/url_redirect.php?id=11163\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=11163) that may impact application requirements.
- **January 23, 2026** - NIH Pause on New Submissions to the NIH Human Embryonic Stem Cell Registry and Request for Information on Reducing Reliance on Human Embryonic Stem Cells in NIH-Supported Research. See Notice, [NOT-OD-26-031 \(https://grants.nih.gov/grants/guide/notice-files/NOT-OD-26-031.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-26-031.html).

Funding Opportunity Number (FON)
RFA-AR-28-001

Companion Notice of Funding Opportunity
None

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

Assistance Listing Number(s)
93.846, 93.313

Notice of Funding Opportunity Purpose

The overall goal of this program is to accelerate scientific discovery, improve research efficiency, and enhance the translation of research findings into improved health outcomes. Centers funded under this program will also foster multidisciplinary collaboration, support workforce development across career stages, and promote training in emerging areas such as data science, artificial intelligence, and implementation research. The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) requests applications for the NIAMS P30 Centers Program to support integrated research Centers within its mission areas of skin biology and diseases; bone, muscle, and orthopaedic research; and rheumatic diseases.

The NIAMS P30 Centers Program supports Centers that provide coordinated research infrastructure, shared resources, and methodological expertise to advance basic, translational, and clinical research.

These Centers are expected to integrate state-of-the-art research resources with capabilities that support clinical and translational research, including the development, testing, and dissemination of novel analytical methods, study designs, outcome measures, and data-driven approaches.

Funding Opportunity Goal(s)

The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) mission is to support research into the causes, treatment, and prevention of arthritis and musculoskeletal and skin diseases; training of basic and clinical scientists to carry out this research; and dissemination of information on research progress in these diseases. The Extramural Program promotes and supports basic, translational, and clinical studies of Systemic Rheumatic and Autoimmune Diseases, Skin Biology and Diseases, Bone Biology and

Key Dates

Posted Date					
October 09, 2026					
Open Date (Earliest Submission Date)					
January 01, 2027					
Application Due Dates			Review and Award Cycles		
New	Renewal / Resubmission / Revision (as allowed)	AIDS - New/Renewal/Resubmission/Revision, as allowed	Scientific Merit Review	Advisory Council Review	Earliest Start Date
February 01, 2027	March 01, 2027	Not Applicable	July 2027	October 2027	December 2027
February 01, 2028	March 01, 2028	Not Applicable	July 2028	October 2028	December 2028
February 01, 2029	March 01, 2029	Not Applicable	July 2029	October 2029	December 2029

All applications are due by 5:00 PM local time of applicant organization.

Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.

No late applications will be accepted for this Notice of Funding Opportunity (NOFO).

Expiration Date					
March 02, 2029					
Due Dates for E.O. 12372					
Not Applicable					

Required Application Instructions

It is critical that applicants follow the Multi-Project (M) Instructions in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400), except where instructed to do otherwise (in this NOFO or in a Notice from 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)). Conformance to all requirements (both in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) and the NOFO) is required and strictly enforced. Applicants must read and follow all application instructions in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400), 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 \(https://public.era.nih.gov/assist/public/login.era\)](https://public.era.nih.gov/assist/public/login.era) 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 \(https://public.era.nih.gov/commons/\)](https://public.era.nih.gov/commons/) to track your application. Check with your institutional officials regarding availability.

Table of Contents

[Part 1. Overview Information](#)

[Key Dates](#)

[Part 2. Full Text of Announcement](#)

[Section I. Notice of Funding Opportunity Description](#)[Section II. Award Information](#)[Section III. Eligibility Information](#)[Section IV. Application and Submission Information](#)[Section V. Application Review Information](#)[Section VI. Award Administration Information](#)[Section VII. Agency Contacts](#)[Section VIII. Other Information](#)

Part 2. Full Text of Announcement

Section I. Notice of Funding Opportunity Description

Background

NIAMS utilizes the P30 Center Core Grant mechanism to support integrated Centers that combine shared research infrastructure, scientific expertise, and collaborative scientific leadership to advance research within the NIAMS mission.

Centers supported under this NOFO are expected to provide shared resources, foster team science, and support basic, translational, and/or clinical research as appropriate to the Center's focus. The Center's components should work together as an integrated whole to accelerate scientific discovery, improve research efficiency, and enhance translation to improved health outcomes.

Centers supported under this NOFO must:

- Provide shared research infrastructure and resources
- Include expertise appropriate to the scientific and research needs of the Center's research community
- Foster team science and multidisciplinary collaboration
- Enhance career development and training
- Promote data-driven and methodologically rigorous research

Center Component	Requirement
Administrative Core	Required
• Advisory Committee	Required (within Administrative Core)
• Career Enhancement Program	Required (within Administrative Core)
• Pilot and Feasibility (P&F) Program	Optional (within Administrative Core)
• Sustainability Plan	Required (within Administrative Core)
Resource Core(s)	Required (minimum of one)

Resource Cores may include a wide range of shared services and expertise, including but not limited to technological, analytical, methodological, computational, clinical, or translational support, as appropriate to the needs of the research community.

Potential applicant(s) are strongly encouraged to contact the Scientific/Research Contact listed in Section VII. Agency Contacts early in the application planning process to discuss the NIAMS mission relevance and NOFO responsiveness.

Applications Not Responsive to this NOFO

The following types of applications are not responsive to this NOFO and will not be reviewed:

- Centers that do not include shared research infrastructure and do not demonstrate how proposed resources address the needs of the research community
- Centers that do not describe how the proposed components function as an integrated Center
- Centers lacking a defined research community or clear plan for use of shared resources

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

Section II. Award Information

Funding Instrument

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

Application Types Allowed

New
Renewal

The [OER Glossary](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11116) (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11116) and the [How to Apply - Application Guide](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) (https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) provides details on these application types. Only those application types listed here are allowed for this NOFO.

Clinical Trial?

Not Allowed: Only accepting applications that do not propose clinical trials.

[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

NIAMS intends to commit up to \$17 million direct costs to fund up to 30 awards over the duration of this NOFO. Awards pursuant to this funding opportunity are contingent upon the availability of funds and the submission of a sufficient number of meritorious applications. Future year amounts will depend on annual appropriations.

NIAMS intends to fund a minimum of one new center that has not yet received NIH Centers funding, based on the scientific and technical merit of the proposed Resource Cores as determined by peer review, availability of funds, and relevance of the proposed application to scientific priorities.

Award Budget

Application budgets are limited to \$500,000 direct costs per year.

Award Project Period

The scope of the proposed project should determine the project period. The maximum project period is 5 years.

NIH grants policies as 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) will apply to the applications submitted and awards made from this NOFO.

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

Higher Education Institutions - Includes all types

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

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
- 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 Organizations/International Collaborations

Non-domestic (non-U.S.) Entities (Foreign Organization) **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 \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11118\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11118), **are** allowed.

NIH will no longer issue awards (i.e., new, renewal, or non-competing continuation) to domestic or foreign entities that involve foreign subawards/subcontracts. All NIH-funded research involving foreign subawards/subcontracts must be submitted in response to a NOFO that is specifically designated for funded international collaborations. See [NIH Grants Policy Statement 16.8 Collaborative International Research Awards \(https://grants.nih.gov/grants/policy/nihgps/HTML5/section_16/16.8_collab_int_res_awards.htm\)](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_16/16.8_collab_int_res_awards.htm).

Applications involving foreign subawards/subcontracts submitted in response to this NOFO will be deemed noncompliant and will not be considered for funding. This policy applies to all monetary international collaborations resulting in foreign subawards/subcontracts, however, it does not preclude unfunded international collaborations or [foreign components \(https://grants.nih.gov/grants/policy/nihgps/HTML5/section_1/1.2_definition_of_terms.htm\)](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_1/1.2_definition_of_terms.htm), funding for foreign consultants, or procurement of unique equipment or supplies from foreign vendors.

Required Registrations

Applicant organizations

Applicant organizations must complete and maintain the following registrations as described in the [How to Apply- Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) 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. Failure to complete registrations in advance of a due date is not a valid reason for a late submission, please reference [NIH Grants Policy Statement Section 2.3.9.2 Electronically Submitted Applications \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=82423\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=82423) for additional information.

- [System for Award Management \(SAM\) \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82390\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82390) – 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. Foreign organizations must obtain a [NATO Commercial and Government Entity \(NCAGE\) Code \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11176\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11176) (in lieu of a CAGE code) in order to register in SAM.
 - Unique Entity Identifier (UEI)– A UEI is issued as part of the SAM.gov registration process. The same UEI must be used for all registrations, as well as on the grant application.
- [eRA Commons \(https://era.nih.gov/\)](https://era.nih.gov/) - Once the unique organization identifier is established, organizations can register with eRA Commons in tandem with completing their Grants.gov registration; 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 \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=82300\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=82300) – Applicants must have an active 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.

All PD(s)/PI(s) must be registered with [ORCID \(https://orcid.org/\)](https://orcid.org/). The personal profile associated with the PD(s)/PI(s) eRA Commons account must be linked to a valid ORCID ID. For more information on linking an ORCID ID to an eRA Commons personal profile see the ORCID topic in our eRA Commons online help.

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.

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 [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400).

2. Cost Sharing

This NOFO does not require cost sharing as defined in the [NIH Grants Policy Statement \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11126\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11126) [Section 1.2- Definitions of Terms. \(https://grants.nih.gov/grants/policy/nihgps/HTML5/section_1/1.2_definition_of_terms.htm\)](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_1/1.2_definition_of_terms.htm)

3. Additional Information on Eligibility

Number of Applications

Applicant organizations may submit more than one application, provided that each application is scientifically distinct.

The NIH will not accept duplicate or highly overlapping applications under review at the same time per [NIH Grants Policy Statement Section 2.3.7.4 Submission of Resubmission Application \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=82415\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82415). 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 [NIH Grants Policy Statement 2.3.9.4 Similar, Essentially Identical, or Identical Applications \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=82423\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82423)).

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 NOFO. See the administrative office for instructions if planning 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 [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400), except where instructed in this notice of funding opportunity to do otherwise (in this NOFO, in a [policy notice \(https://grants.nih.gov/grants/guide/url_redirect.php?id=11163\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=11163), or other notice from [NIH Guide for Grants and Contracts \(https://grants.nih.gov/grants/guide/url_redirect.php?id=11164\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=11164)) and where instructions in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) are directly related to the Grants.gov downloadable forms currently used with most NIH opportunities. Conformance to the requirements in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

Page Limitations

All page limitations described in the [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) and the [Table of Page Limits \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=61134\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=61134) must be followed.

Component	Component Type for Submission	Page Limit	Required/Optional	Minimum	Maximum
Overall	Overall	12	Required	1	1
Admin Core	Admin Core	12	Required	1	1
Resource Core	Core	12	Required	1	NA

Instructions for the Submission of Multi-Component Applications

The following section supplements the instructions found in [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) and should be used for preparing a multi-component application.

Overall Component

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

All instructions in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) must be followed, with the following additional instructions, as noted.

SF424(R&R) Cover (Overall)

Complete entire form.

PHS 398 Cover Page Supplement (Overall)

Research & Related Other Project Information (Overall)

Follow standard instructions.

Facilities and Other Resources: For each institution that is hosting a Resource Core(s), briefly describe the features of the institutional environment that are relevant to the effective implementation of the proposed Center. List institutional resources available to the Center and elaborate on how these resources will contribute to the success of the Center. As appropriate, describe available resources, such as clinical and laboratory facilities, participating and affiliated units, patient populations, geographic distribution of space and personnel, and consultative resources. Include a list of who occupies specific space, the square feet and equipment in that space, and a designation of the Center functions associated with the

spaces. Applicants may include Campus maps and floor plans to illustrate the physical space available for the proposed Resource Cores and Administrative Core. Describe institutional commitments for space or other resources for the proposed Center.

Required Attachment: Resource Utilization and Impact Summary (2 pages maximum):

Applicants must include this attachment as part of their application. This summary should provide evidence that summarizes the impact, high demand for, and productivity of the resource for the expected project period.

The summary should include data with projections of how the resource achieves or will achieve economies of scale. Existing resources should document their support of a substantial number of users. For new resources, applicants should provide well-justified projections of a substantial user base for the resource.

Additional evidence that should be provided may include: (a) the number of publications enabled by the resource through collaboration or service activities, (b) service hours provided, (c) number of users, (d) summaries of instrument use time logs, (e) requests for access, and (f) white papers and editorials that demonstrate community interest.

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 NOFO) 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.

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)

Introduction to Application: For Resubmission and Revision applications, an Introduction to Application is required in the Overall component.

Specific Aims: Describe the broad long-term objectives and specific aims of the proposed Center. Include the objectives for each of the Cores proposed, as well as the objectives of the Administrative Core.

Research Strategy:

The Research Strategy section of the Overall Component describes the overall significance and innovation of the Center. This section also highlights how the Center and its unique resources will impact the research community and the field(s) covered by the Center. A clear description of the Center's major research objectives, the focus (or theme) of research addressed, and details about the placement/contribution of each core in the overall scheme of the center must be included.

A description of how the center as a whole will benefit from any unique cohorts and samples, collaborations, or resources should be included, as well as a summary of any special features in the environment and/or resources that make the overall center strong or unique. When applicable, the research community or those who will use Center resources must be defined. For the purposes of this NOFO, members of a research community may work in the same field or related fields and interact through meetings, collaborations, and/or shared activities.

If the Center involves clinical research, concisely describe overall plans for ensuring the feasibility of recruiting sufficient participants from the proposed population(s) to achieve the stated objectives.

The Research Strategy section of the Overall Component should be organized in the following fashion:

Orientation to the Overall Center Component

- Describe the goals of the Center Component. Explain the scientific, organizational, and management structure.
- Include the leadership structure of the Center and the individual proposed Core(s).
- Define the theme or focus, the research field(s), and the research community.
- Summarize any needs assessments conducted that led to the selection of resources shared through the Center.
- Highlight unique aspects of the resources and services offered by the Core(s).

Research Community

- Provide an overview of current research on the topics of focus conducted by the research community.
- Define the research community, which may be local, regional, or national, and may include foreign collaborators.
- Ensure the research community is of sufficient size to justify the Center's impact.
- Summarize the strengths of the investigators in the research community and describe how the Core(s) can enhance their projects.

Significance

- Expand on the Center's goals and its impact on the research community and the chosen field(s) of research.
- Explain the importance of the shared resources within the Center and the expected effect of providing access to them.
- Describe how the Center will accelerate progress, improve efficiency, and enhance productivity.
- Explain how the Center will expand and enhance the capabilities of investigators engaged in related research.
- Provide examples of research projects that would be enabled or significantly enhanced by access to unique, highly specialized resources.

Innovation

- Describe how the Center will evolve with the science conducted by Center Investigators and challenge current research paradigms.
- Outline plans to develop or adapt new or unique state-of-the-art core services through technology development or adaptation.
- Explain how the synergy between the Center and the research community will lead to novel services and resources.
- Highlight the potential for interdisciplinary collaborations.
- For non-innovative Core(s), explain their essential role in advancing the field.

Approach

- Summarize the services and resources provided by the Center and how they are managed and coordinated.
- Describe how the Center will address the scientific, methodological and/or translational research needs of the research community.
- Indicate if any proposed Cores will utilize or expand existing cores at participating institutions.
- Explain how the Center will make existing resources broadly available, leverage existing resources, and fill service gaps.
- Outline enrichment activities to expand the research community and promote innovative research.
- Demonstrate added value provided by the Center beyond standard fee-for-service access.
- Identify and describe interactions with the Clinical Translational Science Award (CTSA) if relevant.

Progress Report (if application is a Renewal Application)

Provide the following information in composite summary/progress report:

- Describe the impact of the Center on the institution(s) and Center's research community.
- Summarize the aims and accomplishments of each core supported by the Center during the previous grant period.
- Detail the results of each Pilot and Feasibility (P&F) project supported by the Center over the previous grant period (if applicable).
- List publications that acknowledged the Center's resources and cores, ensuring compliance with the [Public Access Policy \(https://grants.nih.gov/policy-and-compliance/policy-topics/public-access/nih-public-access-policy-overview#public-access-policy-details#public-access-policy-details?redirected=true\)](https://grants.nih.gov/policy-and-compliance/policy-topics/public-access/nih-public-access-policy-overview#public-access-policy-details#public-access-policy-details?redirected=true).
- Include a list of changes, if any, in the professional staffing since the last competitive review; a list of research Projects and Core(s), in tabular form, that have been discontinued, modified, or completed since the last competitive review, identified by number and title, with a brief explanation of the actions taken
- Include a list of research Cores in the current Center, identifying each as a "new" or "continuing" component.
- If it is helpful to use a table to provide details of core facility usage, be sure to include a note about the table in the Progress Report section of the Overall and relevant Core elements.

Letters of Support: Include letters of support from appropriate institutional officials of each performance site. These letters should confirm commitments of space and other resources required by the Center. Include a letter of agreement from existing resources (such as the CTSA PD(s)/PI(s)) if collaborative linkages are being developed. Letters from research community investigators should document their research interests, interactions with other Center investigators, the need for and impact of shared resources, and likely use of Center resources. Provide a table listing individuals providing letters of support and their institutions.

Resource Sharing Plan:

Individuals are required to comply with the instructions for the Resource Sharing Plans as provided in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400).

Other Plan(s):

All instructions in the [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) must be followed, with the following additional instructions:

- A Data Management and Sharing Plan (DMS Plan) is required for any NIH-funded or conducted research that will generate scientific data. Applicants must submit the DMS Plan at the time of application using the [NIH DMS Plan Format Page \(https://grants.nih.gov/grants-process/write-application/forms-directory/data-management-and-sharing-plan-format-page\)](https://grants.nih.gov/grants-process/write-application/forms-directory/data-management-and-sharing-plan-format-page). The DMS Plan must address the elements in the structured format. Where the DMS Plan Format Page requires a "Yes or No" response, no additional narrative is allowed. The Data Management and Sharing (DMS) Plan must be provided in the Overall component.

Appendix:

Only limited items are allowed in the Appendix. Follow all instructions for the Appendix as described in [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); any instructions provided here are in addition to the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) instructions.

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 [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400), 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 [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) must be followed.

Delayed Onset Study

Note: [Delayed onset \(https://grants.nih.gov/grants/glossary.htm#DelayedOnsetStudy\)](https://grants.nih.gov/grants/glossary.htm#DelayedOnsetStudy) does NOT apply to a study that can be described but will not start immediately (i.e., delayed start). All instructions in the [How to Apply- Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) must be followed.

PHS Assignment Request Form (Overall)

All instructions in the [How to Apply- Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) must be followed.

Administrative Core

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

All instructions in the [How to Apply- Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) 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 (optional)
- Descriptive Title of Applicant's Project
- Proposed Project Start/Ending Dates

PHS 398 Cover Page Supplement (Administrative Core)

Follow standard instructions. 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.
- Personnel of the Administrative Core should include the PD/PI or Center Director who is responsible for the organization and operation of the Center, and an Associate Director, who will be involved in the administrative and scientific aspects of the Center and will serve as Acting Center Director in the absence of the PD/PI or Center Director.
- List administrators and staff for the Administrative Core (not individual Resource Cores). If Resource Core Directors also help administer the overall Center, list them as well.
- Detail the focus of research conducted by Center Investigators and how their research interests align with the Center's focus or theme.
- Reference the Biographical Sketches and Letters of Support for detailed documentation of investigators and their contributions.
- Highlight past successful collaborations and their outcomes (e.g., publications, grants, scientific advances).

Budget (Administrative Core)

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

The budget of the Administrative Core may include appropriate salary for the Director, Associate Director, and support personnel, expenses related to the Advisory Committee (e.g., travel, teleconferences, etc.), expenses associated with outreach to the broader research community, and expenses associated with the Career Enhancement Program or Pilot & Feasibility Program. Carefully explain and justify requested support.

Indicate the level of time commitment by the Director and Associate Director devoted specifically to the Center. Administrative support personnel may be budgeted at no more than one full-time equivalent (FTE), which may be divided among one or more positions. This FTE must be fully justified.

The Center Director is expected to make a commitment of at least 1.8 person months (PM) to the overall administration of the Center; while the Center Associate Director is expected to commit at least 1.2 PM to Center administration efforts. These commitment levels cannot be reduced in later years of the award.

Required PM effort for Directors of the Resource Core(s) should equal 1.8 person months. This commitment cannot be reduced in later years of the award. Note that this is a minimum level of effort that should be increased as appropriate to meet the needs of the work. Applicants should justify minimum effort, based on the proposed activities of the Core.

The Center must allocate a minimum of \$20,000 and up to \$100,000 direct costs each year to the Career Enhancement Program, which will be administered through the Administrative Core.

The Administrative Core may allocate a minimum of \$25,000 and up to \$60,000 direct costs in each year (except year 1) to its Pilot and Feasibility (P&F) Program. There is a maximum of two P&F awards per year.

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: Describe the broad long-term objectives and goals of the proposed Administrative Core. In addition, state the Core's relationship to the associated Resource Core(s)

Research Strategy:

The Administrative Core manages the overall Center, including the Pilot and Feasibility (P&F) Program (if proposed) and the Career Enhancement Program (if applicable). Applicants are encouraged to organize the Research Strategy section of the Administrative Core to align with the Centers' review criteria for the Administrative Core. Please include the following headings:

Leadership

Define the responsibilities of the Director and Associate Director, Advisory Committee, Core Directors (if applicable), institution officials, and other involved parties.

The Administrative Core will also manage interactions with the Advisory Committee. Describe the plans and procedures for nominating and selecting members of this committee. Describe the expected composition of the Advisory Committee (e.g., number of members, types of expertise, etc.), but do NOT name the members of the committee who are not from the Center Institution in the application. The Advisory Committee should include both users of the Cores and investigators external to the Center who may have expertise in the design and management of other core facilities or expertise in the technologies, services, or resources offered by the Cores or expertise in the research fields covered by the research community.

Management and Evaluation

The Administrative Core is responsible for coordinating and integrating the Center components and activities.

- **Management Plans:** Describe plans for fiscal administration, procurement, property and personnel management, planning, budgeting, and coordination across multiple institutions if applicable. Include conflict of interest management relating to intellectual property.
- **Cost Recovery:** If applicable, explain how Resource Core(s) will set user fees, considering applicable Federal cost principles ([NOT-OD-13-053](https://grants.nih.gov/grants/notice-files/NOT-OD-13-053.html) (<https://grants.nih.gov/grants/notice-files/NOT-OD-13-053.html>)).
- **Supply and Demand Management:** Describe criteria for establishing priorities or strategies for managing supply and demand if the services or resources exceed availability.
- **Evaluation and Assessment:** Describe plans for ongoing evaluation of the Center's activities, including the use and quality of Core services, outreach effectiveness, and adapting to the research community's needs. Explain the role of the Advisory Committee in this process, including meeting formats and integration of recommendations.
- **Advisory Committee:** Indicate the submission of an annual Advisory Committee executive summary independent of the research performance progress report (RPPR) to the NIAMS Program Officer/Program Director. Describe the plans for the Director, Associate Director, and Core Directors to engage regularly with the members of this committee.

Describe any reports on Center activities that will be provided to the committee members and how the committee may convey comments and recommendations back to the Center leadership. Describe how the recommendations from this committee will be integrated into the planning and management of the Center over the course of the award.

Communication

Describe plans for maintaining effective communication within the Center and with the research community and other potential users of the Core(s). Explain how communication plans will coordinate and integrate the investigators and activities of the Center. Describe plans for effectively communicating with Center investigators and Core Directors who are physically located 100 miles or more away from the primary Center.

Career Enhancement Program

Incorporate enrichment activities and educational opportunities to support investigators at varying levels (e.g., ESIs, NIs, students, fellows).

- **Multidisciplinary Approaches:** Describe activities to foster multidisciplinary research in skin, musculoskeletal, and rheumatic diseases and attract new investigators or investigators with relevant expertise.
- **Educational Activities:** Explain how enrichment activities will promote the use of Center resources and expand the research community. Applicants are encouraged to suggest coordinated efforts to help build a community of researchers in the skin, musculoskeletal, and/or rheumatic disease fields and promote scientific exchange among investigators with research interests in these topic areas. Such efforts and education activities may be: seminars, workshops, and visiting scientists to build a research community and promote scientific exchange. Each Center may choose the activities that best suit the needs of the research community but should justify how the activities fulfill these goals as well as the overall goals of the Center. Types of activities that may be part of a Career Enhancement Program include (but are not limited to) high-quality mentoring programs and activities and/or Pilot and Feasibility (P&F) programs (mentored, non-mentored, or technology development focused).
- **Outreach Activities:** Explain how enrichment activities will promote the use of Center resources and expand the research community to allow Center resources to be more accessible to external institutions. If applicable, describe activities occurring within the context of and/or with the involvement of the Resource Core(s).

Pilot and Feasibility Program (optional)

If included, describe plans for soliciting, reviewing, selecting, managing, and reporting on pilot and feasibility (P&F) projects. Include any plans to select mentees and their projects in the application.

- **Solicitation and Review:** Outline internal institutional plans and procedures to ensure compliance with Federal regulations, policies, and guidelines, including those with research involving human subjects and/or animal subjects. Include the evaluation of risks and protections in project proposals and appropriate ethical oversight of funded P&F projects.
- **Approval Process:** Describe the internal institutional plans and procedures to ensure that all projects supported from this award will comply fully with all applicable Federal regulations, policies, and guidelines, including those for research involving human subjects and including the evaluation of risks and protections in project proposals and appropriate ethical oversight of funded projects.
 - Human Subject and Animal Subject approval dates for P&F projects (if applicable) should NOT be submitted with the application but should be provided to NIAMS for approval with Just in Time (JIT) information for P&F projects considered in the first year or with the annual progress reports in subsequent years. Otherwise, please indicate in the appropriate section that human subjects or vertebrate animals are not involved. A Pilot and Feasibility program should not be used to fund clinical trials.

Sustainability Plan

Include a plan for transitioning to self-sustainable funding during the project period. Describe steps to increase the likelihood of continuing the Center's positive impact post-NIAMS support.

Examples of Sustainability: Commitments of institutional support, partnerships with existing institutional resources, future plans for obtaining external funding, self-sustaining business models, or maintaining collaborations.

Resource Sharing Plan: Individuals are required to comply with the instructions for the Resource Sharing Plans as provided in the [How to Apply- Application Guide \(https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400), with the following modification:

Other Plan(s):

All instructions in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400) must be followed, with the following additional instructions:

- Do not include a Data Management and Sharing (DMS) Plan within this Component. If a DMS Plan is required for this NOFO, it must be included within the Overall Component.

Appendix:

Only limited items are allowed in the Appendix. Follow all instructions for the [How to Apply- Application Guide \(https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400); any instructions provided here are in addition to those in the [How to Apply- Application Guide \(https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400) 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 [How to Apply- Application Guide \(https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400), 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 [How to Apply- Application Guide \(https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400) must be followed.

Delayed Onset Study

Note: [Delayed onset \(https://grants.nih.gov/grants/glossary.htm#DelayedOnsetHumanSubjectStudy\)](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 [How to Apply- Application Guide \(https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400) must be followed.

Resource Core

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

A Resource Core can be defined in multiple ways and may provide shared technologies, services, expertise, or resources that enable investigators to conduct research more efficiently and effectively.

Resource Cores may support basic, translational, and/or clinical research and may include, but are not limited to:

- Laboratory-based technologies, and instrumentation
- Data generation and processing
- Computational and bioinformatics support
- Analytical and quantitative expertise

- Methodological support (e.g. study design, biostatistics, data science, AI/ML)
- Clinical or translational research support
- Regulatory or translational support (e.g. IND-enabling activities, clinical protocol development)

Resource Cores may also provide analytical, methodological, computational, or translational expertise tailored to the needs of the research community. These capabilities should be appropriate to the Center's focus and may support basic, translational, and/or clinical research.

Resource Cores should be justified by the needs of the research community and should be appropriate for the focus of the Center. This may include cores that provide methodological, analytical, or translational expertise.

All instructions in the [How to Apply- Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) must be followed, with the following additional instructions, as noted.

SF424 (R&R) Cover (Resource Core)

Complete only the following fields:

- Applicant Information
- Type of Applicant (optional)
- Descriptive Title of Applicant's Project
- Proposed Project Start/Ending Dates

PHS 398 Cover Page Supplement (Resource Core)

Follow standard instructions. Research & Related Other Project Information (Resource 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) (Resource 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 (Resource 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 (Resource Core)

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

Required PM effort for Directors of the Resource Cores should equal 1.8 person months per year to the Core. This commitment cannot be reduced in later years of the award. Note that this is a minimum level of effort that should be increased as appropriate to meet the needs of the work. Applicants should justify minimum effort, based on the proposed activities of the Core.

Resource Core support may include personnel, equipment, supplies, services, and facilities. It is important to provide comprehensive budgetary justifications and to discuss mechanisms for reimbursing Core services.

This NOFO is not intended for acquisition of high-cost equipment. Equipment purchases in excess of \$25,000 for any year of the grant requires special justification. Under unusual circumstances where costly items of equipment are requested, the application must document available equipment within the institution and provide clear justification in terms of core service to be provided by the Center. Costly items of equipment should be funded through other sources.

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 (Resource Core)

Introduction to Application:

The most commonly referenced Research Plan attachments are listed below for your convenience.

Specific Aims: Describe the broad, long-term objectives and the specific aims to be accomplished by the Core. Include any proposed research to enhance the Core's capabilities (e.g. development or adaptation of technologies, methodologies, analytical approaches, or services) and/or education and training activities.

Research Strategy:

Describe the background information and gaps that led to the proposal of the Resource Core. Explain why the proposed shared resources, services, or expertise are essential for the Center and for independently-funded Center investigators?

Background and Importance: Document the value added to the research community by support through the Center, beyond what could be achieved by purchasing similar services from another source. Highlight the importance of these resources for the research of multiple independently-funded Center investigators.

If there are plans to buy into an existing institutional core, a description about how the Resource Core will enhance the research productivity of users from the research community should be described. This may include cores that provide technological, analytical, methodological, computational, or translational support, as appropriate to the needs of the research community.

Techniques and Services: Describe each proposed technique or service in detail, including quality control and data analysis where applicable. Whenever possible, describe plans to customize generic services (e.g., histology, flow cytometry, genetically engineered animals, data science, computational analysis, imaging analytics, study design, biostatistics, or

other analytical or methodological approaches), to meet the needs of the research community. For Cores offering access to unique resources (e.g., patient cohorts, tissue or cell banks), provide detailed descriptions emphasizing the impact of access to these resources. Include specifics such as size, clinical characteristics, clinical data, patient samples available, and whether patients can be re-contacted. If resources are provided to investigators at distant sites, describe in detail how this will be accomplished. Resource Cores may also provide methodological, analytical, computational, or translational expertise, including support for study design, data analysis, data integration, and other quantitative or research methodologies, as well as regulatory and clinical research support, where appropriate.

Organization and Operation: Present the organization and proposed mode of operation for the Core. Outline the plan to prioritize investigator use of the Core and define qualified users. Ensure this definition supports the goal of expanding the ranks of investigators engaged in research supported by the Center and promoting interdisciplinary research. Address issues such as quality control, procedures for selecting projects that use the core, cost-effectiveness, and increased efficiency. For cores providing analytical or methodological expertise, applicants should describe how consultation and collaboration with investigators will be coordinated and prioritized.

Sustainability and Reimbursement: Explain how the Resource Core will be sustainable, which may include cost recovery mechanisms such as user fees, where appropriate. Describe the plan for setting and managing user fees, considering efficient resource usage and enhancing Core sustainability.

Quality Control and Evaluation: Cores are expected to have an ongoing program that assesses the quality and use of services and resources provided. Describe the evaluation plan to ensure the Core meets the needs of the research community. This evaluation should consider both the quality and impact of services and their alignment with the evolving needs of the research community.

Renewal Applications: Renewal applications must include a recent progress report on the research core. This report should not duplicate the content included in the overall progress report included in the Overall component. Past performance and accomplishments of the Resource Core, ongoing or completed core activity that has enhanced or facilitated the aims of the Core, and the effect of provided services on investigator's productivity should be described. A succinct account of the published and unpublished results must be provided, indicating progress toward achieving the aims of the Resource Core. Indicate if the Progress Report Publication Lists are included in the Overall component rather than in the Research Core component. Please also note if a table of use of the core facility has been included in the Overall component.

Letters of Support: Provide letters of support from outside consultants that will help develop services or provide resources for sharing. Also provide letters of support from potential users of the resources provided by the Resource Core documenting the services and resources that would be used by each investigator and the potential for specific and direct impact on the research projects using those services and resources. If these documents are included in the Overall component, please state so.

Resource Sharing Plan: Individuals are required to comply with the instructions for the Resource Sharing Plans as provided in the [How to Apply- Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400), with the following modification:

Other Plan(s):

All instructions in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) must be followed, with the following additional instructions:

- Do not include a Data Management and Sharing (DMS) Plan within this Component. If a DMS Plan is required for this NOFO, it must be included within the Overall Component.

Appendix:

Only limited items are allowed in the Appendix. Follow all instructions for the [How to Apply- Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400); any instructions provided here are in addition to those in the [How to Apply- Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) instructions.

PHS Human Subjects and Clinical Trials Information (Resource 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 [How to Apply- Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) 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 [How to Apply- Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) must be followed.

Delayed Onset Study

Note: [Delayed onset \(https://grants.nih.gov/grants/glossary.htm#DelayedOnsetHumanSubjectStudy\)](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 [How to Apply- Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) must be followed.

3. Unique Entity Identifier and System for Award Management (SAM)

See Part 2. 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. 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 \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82380\)](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 \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11128\)](http://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 \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11123\)](http://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 Grants Policy Statement Section 2.3.9.2 Electronically Submitted Applications \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=82423\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=82423).

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 [How to Apply- Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400)

5. Intergovernmental Review (E.O. 12372)

This initiative is not subject to [intergovernmental review \(https://grants.nih.gov/grants/policy/nihgps/html5/section_10/10.10.1_executive_orders.htm\)](https://grants.nih.gov/grants/policy/nihgps/html5/section_10/10.10.1_executive_orders.htm).

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 \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11120\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11120).

Pre-award costs are allowable only as described in the [NIH Grants Policy Statement \(http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11143\)](http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11143) [Section 7.9.1 Selected Items of Cost, \(https://grants.nih.gov/grants/policy/nihgps/HTML5/section_7/7.9_allowability_of_costs_activities.htm#Selected\)](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_7/7.9_allowability_of_costs_activities.htm#Selected)

7. Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400). Paper applications will not be accepted.

For information on how applications will be automatically assembled for review and funding consideration after submission, refer to:

http://grants.nih.gov/grants/ElectronicReceipt/files/Electronic_Multi-project_Application_Image_Assembly.pdf (http://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 \(https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400). 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) and component Project Leads must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile form. Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to NIH.

The applicant organization must ensure that the unique entity identifier provided on the application is the same identifier used in the organization's profile in the eRA Commons and for the System for Award Management. Additional information may be found in [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400).

See [more tips \(http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11146\)](http://grants.nih.gov/grants/guide/uri_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.

Mandatory Disclosure

Recipients or subrecipients must submit any information related to violations of federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the federal award. See Mandatory Disclosures, [2 CFR 200.113 \(https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200/subpart-B/section-200.113\)](https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200/subpart-B/section-200.113) and [NIH Grants Policy Statement Section 4.1.35 \(https://grants.nih.gov/policy-and-compliance/nihgps\)](https://grants.nih.gov/policy-and-compliance/nihgps).

Send written disclosures to the NIH Chief Grants Management Officer listed on the Notice of Award for the IC that funded the award and to the [HHS Office of Inspector Grant Self Disclosure Program \(https://oig.hhs.gov/compliance/self-disclosure-info/hhs-oig-grant-self-disclosure-program/\)](https://oig.hhs.gov/compliance/self-disclosure-info/hhs-oig-grant-self-disclosure-program/) at grantdisclosures@oig.hhs.gov (<mailto:grantdisclosures@oig.hhs.gov>).

Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in [the policy \(http://grants.nih.gov/grants/guide/uri_redirect.htm?id=82299\)](http://grants.nih.gov/grants/guide/uri_redirect.htm?id=82299).

Section V. Application Review Information

1. Criteria

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

For this particular announcement, note the following: After the review of the individual components of the application, an overall impact score will be assigned to the application. This score will reflect not only the quality of the Core(s) and Administrative Core, but also how the proposed Center will bring together all these elements in an effective and cohesive unit. The overall score may be higher or lower than the "average" of the components based on the assessment of whether the "whole is greater than the sum of its parts."

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?

Specific to this NOFO

Considering both the scientific importance of the shared resources and the number of investigators that will likely benefit from access to them, will the Center have a significant impact on the broader research community? What is the likelihood that the shared resources and environment of the Center will lead to major advances in the field? Are the Center's resources likely to accelerate progress beyond what can be achieved through access to already supported centralized resources? Does the Center address important scientific and research needs within the NIAMS mission?

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?

Specific to this NOFO:

Are the Core Directors (including all Core components), collaborators, and other researchers well suited to the project? Are the identified investigators well defined in terms of their relationship to the center, and are their letters of support for the application adequate to suggest that center resources will be fully utilized?

Are the leadership and research qualifications of the Director and Associate Director adequate to lead a successful Center? Do the members of the Leadership team have the collective complementary expertise and leadership to identify and sustain a productive research relevant to the Center's scientific focus?

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?

Specific to this NOFO:

Are there adequate plans to develop new and/or unique state-of-the-art core services during the tenure of the Center such that the services and resources provided will evolve with the science conducted by the research community investigators? For the Center that may, by its nature, not be highly innovative, are the contributions essential to advance the field?

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, 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?

Specific to this NOFO

Are there effective Leadership, Management and Evaluation, and Communication plans? Is there likely to be coordination and synergy among the individual Core components and existing research community? Does support for the Cores provide added value beyond that which would be provided through a fee for service or access, especially where support is proposed for an existing resource? Are the Cores cost-effective in providing services and resources to the Center's Investigators?

Is the Career Enhancement Program designed to effectively expand the research community in the area of focus of the Center?

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?

Specific to this NOFO

Does the application define a productive, high quality, and adequately funded (with federal, state, and private peer-reviewed funding awards) research community that needs the services and resources proposed by the Center? Is the research community sufficiently broad to foster new research and to promote interdisciplinary collaborations? Does the proposed Center utilize available resources well? Where support by the Center for existing institutional scientific resources is proposed, does that resource provide a range of services or efficiency that would not otherwise be available to members of the Center? If there will be a connection with an NIH funded CTSA, is the collaboration well described and is there an adequate letter of agreement from the CTSA Program Director(s)/Principal Investigator(s)?

Review Criteria for the Administrative Core

Reviewers will consider the following criteria in the determination of an overall impact score for the Administrative Core, although scores for the individual criterion will not be provided.

Leadership

Do the members of the Leadership team have the leadership and research qualifications to maximize the success of the Center? Have they proposed adequate time commitment to effectively manage the Center? Are appropriate and well-defined responsibilities described for the Administrative Core Leads, Advisory Committee members, Core Directors, institution officials, and other involved parties? Are there adequate plans for establishing the Advisory Committee and regular Leadership engagement with the committee? Are the composition and plans for selecting the members of the committee appropriate?

Management and Evaluation

Is the management plan appropriate for fiscal administration, procurement, property and personnel management, planning, budgeting, etc.? Are the Center budgets appropriate for the proposed work to be done in Cores and for any other proposed programs in relation to the total Center? Are there adequate plans for objectively evaluating the functioning of the Center's Leadership Team, with input from the Advisory Committee? Are there adequate plans for integrating future recommendations of the Advisory Committee into the effective fiscal, personnel, and scientific management of the Center over the course of the grant award?

Communication

Are there adequate plans for the establishment and maintenance of effective internal communication and cooperation among Center Leadership, Core Directors, and members of the Advisory Committee? If the Center will involve multiple sites or institutions, is there a detailed plan of the communication strategies aimed to integrate the distant components and investigators into a coordinated entity? Will the impact of the proposed communication and outreach strategies extend to the broader NIAMS-relevant research community of investigators, as well as to investigators beyond the Center's institution in ways that will expand the pool of users of the Center's Core facilities?

Career Enhancement Program

Do the proposed career enrichment activities (e.g., through the career enhancement program, through a Pilot and Feasibility program, or other proposed mentored activity) provide exposure and new experiences to investigators with a wide range of experience levels (i.e. students, fellows, scholars, Early-Stage Investigators or New Investigators, established investigators who are switching fields)? If the Center chooses to include direct funding for research (e.g., through a Pilot and Feasibility program or mentored activity), are there adequate descriptions of plans for soliciting, reviewing, selecting, managing, and reporting on the results of projects, or plans to select mentees and their projects?

Sustainability Plan

Is the sustainability plan proposed well thought out and feasible? If the sustainability plan is enacted as described, is there a reasonable likelihood the Center will continue to make a sustained positive impact on the NIAMS-relevant research community?

Review Criteria for the Resource Core(s)

Reviewers will consider the following criteria in the determination of an overall impact score for the Resource Cores, although scores for the individual criterion will not be provided.

Significance

Does the Resource Core provide services, expertise or resources that address the scientific and/or methodological needs of the research community? Will the Core be used by multiple investigators? What is the likelihood that the Resource Core will increase efficiency, accelerate progress, and promote new research directions and meaningful collaborations among investigators? This may include technological, analytical, methodological, computational, or translational support, as appropriate to the proposed Core.

Investigators

Are the qualifications, experience, and commitment of the Resource Core Director and their collaborations with Center investigators appropriate to the proposed technical area or shared resource?

Innovation

Are there appropriate plans to develop new or unique state-of-the-art core services, technologies, or methodologies during the tenure of the Center through development or adaptation to meet the needs of the research community? Will the services and resources provided by the Resource Core not only evolve with the science conducted by the Center Investigators, but are they also likely to drive innovation of the science with increasingly sophisticated and powerful technologies? Is the Resource Core likely to promote interdisciplinary research? For a Resource Core that by its nature is not innovative, is it essential to advance the field?

Approach

Are the services, expertise, and resources of the Resource Core well described and of high quality? Does support through the Center provide added value beyond what could be achieved through existing resources or fee-for-service access, especially where support is proposed for an existing resource? Are there adequate plans for: quality control, prioritization of services, efficient and equitable access, cost-effectiveness?

For cores providing analytical, methodological, computational, or translational expertise, are the proposed approaches appropriate to support study design, data analysis, interpretation, and overall research rigor?

Do the Resource Core(s) effectively leverage existing institutional or external resources?

Environment

What is the overall quality of the environment for each Core? Is there adequate institutional commitment to the Center (including physical space for each Resource Core), lines of accountability regarding management of the Core(s), and commitment to the individuals responsible for conducting essential Center functions?

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.

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 \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11175\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11175).

This NOFO only accepts applications that do not propose clinical trials. Note: Applications may propose activities involving human subjects that are not deemed clinical trials.

Inclusion of Human Subjects Policies

When the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for inclusion. For additional information on review of the Inclusion section, please refer to the [Guidelines for the Review of Inclusion in Clinical Research \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11174\)](http://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 three points: (1) a complete description of all proposed procedures including the species, strains, ages, sex, and total numbers of animals to be used; (2) justifications that the species is appropriate for the proposed research and why the research goals cannot be accomplished using an alternative non-animal model; and (3) interventions including analgesia, anesthesia, sedation, palliative care, and humane endpoints that will be used to limit any unavoidable discomfort, distress, pain and injury in the conduct of scientifically valuable research. Methods of euthanasia and justification for selected methods, if NOT consistent with the American Veterinary Medicine Association (AVMA) Guidelines for the Euthanasia of Animals, is also required but is found in a separate section of the application. For additional information on review of the Vertebrate Animals Section, please refer to the [Worksheet for Review of the Vertebrate Animals Section. \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11150\)](http://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

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

Renewals

For Renewals (as applicable), the committee will consider the progress made in the last funding period.

Revisions

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

Additional Review Considerations - 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 Resource Sharing Plan(s) (e.g., [Sharing Model Organisms \(https://sharing.nih.gov/other-sharing-policies/model-organism-sharing-policy#policy-overview\)](https://sharing.nih.gov/other-sharing-policies/model-organism-sharing-policy#policy-overview)) or the rationale for not sharing the resources, is reasonable.

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), in accordance with NIH peer review policies and practices, 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 \(https://grants.nih.gov/grants/policy/nihgps/html5/section_2/2.4.2_appeals_of_initial_scientific_review.htm\)](https://grants.nih.gov/grants/policy/nihgps/html5/section_2/2.4.2_appeals_of_initial_scientific_review.htm) of initial peer review will not be accepted for applications submitted in response to this NOFO.

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 NOFO. Following initial peer review, recommended applications will receive a second level of review by the National Arthritis and Musculoskeletal and Skin Diseases Advisory Council (NAMSAC). 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.

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 Section 2.5.1. Just-in-Time Procedures \(http://grants.nih.gov/grants/guide/uri_redirect.htm?id=82418\)](http://grants.nih.gov/grants/guide/uri_redirect.htm?id=82418). This request is not a Notice of Award nor should it be construed to be an indicator of possible funding.

Prior to making an award, NIH reviews an applicant's federal award history in SAM.gov to ensure sound business practices. An applicant can review and comment on any information in the Responsibility/Qualification records available in SAM.gov. NIH will consider any comments by the applicant in the Responsibility/Qualification records in SAM.gov to ascertain the applicant's integrity, business ethics, and performance record of managing Federal awards per 2 CFR Part 200.206 "Federal awarding agency review of risk posed by applicants." This provision will apply to all NIH grants and cooperative agreements except fellowships.

3. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access their Summary Statement (written critique) via the [eRA Commons \(http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11123\)](http://grants.nih.gov/grants/guide/uri_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 Section 2.4.4 Disposition of Applications \(http://grants.nih.gov/grants/guide/uri_redirect.htm?id=82416\)](http://grants.nih.gov/grants/guide/uri_redirect.htm?id=82416).

Section VI. Award Administration Information

1. Award Notices

A Notice of Award (NoA) is the official authorizing document notifying the applicant that an award has been made and that funds may be requested from the designated HHS payment system or office. The NoA is signed by the Grants Management Officer and emailed to the recipient's business official.

In accepting the award, the recipient agrees that any activities under the award are subject to all provisions currently in effect or implemented during the period of the award, other Department regulations and policies in effect at the time of the award, and applicable statutory provisions.

Recipients must comply with any funding restrictions described in Section IV.6. Funding Restrictions. Any pre-award costs incurred before receipt of the NoA are at the applicant's own risk. For more information on the Notice of Award, please refer to the [NIH Grants Policy Statement Section 5. The Notice of Award \(https://grants.nih.gov/grants/policy/nihgps/HTML5/section_5/5.5_the_notice_of_award.htm\)](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_5/5.5_the_notice_of_award.htm) and NIH Grants & Funding website, see [Award Process. \(https://grants.nih.gov/grants/pre-award-process.htm#award\)](https://grants.nih.gov/grants/pre-award-process.htm#award)

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

Prior Approval of Pilot Projects

Submission of Pilot and Feasibility projects for prior approval will only be accepted with the Just-in-Time or with the annual Research Project Progress Report (RPPR). A complete package must be sent to the appropriate NIAMS Grants Management Specialist and NIAMS Program Director with the following information:

- Institution
- Title of Proposed Study
- Project PI and Co-PI (if applicable)
- Project PI status (i.e., assistant professor, associate professor, professor, graduate student, etc).

- Proposed period of study- include start and end dates
- Total funds
- A narrative similar to the specific aims page in an NIH grant application that includes:
 - A brief background of the project
 - Specific aims, objectives, or hypothesis
 - Significance and relevance to the parent grant
 - Other appropriate information
- Critiques by the Advisory Committee
- If the P&F project involves human and/or animal subjects, applicant must submit an IRB or IACUC approval prior to the start of the P&F project.

Final approval will be provided by the NIAMS Program Director.

Note the following information:

- A Pilot and Feasibility program should not be used to fund clinical trials.
- The recipient institution will comply with the NIH [Guidance on Changes That Involve Human Subjects in Active Awards and That Will Require Prior NIH Approval](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-128.html) (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-128.html>).
- The recipient institution will provide NIH with specific plans for data and safety monitoring and will notify the IRB and NIH of serious adverse events and unanticipated problems, consistent with [NIH DSMP policies](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-128.html) (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-128.html>).

2. Administrative and National Policy Requirements

The following Federal wide and HHS-specific policy requirements apply to awards funded through NIH:

- The rules listed at [2 CFR Part 200](https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200) (<https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200>), Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards.
- All NIH grant and cooperative agreement awards include the [NIH Grants Policy Statement](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-128.html) (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-128.html>) as part of the terms and conditions in the Notice of Award (NoA). The NoA includes the requirements of this NOFO. 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/notice-files/NOT-OD-15-128.html) (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-128.html>) 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/notice-files/NOT-OD-15-128.html) (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-128.html>).

All federal statutes and regulations relevant to federal financial assistance, including those highlighted in [NIH Grants Policy Statement Section 4 Public Policy Requirements, Objectives and Other Appropriation Mandates](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-128.html), (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-128.html>).

By applying for or accepting federal funds from HHS, recipients certify compliance with all federal antidiscrimination laws and these requirements and that complying with those laws is a material condition of receiving federal funding streams. Recipients are responsible for ensuring subrecipients, contractors, and partners also comply.

Applicants and recipients are strongly encouraged to refer to the [NIH Director's Statement of Priorities](https://www.nih.gov/about-nih/nih-director/statements/advancing-nih-mission-through-unified-strategy) (<https://www.nih.gov/about-nih/nih-director/statements/advancing-nih-mission-through-unified-strategy>), entitled "Advancing NIH's Mission Through a Unified Strategy."

Recipients are responsible for ensuring that their activities comply with all applicable federal regulations. Pursuant to 2 CFR 200.340, by accepting an NIH award, the recipient agrees that continued funding for the award is contingent upon the availability of appropriated funds, recipient satisfactory performance, compliance with the Terms and Conditions of the award, and may also otherwise be terminated, to the extent authorized by law, if the agency determines that the award no longer effectuates the program goals or agency priorities, in line with 2 CFR 200.340(a)(4).

Pursuant to the Cybersecurity Act of 2015, Div. N, § 405, Pub. Law 114-113, 6 USC § 1533(d), the HHS Secretary has established a common set of voluntary, consensus-based, and industry-led guidelines, best practices, methodologies, procedures, and processes.

Successful recipients under this NOFO agree that:

When recipients, subrecipients, or third-party entities have:

- ongoing and consistent access to HHS owned or operated information or operational technology systems; and
- receive, maintain, transmit, store, access, exchange, process, or utilize personal identifiable information (PII) or personal health information (PHI) obtained from the awarding HHS agency for the purposes of executing the award.

Cybersecurity plans and procedures **must** at minimum include the following:

- Develop cybersecurity plans and procedures, modeled after the [NIST Cybersecurity framework](https://www.nist.gov/cyberframework) (<https://www.nist.gov/cyberframework>), to protect HHS systems and data:
 - **Identify:**
 - Develop an inventory of all assets and accounts with access to HHS owned and operated information or operational technology systems or which obtain PII or PHI for the purposes of the award.
 - **Protect:**
 - Limit access to HHS owned and operated systems to only those in need of access to complete reward activities.
 - Require all staff to complete annual cybersecurity and privacy awareness training. Visit [405\(d\): Knowledge on Demand \(hhs.gov\)](https://405d.hhs.gov/kod/five-threats) (<https://405d.hhs.gov/kod/five-threats>) to obtain free trainings, if needed.
 - Enable multifactor authentication for all employees, subrecipients, and third-party entities to access HHS owned and operated information or operational technology systems.
 - Regularly backup sensitive data and test backups.
 - **Detect:**
 - Install anti-virus or anti-malware software on all devices, servers, and accounts used to connect to HHS owned and operated systems.
 - **Respond:**
 - Develop an incident response plan. See [Incident-Response-Plan-Basics_508c.pdf](https://www.cisa.gov/sites/default/files/publications/Incident-Response-Plan-Basics_508c.pdf) ([cisa.gov](https://www.cisa.gov/sites/default/files/publications/Incident-Response-Plan-Basics_508c.pdf)) (https://www.cisa.gov/sites/default/files/publications/Incident-Response-Plan-Basics_508c.pdf) to learn about developing incident response plans.
 - Have cybersecurity incident reporting procedures that ensure the relevant HHS awarding agencies are notified of a cybersecurity incident within 48 hours of discovery. A cybersecurity incident is defined as an unplanned interruption to a technology service or reduction in the quality of a technology service, or an occurrence that actually or potentially jeopardizes the confidentiality, integrity, or availability of an information system or the information the system processes, stores, or transmits.
 - **Recover:**
 - Investigate incidents and plug any security gaps identified.

All activities proposed in your application and budget narrative must align with applicable law, including but not limited to statutes, executive orders, federal regulations and applicable judicial holdings. Accordingly, discretionary awards shall not be used to fund, promote, encourage, subsidize, or facilitate; racial preferences or other forms of racial discrimination by the

recipient, including activities where race or intentional proxies for race will be used as a selection criterion for employment or program participation; denial by the recipient of the sex binary in humans, or the belief that sex is a chosen or mutable characteristic; illegal immigration; or any other initiatives that compromise public safety. If an application does not align, the application will not receive funding to the extent permitted by law and applicable court orders.

For applications involving substance abuse, the application must not support harm reduction. Please see [Updated Funding Guidance for Recipients on Supplies and Services](https://www.samhsa.gov/sites/default/files/dear-colleague-letter-updated-hr-funding-guidance.pdf) (<https://www.samhsa.gov/sites/default/files/dear-colleague-letter-updated-hr-funding-guidance.pdf>).

For applications involving funding Medication-Assisted Treatment (MAT) or medications for opioid use disorder (MOUD), this funding should be used to provide comprehensive treatment and recovery support services rather than medication-only models for opioid use disorder. Services should include medications, where clinically indicated, in conjunction with psychosocial and other treatment and recovery support services. Funding can also be used to support individualized tapering and discontinuation of medications when clinically indicated. Please see [Updated Funding Guidance for Recipients on MAT/MOUD](https://www.samhsa.gov/sites/default/files/dear-colleague-letter-mat-moud-guidance.pdf) (<https://www.samhsa.gov/sites/default/files/dear-colleague-letter-mat-moud-guidance.pdf>).

As of October 1, 2025, HHS has adopted [2 CFR Part 200](https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200) (<https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200>), with some modifications included in 2 CFR Part 300. These regulations replace those in 45 CFR Part 75. However, for NIH, under the Consolidated Appropriations Act for FY 2026, ([P.L. 119-75](https://www.congress.gov/bills/119/congress/house-bill/7148) (<https://www.congress.gov/bills/119/congress/house-bill/7148>), Division B, Title II, Sec. 224), the provisions relating to indirect costs in 45 CFR 75 continue to apply to NIH awards. Consistent with the statute, NIH will not apply updated thresholds outlined within 2 CFR Part 200, at this time.

In administering programs under this and all funding announcements, NIH prioritizes:

- Research involving rigorous scientific methods, including for studies related to children and adolescents, where NIH is committed to approaches that reflect the highest standards of clinical care and child safety.
- Biological and physiological integrity: Recognizing the relevance of biological sex to health outcomes, NIH encourages applicants to account for sex-based health factors in program design, data collection, and service delivery where scientifically appropriate.
- NIH will implement these priorities consistent with applicable laws, regulations, court orders, and all required administrative procedures. Applicants are encouraged to describe how their proposed programs align with these priorities in their project narratives. Funded activities must advance NIH's vision of protecting and improving the health and well-being of Americans. The particular focus is on those who are medically vulnerable, or live in areas with limited access to care. NIH's duty is to serve wisely, effectively, and with measurable results that justify every taxpayer dollar invested.

Cooperative Agreement Terms and Conditions of Award

Not Applicable

3. Data Management and Sharing

A Data Management and Sharing Plan (DMS Plan) is required for any NIH-funded or conducted research that will generate scientific data. Applicants must submit the DMS Plan at the time of application using the [NIH DMS Plan Format Page](https://grants.nih.gov/grants-process/write-application/forms-directory/data-management-and-sharing-plan-format-page) (<https://grants.nih.gov/grants-process/write-application/forms-directory/data-management-and-sharing-plan-format-page>). The DMS Plan must address the elements in the structured format. Where the DMS Plan Format Page requires a "Yes or No" response, no additional narrative is allowed. The Data Management and Sharing (DMS) Plan must be provided in the Overall component.

4. Reporting

- When multiple years are involved, recipients will be required to submit the [Research Performance Progress Report \(RPPR\)](http://grants.nih.gov/grants/rppr/index.htm) (<http://grants.nih.gov/grants/rppr/index.htm>) annually and financial statements as required in the [NIH Grants Policy Statement Section 8.4.1 Reporting](http://grants.nih.gov/grants/guide/uri_redirect.htm?id=82419) (http://grants.nih.gov/grants/guide/uri_redirect.htm?id=82419). To learn more about post-award monitoring and reporting, see the NIH Grants & Funding website, see [Post-Award Monitoring and Reporting](https://grants.nih.gov/grants/guide/uri_redirect.php?id=82428) (https://grants.nih.gov/grants/guide/uri_redirect.php?id=82428).

Progress reports should briefly describe status of pilot projects, including data and safety monitoring, and should notify NIH of serious adverse events and unanticipated problems.

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 Section 8.6 Closeout](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.6_closeout.htm) (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.6_closeout.htm). NIH NOFOs outline intended research goals and objectives. Post award, NIH will review and measure performance based on the details and outcomes that are shared within the RPPR, as described at 2 CFR Part 200.301.

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](https://www.era.nih.gov/need-help) (<https://www.era.nih.gov/need-help>) - Questions regarding ASSIST, eRA Commons, application errors and warnings, documenting system problems that threaten submission by the due date, and post-submission issues.

[Grants.gov Support Center](https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fgrants.gov%2Fsupport&data=05%7C02%7Cantoine.caliman%40nih.gov%7Caf6dde64d44478d4e8b08dde6700581%7C14b77578977342d58507251ca2dc2b) (<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fgrants.gov%2Fsupport&data=05%7C02%7Cantoine.caliman%40nih.gov%7Caf6dde64d44478d4e8b08dde6700581%7C14b77578977342d58507251ca2dc2b>)

- Questions regarding Grants.gov registration and services (e.g., Workspace, subscriptions).

Scientific/Research Contact(s)

National Institute of Arthritis and Musculoskeletal and Skin Diseases ([NIAMS](https://www.niams.nih.gov/) (<https://www.niams.nih.gov/>))

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

Office of Autoimmune Disease Research (OADR)

Office of Research on Women's Health (ORWH)

oadrinfo@nih.gov (<mailto:oadrinfo@nih.gov>)

Peer Review Contact(s)

Examine your eRA Commons account for review assignment and contact information (information appears two weeks after the submission due date).

Financial/Grants Management Contact(s)

National Institute of Arthritis and Musculoskeletal and Skin Diseases ([NIAMS](https://www.niams.nih.gov/) (<https://www.niams.nih.gov/>))

Email: NIAMSGrants@nih.gov (<mailto:NIAMSGrants@nih.gov>)

Section VIII. Other Information

Recently issued trans-NIH [policy notices](http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11163) (http://grants.nih.gov/grants/guide/uri_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/uri_redirect.htm?id=11164) (http://grants.nih.gov/grants/guide/uri_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/uri_redirect.htm?id=11120) (http://grants.nih.gov/grants/guide/uri_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 2 CFR Part 200.