Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)

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

Components of Participating Organizations

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK (https://www.niddk.nih.gov/))

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.

Division of Program Coordination, Planning and Strategic Initiatives, Office of Disease Prevention (ODP (https://prevention.nih.gov/))

Office of Nutrition Research (ONR (https://dpcpsi.nih.gov/onr))

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). ICOs that do not participate in this announcement will not consider applications for funding.

Funding Opportunity Title

Nutrition Obesity Research Centers (NORCs) (P30 Clinical Trial Optional)

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) Center Core Grants

Announcement Type

Reissue of RFA-DK-25-007 (https://www.grants.gov/search-results-detail/353678)

Related Notices

- Check for any recent Notices of NIH Policy Changes (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).

Funding Opportunity Number (FON)

RFA-DK-27-120

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)

93.847

Notice of Funding Opportunity Purpose

This Notice of Funding Opportunity (NOFO) invites applications from institutions/organizations that propose to establish core centers that are part of an integrated and existing program of nutrition and/or obesity research. The Nutrition Obesity Research Centers (NORC) program is designed to support and enhance the national research effort in nutrition and obesity. NORCs support three primary research-related activities: Research Core services, a Pilot and Feasibility (P and F) program, and a Scientific Catalyst program. All activities pursued by Nutrition Obesity Research Centers are designed to enhance the efficiency, productivity, effectiveness, and multidisciplinary nature of research in nutrition and obesity.

Funding Opportunity Goal(s)

To promote extramural basic and clinical biomedical research that improves the understanding of the mechanisms underlying disease and leads to improved preventions, diagnosis, and treatment of diabetes, digestive, and kidney diseases. Programmatic areas within the National Institute of Diabetes and Digestive and Kidney Diseases include diabetes, digestive, endocrine, hematologic, liver, metabolic, nephrologic, nutrition, obesity, and urologic diseases.

Key Dates

Posted Date

June 30, 2026

Open Date (Earliest Submission Date)

September 20, 2026

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**
October 20, 2026	October 20, 2026	Not Applicable	March 2027	May 2027	July 2027

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

October 21, 2026

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), 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)). Conformance to all requirements (both in the How to Apply - Application Guide (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) 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), 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) 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/) to track your application. Check with your institutional officials regarding availability.

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Part 2. Full Text of Announcement

Section I. Notice of Funding Opportunity Description

This Notice of Funding Opportunity (NOFO) invites applications for Nutrition Obesity Research Center (NORC) grants to support research in nutrition and/or obesity. The mission of the NORC program is to serve as a key component of the NIDDK-supported research effort to advance nutrition and obesity research inclusive of advancing basic science research, clinical studies and implementation research, and stakeholder engagement as well as the goal of strengthening biomedical research workforce training.

To accomplish this mission, the NORCs:

- Create an environment that supports important and innovative research;
- Attract and retain early-stage investigators and investigators new to nutrition/obesity research;
- Provide core services that leverage funding and unique expertise;
- Foster interdisciplinary collaborations, especially in emerging areas of research, to catalyze new ideas and scientific approaches;
- Raise awareness and interest in fundamental and clinical nutrition and/or obesity research at their institutions, as well as locally, regionally, and nationally;
- Promote the translation of scientific discoveries from bench to bedside to the community to improve public health; and
- Enhance nutrition and obesity research education and training opportunities.

Institution and Research Base

The NORC program is intended to bring together investigators from a variety of scientific disciplines in a manner that enhances and extends the effectiveness of their research. A NORC must be an identifiable unit within a single or a consortium of cooperating institutions, including affiliated universities, medical centers, and/or other research organizations as evidenced by a consistent and outstanding record of productivity and peer-reviewed research funding in the areas of nutrition and/or obesity. NORC funding will provide support for core facilities (shared resources), pilot and feasibility studies, and program enrichment activities. Except for pilot and feasibility studies, NORC funds are not intended to fund or otherwise support individual biomedical or behavioral research projects other than through core usage.

The NORC research base includes only currently-funded, peer-reviewed research grants awarded to the applicant institution/consortium. The research must be in the form of research project grants (e.g. R01, R21, R61/R33, U01, etc.), program project grants (P01), RC2 interdisciplinary science, Career Development Awards (K01, K08, K23, K99, etc.), or other peer-reviewed research that is already funded by NIH, other Federal Agencies, or non-federal groups at the time of submission of the NORC grant application. Investigators and grant funding outside the NORC institution/consortium **may not** be included as part of the NORC research base and funding. Training grants, education grants, other NIH Center awards, and fellowship awards are not considered part of the research base, but opportunities for collaboration and synergy should be discussed. The focus, relevance, interrelationships, quality, productivity, and, to some extent, quantity are all important considerations for the adequacy of the research base. **The quality of the biomedical research base and its relevance to nutrition and obesity research will be given emphasis in the peer review process.**

The funding of the research base for the NORC, including any affiliated academic centers, hospitals, or proposed partners, must consist of at least $3,000,000 in **direct costs** of peer-reviewed research projects. Since "Facilities and Administration" costs vary considerably between institutions, those amounts should not be included in the calculation of the research base. In addition, there must be sufficient Federal support within the base to fulfill the requirement for a minimum of two federally-funded NORC members utilizing each Biomedical Research Core, and at least 50% of funding for the research base must come from Federal agencies or programs.

NORCs are expected to have 'members', and the criteria for becoming a NORC member must be clearly defined and well-justified. Criteria for membership include peer-reviewed independent funding, participation in NORC-related research, and need for the use of core facilities; however, additional criteria for becoming a NORC 'member' are permissible. Additional membership categories based on a researcher's degree of participation or other quantitative measures are acceptable, but eligibility criteria must be clearly defined and well-justified.

Research programs/investigators outside the primary NORC institution or consortium where the NORC is based may utilize the core resources and participate in NORC activities, if space, time, and funds permit, and NORCs are encouraged to explore such opportunities. NORCs at an institution(s) with more than one NIDDK-funded Center, particularly Diabetes Research Centers, Centers for Diabetes Translation Research, or Digestive Disease Centers, must disclose and address any potential for overlap in research base members to avoid inappropriate inflation of the research base of the NORC.

Administrative Core (with Clinical Element and Scientific Catalyst Program)

NORC applications must include an Administrative Core, which is responsible for allocation and oversight of NORC resources. The Administrative Core should have a process to a) assess the productivity, effectiveness, and appropriateness of NORC activities; b) determine the criteria and selection process for NORC membership; and c) foster collaborations and scientific opportunities among its members. In addition, all NORCs are required to maintain an institutional NORC website with the Administrative Core taking primary responsibility for its curation and oversight. The NORC program also maintains a central NORC program website, and individual NORCs are required to regularly communicate with the NORC website administrators to assure that information regarding their NORC is accurate and up to date.

As part of the Administrative Core, NORCs are expected to support program enrichment activities such as seminars, visiting scientists, consultants, and workshops. The NORC Scientific Catalyst program should be designed to advance translational research in nutrition and obesity and promote scientific exchange among investigators with research interests in these topic areas, and to enhance interactions between nutrition and obesity researchers and investigators from other fields with relevant expertise. The Scientific Catalyst program can support activities such as seminars, guest speakers, visiting scientists, consultants, and workshops.

Clinical Element

NORCs are **required** to support clinical research and these efforts must be described in a 'Clinical Element' within the Administrative Core. A NORC's potential or past efforts to develop clinically-relevant specialized services that are applicable and useful for the NORC research base are an important aspect of the NORC program and will be evaluated.

NORCs may support clinical, translational, and implementation research and services through a variety of approaches, as follows:

- A clinical biomedical research core, i.e., clinical research services are provided for and budgeted through stand-alone research core(s)
- The administrative core, or
- A combination of the above in a manner that best meets the needs of the NORC.

The clinical research services offered, the qualifications of the relevant personnel supported within the overall NORC, as well as the number of physician scientists, and basic researchers making use of available/relevant clinical research services should be addressed. Any efforts to encourage collaboration between NORC clinical and basic science investigators should be described in the Clinical Element. NORCs are also strongly encouraged to support clinical research through the pilot and feasibility (P and F) program and the Scientific Catalyst Program.

Biomedical Resource Cores

NORCs are designed around Research Cores that provide shared, specialized technical resources and/or expertise that enhance the efficiency, productivity, and multidisciplinary nature of research performed by NORC-affiliated investigators. The goal of the NORC program is to make state-of-the art technologies and resources readily accessible to a broad spectrum of investigators who are pursuing studies in nutrition, obesity, and other related research areas. Two to five biomedical research Cores are usually included in a NORC. NORCs are encouraged, but not required, to interact with the broader research community, serving as resources to support research of importance to NIDDK.

Each Research Core should provide state-of-the art services to multiple, funded research projects. Examples of biomedical research cores that would be considered responsive to this NOFO may include, but are not limited to:

- Nutrigenomics
- Metabolomics
- Dietary and/or physical activity assessment
- Basic behavioral science
- Implementation research
- Clinical and interventional research
- Molecular biology
- Nutritional biochemistry
- Adipocyte biology
- Imaging
- Bioinformatics
- Biostatistics

Particular emphasis should be placed on services that support and foster interdisciplinary, integrated, and translational approaches to research in nutrition, obesity and related topic areas. Preference will be given to core support services that are not readily available or cost-effective when supplied from commercial sources as well as techniques or technologies that are technically challenging or require specialized expertise, equipment or infrastructure. **The quality, usage, and appropriateness of biomedical research cores for the research base will be given emphasis in the peer review process.**

Justification for proposing a core: The establishment and continued support of biomedical research cores within a NORC are justified based on use by independently funded NORC research base investigators. Proposing to join an institutional core is acceptable but must be well-justified. While investigators holding awards from the NORC pilot and feasibility program are appropriate users of the core facilities, their use does not contribute to justification for establishment or continued support of a core.

Pilot and Feasibility (P and F) Program

The Pilot and Feasibility Program (P and F Program) provides modest support for new initiatives or feasibility research studies. P and F Programs are intended to provide support for investigators to collect preliminary data sufficient to support a grant application for independent research support and/or to test a novel, even high-risk, hypothesis.

It is expected that the majority of P and F project investigators will fall into the new or early stage investigator category, and **only in exceptional circumstances will established investigators be supported**. Efforts to increase the number of P and F awards and availability of funds for the program using program income or alternative funding sources from the application institution/consortium and other relevant organizations are particularly encouraged. NORCs may elect to support senior post-doctoral fellows who have an interest in pursuing an academic research career.

Additional Features

Cooperation, Coordination and Integration*:* The NORC Program has a **NORC Research Resource Center (RRC)** charged with managing common NORC activities with a goal of enhancing the rigor and reproducibility of nutrition and obesity research; providing support for the early-to-midcareer nutrition and obesity researchers; leading an Opportunity Program supporting common NORC activities; providing a Pilot and Feasibility Program; and supporting other related needs for the NORC program more broadly. NORC Directors and key personnel must be willing to work collaboratively with the RRC and the full NORC consortium to advance these goals.

Annual NORC Meeting

Every 12 months, all NORC Directors and administrators are expected to attend an in-person NORC meeting to exchange information, develop trans-NORC programs, and interact with other NORC personnel and NIDDK senior staff.

Applicants are encouraged to consult with NIDDK staff concerning plans for the development of a Nutrition Obesity Research Center and the organization of the application.

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

Applications Not Responsive to this NOFO

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

- Applications that do not demonstrate relevance to nutrition and/or obesity research.

Investigators proposing NIH-defined clinical trials may refer to the Research Methods Resources website for information about developing statistical methods and study designs.

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
Resubmission

The OER Glossary (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) provides details on these application types. Only those application types listed here are allowed for this NOFO.

Clinical Trial?

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

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

Funds Available and Anticipated Number of Awards

NIDDK intends to commit $3,600,000 in FY 2027 to fund up to 3 awards, depending on availability of funds.

Award Budget

Application budgets are limited to $750,000 direct costs per year but need to reflect actual needs of the proposed Center. This budget limit is exclusive of F&A costs for consortium and subcontract arrangements. It is anticipated that the award budget will be directly correlated to the breadth, quality, and relevance to nutrition/obesity and related areas of the research base being served by the Center. Within the direct cost cap, up to $150,000 per year may be requested for the Pilot and Feasibility program.

Award Project Period

The total project period for an application submitted in response to this funding opportunity may not exceed five years.

NIH grants policies as described in the NIH Grants Policy Statement (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), **are not** allowed.

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) 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) for additional information.

- System for Award Management (SAM) (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) (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/) - 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) – 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/). 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).

Because a NORC has a large and complex administrative structure, the PD/PI(s) must have strong leadership abilities and demonstrated proficiency in managing large, multi-component programs. The NORC PD(s)/PI(s) must also be willing to participate in NORC-wide activities, including annual meetings of the NORC Program.

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) Section 1.2- Definitions of Terms. (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_1/1.2_definition_of_terms.htm)

3. Additional Information on Eligibility

Number of Applications

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

Only institutions at which there is an ongoing, strong base of nutrition and/or obesity-related research are eligible. For new applications, at least 50% of the nutritional sciences and obesity or other related research comprising the research base must be supported with funds from Federal Agencies. In renewal applications, the NIH-supported research base may be less than 50% due, typically, to a growing number of investigators entering nutrition and/or obesity research from other fields. Each proposed core must be utilized by a minimum of two federally-funded investigators.

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), 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), or other notice from NIH Guide for Grants and Contracts (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) 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) 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) and the Table of Page Limits (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
Research Core	Core	6	Required	2	5
P and F Program	P and F Program	6	Required	1	1

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)and should be used for preparing a multi-component application.

The application should consist of the following components:

- Overall
- Administrative Core
- Biomedical Research Cores
- Pilot and Feasibility Program

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) must be followed, with the following additional instructions, as noted.

SF424(R&R) Cover (Overall)

Complete entire form.

PHS 398 Cover Page Supplement (Overall)

Follow standard instructions.

Research & Related Other Project Information (Overall)

Follow standard instructions.

Follow standard instructions.

Project Summary/Abstract: Describe the research focus or scientific theme(s) of the NORC and the need for a NORC to support the investigators in the research base. Include the number of NORC members and the overall direct costs present in the research base. Provide a brief overview of the research base as it relates to the theme(s) of the NORC, as well as an overview of the biomedical research cores, the Pilot & Feasibility program, and the Scientific Catalyst program.

Project Narrative: In 1-3 sentences, describe the relevance of the research to be supported and facilitated by NORC activities (Research Cores, Pilot and Feasibility Program, and Scientific Catalyst Program) on public health.

Facilities and Other Resources: Describe the existing environment and facilities briefly in the context of how the NORC will use or change existing access, space, and usage; include space maps as needed. Scientific personnel and institutional resources capable of supporting the research base must be available.

Equipment: A general listing of major, shared pieces of equipment to be used by NORC members should be provided. Note: Specific research core facilities, equipment, and special resources should be listed in each proposed biomedical research core component.

Other Attachments: The following attachments must be included with the NORC Overview to aid in the review of applications. The filename for each attachment will be the name used for the bookmark in the application image. All attachments need to be in .pdf format.

Table of NORC Research Base Investigators: (Required) Title this attachment "NORC Research Base Investigators" and organize alphabetically by investigator's last name. Include R-series, individual K-series, U-series (cooperative agreements), DP-series, R2Cs, P01s, and other similarly peer-reviewed research project grants funded through other Federal Agencies or non-federal groups. The table must include: PI name, the active grant number(s), title(s), amount of funding (Direct Costs only) in the current year, a few descriptive sentences of the investigator's research projects, the cores that the members use, and if not readily apparent, the relevance to nutrition and obesity research. In the research base description, include ONLY those grants awarded or subcontracted to investigators at the applicant institution or consortium, not to investigators at other locations. P&F recipients do not qualify as research base members.

Progress Report Publication List(renewal applications only)**: (**required**,** not to exceed 5 pages**)** Title is attachment "Publication List". In this attachment, list the titles and complete references for representative examples of publications attributed to core usage and manuscripts accepted for publication that have resulted from the NORC since it was last reviewed competitively. Identify the core(s) utilized in association with the publication.

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 of the proposed NORC. Provide a brief overview of the research focus or the central theme(s) of the NORC. The focus/theme may be broad or targeted, depending upon the goals of the Center. However, it should also be cohesive and well-articulated to ensure that the NORC will substantially advance a defined area of nutrition/obesity-related science. Outline the existing skills and technologies available in the research base as well as other resources at the institution(s) and summarize how the NORC will enhance ongoing projects, assist in the development of new projects, respond to future opportunities, and promote collaborations leading to advances in nutrition and obesity research.

Research Strategy: The Research Strategy should include the following sections:

*Research Base***:**The research base will be evaluated and should address all of the components below. The NORC program provides a mechanism for fostering interdisciplinary cooperation within a group of established investigators conducting high quality research on nutrition/obesity and related areas. Therefore, applicants should demonstrate the existence of a strong, substantial funded research base in nutrition/obesity or related topics and describe how that research base will benefit from the establishment of a new or continuation of an existing NORC. The quality and relevance of the research base members' grant funding to nutrition and obesity research as well as the proposed cores will be evaluated.

Membership: The applicant should state considerations for NORC membership with specific reference to the potential of members to form interactive, collaborative, and synergistic relationships. Specific membership criteria, and any affiliation categories (if applicable), should be clearly defined to better organize and facilitate the focus of the NORC's mission. Suitable criteria for membership include, but are not limited to, peer-reviewed independent funding, participation in nutrition/obesity-related research and clear need for the use of core facilities. All research base investigators must be NORC members. Designation as a NORC member without the need for the use of core facilities must be well-justified. Since most, if not all, of the research base will have undergone separate peer review, the quality of the individual funded projects should already be established. The more important aspects are: (a) interactions and interrelationships of the research efforts; (b) uses and benefits of core services; (c) plans to develop productive collaborations among NORC investigators; and (d) willingness of NORC members to contribute to the overall objectives of the NORC.

Collaborative activities with individuals outside of the applicant institution/consortium or between NORCs is encouraged but optional. How any such collaboration benefits the research base can be described. Examples of benefits include more efficient use of resources by cooperating across NORCs, an augmented Scientific Catalyst program, enhanced quality/impact of the NORC's scientific output, incorporation of additional perspectives, increased productivity, or peer-reviewed funding arising directly from the collaboration.

Goals and directions – Describe the current and future directions for the NORC in the forthcoming project period. Indicate how the research supported by the NORC will impact the understanding of nutrition/obesity and, ultimately, public health. Describe the short, mid-, and long-term goals and measures of success.

Summarize the services and resources provided by the NORC, briefly describe how the biomedical research cores will address the scientific needs of the research base and explain how the biomedical cores are managed. Relevant examples of ongoing or planned research should be discussed as appropriate with reference to the supporting Core. Describe any basic science work that has successfully been translated to the bedside or community or plans to enhance that translation in the next project period.

Renewal applications must also describe the accomplishments of the NORC in the preceding project period and how it intends to build upon its successes. These accomplishments should be presented, as appropriate, in the areas of basic science, clinical research, and public health research. The impact of NORC-based science should be discussed in detail.

Building research capacity – Within this section, describe the research capacity and clearly identifiable major scientific focus in nutrition/obesity research and how it will advance nutrition and obesity research. Provide details on the special talents and resources that will be drawn to and built upon at the NORC.

Describe how the NORC will address the ongoing and future scientific needs of the research base, including plans to determine the need for services and instrumentation of the NORC. Indicate if any of the proposed cores will utilize or expand cores already existing at the institution. In cases where cores have been discontinued and/or replaced over the prior project period, describe the rationale and justification for the new/modified core.

Leveraging existing resources is strongly encouraged, particularly when this provides a range of services or efficiency that would not otherwise be available. Applicants must demonstrate that support for an existing resource through the NORC provides added value to the resource beyond that which would be provided by paying for use of the resource through an existing fee-for-service structure.

For renewal applications: Briefly describe the progress in the research base during the previous project period including development of multidisciplinary, collaborative, and cooperative interrelationships, and any alterations in the original NORC design to meet the evolving needs of the research base. These accomplishments should be presented, as appropriate, in the areas of basic science, clinical research, public health, prevention, and translational research. Since one of the objectives of the NORC is to extend research relevant to nutrition/obesity, new areas of research and acquisition of new funding should be highlighted in the overview.

Letters of Support: Include any letters of support for the proposed NORC by appropriate institutional officials.

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).

Other Plan(s):

All instructions in the How to Apply- Application Guide (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). 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); 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) 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), 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) must be followed.

Delayed Onset Study

Note: Delayed onset (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) 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)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)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 'NORC Director(s)' 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.
- In this component, also provide biographical sketches for any consultants, i.e, for Internal or External Advisory Committees/Boards. For **renewal applications only**, provide biographical sketches for the members of the External Advisory committee (EAC). In the additional Senior/Key Profiles section, list these Senior/Key persons in the Project Role of 'Other' with Category of 'Consultant,' or 'Advisory Committee.' **New applications should NOT provide names or biosketches for External Advisory Committee members**. Overall qualifications and areas of scientific expertise for the EAC members may be included.

Budget (Administrative Core)

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

Personnel: The Center Director must devote a minimum of 2.4 person months to the NORC and at least 1.2 of those months must be within the Administrative Core to ensure adequate oversight of the NORC. In a multiple-PD/PI application, the combined effort of the PD(s)/PI(s) must be 2.4 person months. Most NORCs find that the size and complexity of a NORC warrant inclusion of a program administrator, so salary support for this individual should be included in the Administrative Core.This category should also include salary support for any additional key personnel, including the Scientific Catalyst Program Director and any other professional and administrative personnel.

Equipment: If pieces of specialized equipment or computers costing more than $5,000 are requested, the application must identify similar equipment already available within the institution and provide a clear justification for purchase based on core service provided to NORC investigators. Requests for general-purpose equipment should be included only after ascertaining the availability of such items within the institution. Justify the request based on this availability. Equipment may only be requested in the initial budget period.

Travel: Include the costs of domestic and foreign travel only if the travel is directly related to the activities of the NORC. Include travel costs for the NORC Director, Associate Director, Program Administrator, and others as appropriate (i.e., Core Directors) to attend in-person NORC meetings held every 12 months. Travel funds to support visiting scientists under the auspices of the Scientific Catalyst Program may be requested.

Supplies: Consumable supplies directly related to the operational aspects of the Administrative Core facilities are an allowable expense.

Consultants: Include costs associated with consultants (consultant fees, per diem, virtual meetings, and travel, if applicable) when their services are required by the NORC, such as the members of the External Advisory Board. Include costs associated with consultants (e.g., consultant fees/honoraria, per diem, and teleconferences) when their services are required by the Scientific Catalyst Program.

Alterations and Renovations: Funds for the alteration and renovation of an existing structure to provide suitable space for core facilities may be requested. 'Cosmetic' renovations are not appropriate.

Other Expenses: Funds for development/maintenance of the NORC's website may be requested.

Include funds to support Scientific Catalyst Program activities such as workshops, research fora, symposia, NORC retreats and seminar series. Funds for Scientific Catalyst Program-associated activities such as the printing and distribution of brochures, programs, and meeting materials, as well as posters and other advertisement materials, may be requested.

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)

Introduction to Application: For Re-submission applications, an Introduction to Application is allowed for each component.

Specific Aims: Clearly state how the Administrative Core will contribute to the goals of the NORC and outline interactions of the Administrative Core with each of the other Cores and Programs (P and F and Scientific Catalyst). Provide an overview of how the Administrative Core will set the overall direction of the Center and ensure optimal utilization of NORC resources. Provide a description of the objectives and operation of the Scientific Catalyst Program..

Research Strategy: The NORC must be an identifiable organizational unit within a university or academic medical center or a consortium of cooperating institutions including the university-affiliated NORC. The Administrative Core plays a key role in the coordination and functioning of the NORC.

Within the Research Strategy, the applicant should describe how the leadership of the Administrative Core are appropriate and capable of assuring the synthesis of findings and activities from research projects and cores towards solving the central problem proposed by the NORC. In addition, direct lines of communication between the Administrative Core, Biomedical Research Cores, the P and F Program, and the Scientific Catalyst Program should be delineated, as all of these cores/programs serve critical roles for NORC integration. A process must be in place, and should be described in the application, that would be used to recommend a successor to the Director, if needed.

Clinical Element (required)- Provide an overview of how the Administrative Core of the NORC will support and encourage clinical/translational research. Clinical/translational services may be provided within the Administrative Core, a Biomedical Research Core(s), or a combination thereof. A summary of the services, relevant personnel, as well as the number of physician scientists and/or translational scientists who will make use of available/relevant clinical research services should be addressed. Any efforts to encourage collaboration between NORC clinical and basic science investigators should be described in the Clinical Element. Refer to, but do not duplicate, information provided within biomedical research cores that have a clinical/translational research focus.

NORC Evolution: Applicants must describe policies and procedures for ensuring continuing evolution of NORC activities, such as core services, in response to changing needs. NORCs should address the issue of allocation of resources to development of new technologies versus provision of services with existing technologies.

The administrative structure must include an Internal Advisory Committee (IAC) and an External Advisory Committee (EAC). **New applications should NOT list members of the EAC** but should describe what expertise is needed and the process by which they will be selected should be described. Renewal applications should provide information on membership of the IAC/EAC and must document the functions and effectiveness of the External and Internal Advisory Committees. NORCs may consider development of a Community Advisory Board or community members/patient advocates serving on the IAC and/or EAC.

The Administrative Core is also expected to provide support for a NORC Scientific Catalyst program. Applicants should discuss how the Scientific Catalyst Program will advance translational research in nutrition and obesity and promote scientific exchange among investigators with research interests in these topic areas, and to enhance interactions between nutrition and obesity researchers from other fields with relevant expertise. The Scientific Catalyst program can support activities such as seminars, guest speakers, visiting

scientists, consultants, and workshops. NORC applicants should provide information on nutrition/obesity-related NIDDK or other NIH Institute T32 programs at the NORC institution(s), and describe how the NORC will help to integrate, facilitate and enhance activities of any T32-supported trainees, if appropriate.

Letters of Support: Include any letters of support for the proposed Administrative Core, as appropriate. Include any letters of support from community members who serve on the IAC or Community Advisory Board (CAB), as applicable. Letters from members of CABs dedicated to specific Cores should be included in that Core's Letters of Support.

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), with the following modification:

Generally, Resource Sharing Plans are expected, but they are not applicable for this component.

Other Plan(s):

All instructions in the How to Apply - Application Guide (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); 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) 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/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) must be followed.

Delayed Onset Study

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

Biomedical Research Core

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

All instructions in the How to Apply- Application Guide (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 (Biomedical Research 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 (Biomedical Research Core)

Follow standard instructions.

Research & Related Other Project Information (Biomedical Research 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.

Facilities and Other Resources: The description of the physical arrangements and instrumentation for the cores should be given special attention. Arrangements for sufficient space for core activities or for access to appropriate established facilities must be made. NORCs may enter into cooperative arrangements with cores already established within their institution, or with other NORCs/Centers, when the existing cores offer the services needed. These arrangements are important whenever greater efficiency or cost savings can be realized by such an agreement. When proposing the use of a shared facility, details about access, fee-schedules, and prioritization of NORC members' use of the shared facility must be described. It may be advantageous for a NORC to provide additional support for appropriate personnel to work specifically for NORC members in an existing facility/core (e.g., animal facility) at the institution. In that case, the designated NORC Core Director must work closely with the parent facility Core Director to coordinate services, unless the same individual assumes both roles.

Other Attachments: The following attachment must be included to aid in the review of applications. The filename provided for the attachment will be the name used for the bookmark in the application image. The attachment should be in .pdf format.

Core Facility Use: (Required, up to 3 pages per Biomedical Research Core). Please title this attachment "Core Facility Use" and indicate the types of services available, funded researchers using the cores, the period of core use, and estimate of actual use (for renewal applications) or estimated use (for new applications) Identify in **bold** core users who are research base members. Renewal applications may describe productivity within a biomedical core that was discontinued during the prior project period. The prior use of the discontinued core may be presented in a Table(s).

Project /Performance Site Location(s) (Biomedical Research 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 (Biomedical Research Core)

- In the Project Director/Principal Investigator section of the form, use Project Role of 'Other' with Category of 'Core Director(s)' 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. Do not duplicate biosketches.
- If more than 100 Senior/Key persons are included in a component, the Additional Senior Key Person attachments should be used.

Budget (Biomedical Research Core)

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

Personnel: This category should include salary support for key personnel, including the core director, co-director(s), and other professional and technical personnel. The Core Director must devote a minimum of 1.2 person months to the Core to ensure adequate oversight. The salary amount charged to the NORC grant must be commensurate with the time spent on Core activities and is subject to institutional and NIH salary policies. A Core Director with requisite expertise may devote a greater effort to the core and with exceptionally strong justification could devote up to 12 person months. Salary support for technicians and other core personnel is allowable in accordance with the volume and type of work in the core. Stipends (and tuition) for research trainees (e.g. graduate students, postdoctoral fellows) are not available through the NORC. Such funding must be sought through other grant mechanisms.

Equipment: If specialized equipment costing more than $5,000 per piece is requested, the application must identify similar equipment already available within the institution. Requests for general-purpose equipment should be included only after ascertaining the availability of such items within the institution. Justify the request based on this availability. This includes all equipment in future budget years as well as the initial budget period.

Travel: Funds for NORC investigators/faculty to attend national or international scientific meetings or workshops aside from annual NORC meetings may not be requested. If well-justified and related directly to Core activities/functions, limited travel funds for Core professional staff may be requested to support travel to national scientific meetings/workshops.

Supplies: Consumable supplies directly related to the operational aspects of the NORC core facilities are an allowable expense. This includes office materials as well as laboratory supplies. The supply budgets of separately funded individual research projects must be appropriately reduced to reflect such support, thus eliminating duplication.

Research Patient Care Costs: Research patient care costs (both in-patient and out-patient) are an allowable expense. Attempts should be made to utilize existing clinical facilities, such as those supported by Clinical and Translational Science Awards (CTSAs) and individually supported beds. If the CTSA is to be used, include a letter of agreement from the PD/PI of the CTSA; such a letter (in .pdf format) may be attached as a 'Letter of support' for the appropriate Biomedical Research Core(s).

Request costs relating to the clinical research efforts of NORC investigators ONLY if there is no overlap with other funding. Costs already budgeted in individual projects should be appropriately reduced if such costs are to be transferred to the Center. NORCs are not intended to serve as a facility for health care delivery. Thus, only those patient costs directly related to research activities may be charged to the NORC.

Other Expenses: Funds for equipment maintenance/service contracts may be requested but should reflect only an equivalent percentage of the service contract based on the overall use of the specified equipment by NORC members versus other users. The budget justification for any maintenance/service contracts should document usage of the equipment by NORC members. Only in very rare cases should full support for a maintenance/service contract be requested, and strong justification must be provided in such cases.

Alterations and Renovations: Funds for the alteration and renovation of an existing structure to provide suitable space for core facilities may be requested. 'Cosmetic' renovations are not appropriate.

Consultants: Include costs associated with consultants (e.g., consultant fees, per diem, virtual meeting attendance, and travel) when their services are required by the core.

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 (Biomedical Research Core)

Introduction to Application: For Re-submission applications, an Introduction to Application is allowed for each component.

Specific Aims: Clearly state the aims of the Biomedical Research Core.

Research Strategy: A biomedical research core is a shared facility designed to furnish a group of investigators with materials, techniques, determinations, instrumentations, and/or quality control to enhance research and contribute to cost-effectiveness. A Core may be proposed to support any research activity of the NORC but usually falls into one of five categories: (1) provision of a technology that lends itself to automation or preparation in large batches; (2) complex instrumentation; (3) animal preparation, care, and characterization; (4) clinical resources; and (5) services, including study design, statistical support, and training. Limited developmental research is also an appropriate function of a core facility. Such activities, however, must be directly related to enhancing the function or utility of the Core.

The need for core support from the NORC must be well justified, with clear documentation of a broad user base of federally-funded investigators pursuing research activities in NORC topic areas, as well as nutrition/obesity investigators with other sources of peer-reviewed support. Provide the rationale for establishing or continuing the core and the activities of the core.The description of the Core should indicate how it will support the NORC's research effort in a cost-effective manner. Include a definition of qualified users and overview of research base investigators who will use the core, including the expected extent of their proposed use. The Core must be utilized by a minimum of two federally funded investigators who are NORC members. Criteria for use and for prioritization must be included in the application. The application should also describe the process for assuring that all the research cores meet evolving needs of the research base. In addition, if NORCs provide any discounts for core use by NORC members.

Each core must have an operational plan which must include methods to:

- Assure quality control;
- Prioritize investigator use;
- Monitor core use; and
- Adapt to new technology based on the needs of the NORC members.

NORCs are encouraged to enter cooperative arrangements with cores already established within their institution or with other NORCs or Centers, when the existing cores offer the services needed. These arrangements are important whenever greater efficiency or cost savings can be realized by such an agreement. It may be advantageous for a NORC to provide support for appropriate personnel to work specifically for NORC members in an existing facility/core (e.g., transgenic animal core) at the institution. In this case, the designated NORC Core Director must work closely with the parent facility Core Director to coordinate services, unless the same individual assumes both roles. A financial justification, such as comparative costs of other sources of proposed core services from users should be detailed. Plans for cost recovery should be detailed.

For NORCs proposing to join an institutionally-shared research core, a clear rationale must be described, including but not limited to the following:

- Support for the existing resource through the NORC will provide added value and access to the resource beyond that which would be provided by paying for the use of the resource through a fee-for-service process, and/or the NORC would expand the services available within that core;
- The institutional/departmental core represents a unique resource which would not otherwise be available (e.g., is too costly, too labor-intensive, or too specialized to be available to individuals);

- The institutional/departmental core provides a service done more effectively (i.e., more inexpensively or by specially trained personnel or requiring specialized facilities) than would be feasible in individual cores, e.g., histology, animal facilities, and thus using the institutional/shared core avoids duplication and lowers cost for NORC-center members; and/or
- The service/instrumentation/expertise in the centralized core can only exist with the participation of multiple centers and their user fees and NORC members need the service; instrumentation, and/or expertise in proportion to the buy-in from the center to which they belong; and
- NORC members would receive priority access to the institutional core.

When a NORC proposes to join an institutional or shared core, the application must describe how the research base members benefit **beyond** gaining access to pre-existing services already available to them through an established fee-for-service or charge-back system. The potential for overlap should be addressed, and it should be clear that the NORC works appropriately with the institutional Core Director/staff and has a role in oversight, management, and prioritization of core and service utilization. The description of the institutional/shared cores should include information related to access, fee-schedules, the prioritization plan, quality control, and the methods to monitor use of the shared core by the NORC research base.

Program Income: NORCs are encouraged, where appropriate, to develop a program income (re-charge/fee-for-service) system for use of core services. Such a program income system would constitute a method of charging core users for their usage of expertise and research resources. Program income must be re-invested in direct support of NORC - related activities and/or expenses and may not generate a profit for the NORC.

Renewal applications only: Past performance and accomplishments should be described and highlighted. The effect of the service provided by a core on investigator productivity and cost-effectiveness should also be addressed. If a research core that was supported during the prior project period has been discontinued or substantially modified, the rationale for that change and past performance of the core should be appropriately described.

Letters of Support: For any collaborative linkages between the CTSA and a specific Biomedical Research Core, a letter of support should be included within the specific Biomedical Research Core component of the application. Also provide letters to address the career potential of and institutional commitment to junior scientists who serve as core managers/technical directors. In addition, other letters of support for the proposed Core may be included, as appropriate.

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), with the following modification:

Generally, Resource Sharing Plans are expected, but they are not applicable for this component.

Other Plan(s):

All instructions in the How to Apply - Application Guide (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); 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) instructions.

PHS Human Subjects and Clinical Trials Information (Biomedical Research 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) 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) must be followed.

Delayed Onset Study

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

Pilot and Feasibility Program

When preparing your application, use Component Type 'P and F Program'

All instructions in the How to Apply- Application Guide (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 (P and F Program)

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 (P and F Program)

Follow standard instructions.

Research & Related Other Project Information (P and F Program)

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.

Other Attachments: The following attachments must be included in order to aid in the review of applications. The filename provided for each attachment will be the name used for the bookmark in the application image. All attachments should be in .pdf format.

Pilot Project Outcomes (renewal applications only) (Required, limited to 6 pages): Please title this attachment "Pilot Project Outcomes" and list all Pilot Projects supported in full, or in part, by the NORC during the most recent 5 years. NORCs with 10 or more years of continuous funding may elect to provide information on the most recent 10-year period. Include the name of P & F recipient , years funded, dates and amount of P and F funding, pilot project title and brief description of the project, P and F recipienttype (i.e., new investigator; established investigator), numbers of abstracts and publications derived from pilot support, grants funded or pending applications (including grant number/funding agency and project period), and whether the P and F recipient is still involved in nutrition/obesity research.

Project /Performance Site Location(s) (P and F Program)

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 (P and F Program)

- In the Project Director/Principal Investigator section of the form, use Project Role of 'Other' with Category of 'P and F Program Director(s)' 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. Do not duplicate biosketches.
- If more than 100 Senior/Key persons are included in a component, the Additional Senior Key Person attachments should be used.

Budget (P and F Program)

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

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.

Personnel: This category should include salary support for key personnel, including the P and F Program Director, and other professional and administrative personnel. The P and F Program Director must devote a minimum of 0.6 calendar months to the Program to ensure adequate oversight. The salary amount charged to the Nutrition Obesity Research Center grant must be commensurate with the time spent on P and F Program activities and is subject to institutional and NIH salary policies.

Other Expenses: Include funds to support individual Pilot and Feasibility projects. Typically, at least 20-25% of the overall Center direct costs, exclusive of equipment, should be for support of P and F projects. It is anticipated that up to $50,000 in direct costs per year for up to two years will be provided for the majority of approved P and F projects. However, a limited number of P and F applications may be selected for support as enhanced P and F awards with prior NIDDK approval. These enhanced awards may be funded at up to $100,000 direct costs per year and for up to two years. Efforts to increase the number of P and F awards and availability of funds for the program using program income or alternative funding sources are particularly encouraged. Allowable expenses for P&F awards are at the discretion of the institution. P&F awards may provide salary support for the P&F recipients along with other expenses as appropriate for the project.

Consultants: Include costs associated with consultants (e.g., consultant fees/stipends, per diem, and teleconferences) when their services are required by the Pilot and Feasibility Program, such as any external reviewers for P and F applications.

PHS 398 Research Plan (P and F Program)

Introduction to Application: For Re-submission applications, an Introduction to Application is allowed for each component.

Specific Aims: Clearly state the aims of the Pilot and Feasibility Program.

Research Strategy: Describe the overall goals and structure of the Pilot and Feasibility Program. NORCs are required to propose a minimum of 2 pilot and feasibility studies to be supported from NIDDK funds each year.

P and F award eligibility and related guidelines: Investigators eligible for pilot and feasibility funding generally fall into three categories: (1) new investigators without current or past NIH research support as a PD/PI (current or past support from other sources should have been modest); (2) established investigators who will have no independent R01 or R01-equivalent grant support if they do not secure a substantial grant award in the near future; and (3) investigators from other areas of biomedical research to apply their expertise to an area of need in nutrition and obesity research. It is expected that the majority of the investigators will fall into the first category and in only rare cases will projects in category 3 be funded. Each pilot and feasibility study proposal should clearly state the justification for eligibility of the investigator under one of the above three criteria. P and F awards are not intended to serve as 'bridge' funding for established nutrition/obesity researchers who may be experiencing a gap in research funding.

A proposed pilot and feasibility study should present a testable hypothesis and clearly delineate the question being asked, detail the procedures and approaches to be followed, and discuss how the data will be analyzed. It must be on a topic related to the objectives of the Center. Individual investigators are eligible only once for this P and F support unless the additional proposed pilot and feasibility study constitutes a real departure from his/her ongoing research.The application should clearly describe and justify the pool from which potential pilot and feasibility applications will be selected. Applicants should propose and describe specific metrics for assessing the productivity and success of the P&F program, which may include, but is not limited to outcomes such as publications, grant applications submitted to Federal or other organizations and foundations, grant awards, jobs or promotions, and whether recipients have remained in nutrition/obesity research. A NORC may elect to pursue the goal of enhancing the next generation of nutrition and obesity researchers who are earlier in their career trajectory, i.e., senior post-doctoral fellows intending to pursue research careers.

Each Center must propose a minimum of 2 pilot and feasibility studies to be supported from NORC funds each year. Renewals of pilot and feasibility awards are allowed and do not have to occur in consecutive years; gaps between the first and second year of a P&F project, as appropriate for the project, are permitted.

The major responsibilities of the P and F Program Director and the committee will be to:

(1) Prepare and ensure appropriate distribution of announcements of the availability of pilot and feasibility funding to all eligible applicants;

(2) Arrange and preside over the scientific merit review of proposals. At least one reviewer from outside the parent institution must be used for each proposal. All reviewers should assign impact scores in accordance with the NIH system. Copies of all of the proposals with written documentation of their reviews, impact scores, and final action must be retained by the Center. These records should be available to NIH staff, if requested. The application should explain how the review process will be free of bias and aligned with the P and F program's vision or mission statement.

(3) Maintain oversight and review of progress for ongoing pilot and feasibility studies;

(4) Make recommendations to the Center for final funding decisions. A record of actions by this committee must be documented;

(6) Develop and maintain a mechanism for the oversight and review of ongoing P and F projects; this is especially important as a requirement for a second year of P and F support;

(7) Make recommendations regarding termination or other actions to the Center; and

(8) Maintain, insofar as it is possible, a record of subsequent career events of each pilot and feasibility study recipient. This record must also be made available to reviewers at the time of the renewal application.

For applications proposing P and F Programs that will accept projects that include Delayed Onset Human Subjects Research or Delayed Onset Clinical Trials, a plan to assure compliance with applicable federal regulations and NIH policies for the protection of human research participants, including the evaluation of risks and protections in project proposals, appropriate ethical oversight of funded projects, and plans for monitoring data and safety in clinical research projects should be included.

Pilot and feasibility program in new applications: Provide relevant information on potentially eligible investigators at the applicant institution/consortium who might compete for P&F awards, how the funding opportunity would be promoted, and any proposed or funded projects that have been submitted or awarded, if relevant. Although not required, any funded projects should be the best applications received by the NORC should be reviewed in the manner proposed for all future P and F applications.

Pilot and feasibility program in renewal applications: In general, a renewal application should include: (1) an historical overview; (2) a description of the management of the program; (3) a description of the method for solicitation for pilot and feasibility projects and the number of respondents received for each solicitation; and (4) a statement of the benefits of the program to the Center and the nutrition/obesity community more broadly as well as the contribution of the uniqueness of the Center environment to the program. The historical overview should cover the pilot and feasibility program since the inception of the Center.

Oversight Plan for NORC P&F Programs involving HS research (required):

Although all P&F projects should be monitored for productivity, NORCs that fund P&F projects involving Humans Subjects Research must develop a detailed, formal plan for assuring compliance with all relevant NIH regulations. The plans for implementation of this oversight plan must be included in the application, as appropriate for either clinical studies or clinical trials. Do not duplicate information already provided in the PHS Human Subjects Clinical Trial Information form.

The following elements or procedures are required as part of the oversight plan:

- Development and implementation of appropriate data and safety monitoring plans,
- Documentation of IRB approval,
- Registration of all clinical trials in https://clinicaltrials.gov/ (https://clinicaltrials.gov/)
- Development and monitoring of appropriate milestones,
- Oversight of participant recruitment and retention,
- Results reporting in https://clinicaltrials.gov/ (https://clinicaltrials.gov/) as appropriate, and
- Planning for dissemination of research results.

Letters of Support: Include any letters of support for the Pilot and Feasibility Program by appropriate institutional officials at partnering organizations (other than the parent institution), if applicable.

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), 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) 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); 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) instructions.

PHS Human Subjects and Clinical Trials Information (P and F Program)

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) 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) must be followed.

Delayed Onset Study

Note: Delayed onset (https://grants.nih.gov/grants/glossary.htm#DelayedOnsetHumanSubjectStudy) does NOT apply to a study that can be described but will not start immediately (i.e., delayed start). All instructions in the How to Apply- Application Guide (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), 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) (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), 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).

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)

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).

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).

Pre-award costs are allowable only as described in the NIH Grants Policy Statement (http://grants.nih.gov/grants/guide/url_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)

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/url_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/url_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) 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/url_redirect.htm?id=82400).

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

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

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) and NIH Grants Policy Statement Section 4.1.35 (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/) 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/url_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/url_redirect.htm?id=11149) are evaluated for scientific and technical merit through the NIH peer review system.

For these P30 Center applications, reviewers will be asked to evaluate the following individual sections. The overall impact score is not the average of the scores for all these components.

- *Research base*, including the focus, quality of research base, collaborations among members, relevance to the NORC's stated research focus, and, for renewal applications, the stability or growth, re-focusing, or evolution of the research base.
- Each *Biomedical Research Core*, including the documented need for the proposed services; number of users; qualifications of personnel; management, including prioritization and responsiveness to the needs of the users; quality control management; and any appropriate developmental work.
- *Administrative Core*, including NORC Director(s), committee structure, NORC membership criteria, and lines of communication. The appropriateness and caliber of support for clinical research will be evaluated. The quality of the Scientific Catalyst Program, including the quality of proposed activities and likelihood for promoting new scientific collaborations and directions/approaches will also be assessed. Support for clinical research will be evaluated.
- *Pilot and Feasibility Program*, including the organization of the overall process of solicitation, review, and monitoring of P and F projects, and for renewal applications the quality, appropriateness and outcomes of supported P and F projects. The Named New Investigator, if requested, will also enter into this evaluation.

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

Overall Impact - Overall

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

Scored Review Criteria - Overall

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

Significance

Does the project address an important problem or a critical barrier to progress in the field? Is the prior research that serves as the key support for the proposed project rigorous? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Specific to this NOFO: How strong is the Center as a whole, including the quality of the research base (its breadth and depth); the research services provided? To what extent will the Center members benefit from the research core services and other required programs supported by the NORC? Are the Administrative Core, the Biomedical Research cores; the P&F program, and the Scientific Catalyst Program appropriate and well-integrated into the Center? Will all of the research cores, the P&F program, and the Scientific Catalyst Program be operated in a rigorous manner with appropriate oversight and quality assurance methods? Will the NORC and the research cores appropriately support the clinical research conducted by the research base and the P&F recipients? What is the likelihood that the NORC and all of its components will increase efficiency; facilitate interactions and collaborations among the investigators; encourage new research directions; support new investigators through the P and F Program; and prove cost-effective? If collaborations with other NORCs or individuals outside of the research base are described, how do they benefit the Center? For example, do they enhance the productivity or quality of the research base; enhance the services offered by the NORC; strengthen the Scientific Catalyst Program; allow for a more efficient use of the NORC's available resources; or otherwise benefit the research base?

In addition, for applications involving clinical trials

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

Investigator(s)

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

Specific to this NOFO: Are the NORC Directors and Core/Program Directors able to devote adequate time to provide effective management of the Center program? Is the plan for communication amongst the NORC Director(s), Core Directors, and other Program Directors appropriate? Are the roles and qualifications of the proposed internal and external Advisory Boards clear and appropriate for effective oversight of the NORC? Is there a succession plan should the NORC Director(s) leave or otherwise not be able to lead the NORC?

In addition, for applications involving clinical trials

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

Innovation

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Specific to this NOFO: To what extent do all of the proposed Cores provide the appropriate resources, technical support, and new methods that will advance the Center members' research? Does the NORC demonstrate the ability or have a plan to adapt to support investigators in emerging areas of nutrition and obesity research, as appropriate to the purpose of the Core and the research supported by the Center? How successfully does the Center appear to encourage innovative ideas and approaches through their P and F Program and Scientific Catalyst Program?

In addition, for applications involving clinical trials

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

Does the project use innovative designs such as platform trials, real-time adaptive methods, seamless Phase I/II designs, Bayesian designs or decentralized trial elements, as applicable?

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: To what extent will the Cores benefit the research base/users by providing opportunities not otherwise available to the members of the NORC? How appropriate is the administrative organization proposed for internal oversight, communication, and collaboration between center members? How clear and appropriate are the criteria for membership in the NORC? Are the professional or technical expertise for all of the cores/services appropriate for the NORC? How appropriate is the administrative organization proposed for the following: (a) coordination of ongoing research between the separately funded projects and the NORC, including mechanisms for internal monitoring; (b) establishment and maintenance of internal communication and cooperation among the Center investigators; (c) selecting and replacing professional or technical personnel within the Cores; and (d) managing resources, including fiscal administration, procurement, property and personnel management, planning, budgeting, and other appropriate capabilities?

How appropriate are the modes of operation for the NORC as a whole across all of the components (Admin. Core, Biomedical Research Cores, P&F program, and Scientific Catalyst Program), including the funding model, quality control, prioritization of requests for services, and interaction with other institutional cores or Centers/CTSAs, etc.? Are there any significant weaknesses in any of the biomedical cores, the P&F Program, and/or the Scientific Catalyst Program? How strong and productive will the P&F program be? Will the planned use of the limited Scientific Catalyst funds contribute to the stated goals of the NORC and development of the nutrition and obesity research workforce more broadly?

In addition, for applications involving clinical trials

Does the application adequately address the following, if applicable

Study Design

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

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

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

Data Management and Statistical Analysis

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

Environment

Will the 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: How supportive is the institutional commitment to the NORC's management and scientific impact?

In addition, for applications involving clinical trials

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

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

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

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

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 core or program that by its nature is not innovative may be essential to advance the field and the NORC as a whole.

Scored Review Criteria - Overall

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: What are the strengths of the Center's research base (its breadth and depth)? To what extent are the Center's research base/members aligned with the theme of the NORC (if provided) and the research core services/programs supported by the NORC? What is the likelihood that the research base will interact and develop or continue collaborations and encourage new research directions? For example, how do those collaborations enhance the productivity or quality of the research base; enhance the services offered by the NORC; allow for a more efficient use of the NORC's available resources; or otherwise benefit the research base? How strong is the administrative oversight plan, including internal and external Advisory Boards? How appropriate is the P&F program for advancing the careers and scientific productivity of P&F program recipients? How aligned is the Scientific Catalyst program with the goals of the Center?

In addition, for applications involving clinical trials

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

Investigator(s)

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

Specific to this NOFO: Is there an existing funded research base of relevance to nutrition and obesity, and has the research base demonstrated a strong contribution to the advancement of nutrition and/or obesity research? Are the research base members appropriate users for each of the proposed cores and Programs? Do they demonstrate existing or the potential for future collaborations?

In addition, for applications involving clinical trials

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

Innovation

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Specific to this NOFO: How innovative is the research conducted by the research base/Center members and how likely is the NORC to enhance and advance nutrition and obesity research? To what extent will the research base benefit from the overall resources, technical support, and new methods that will advance the Center members' research? Does the NORC demonstrate the ability or have a plan to adapt to support the research base members in emerging areas of nutrition and obesity research, as appropriate to the purpose of the Core and the research supported by the Center?

In addition, for applications involving clinical trials

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

Approach

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

If the project involves human subjects and/or NIH-defined clinical research, are the plans to address:

1) the protection of human subjects from research risks, and
2) inclusion (or exclusion) of individuals on the basis of sex, 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: To what extent will the research base/users and P&F recipients benefit from opportunities and services provided by the NORC that are not otherwise available at the institution/consortium, i.e., institutional cores, Centers, and/or CTSAs? How clear, appropriate, and free of bias are the criteria for membership in the NORC? Are the criteria for terminating membership appropriate, if applicable?

In addition, for applications involving clinical trials

Does the application adequately address the following, if applicable

Study Design

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

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

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

Data Management and Statistical Analysis

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

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: How supportive is the institutional commitment to the NORC's research base? How strong is the potential for scientific interactions?

In addition, for applications involving clinical trials

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

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

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

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

Scored Review Criteria - Research Core

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: What are the strengths of the proposed Research Cores? Are the individual Research Core's services appropriate for the Center's research base? What is the likelihood that the proposed research cores will increase efficiency, quality, and productivity? Are the research cores likely to facilitate interactions and collaborations among the

investigators? If a research core leverages or resides within an institutional core, will the NORC members benefit beyond what is already available through fee-for-service or other access models within other Centers, CTSAs, or other cores/service centers at the institution or consortium?

In addition, for applications involving clinical trials

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

Investigator(s)

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

Specific to this NOFO: Are the identified core users likely to use all of the proposed core services? Is the Core Director(s) able to devote adequate time to provide effective management of the Center program?

In addition, for applications involving clinical trials

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

Innovation

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Specific to this NOFO: To what extent do the proposed Research Cores provide the latest or state-of-the-art resources, technical support, and new methods that will advance the Center members' research? Does the NORC demonstrate the ability or have a plan to adapt to support investigators in emerging areas of nutrition and obesity research, as appropriate to the purpose of the Core and the research supported by the Center?

In addition, for applications involving clinical trials

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

Approach

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

If the project involves human subjects and/or NIH-defined clinical research, are the plans to address:

1) the protection of human subjects from research risks, and
2) inclusion (or exclusion) of individuals on the basis of sex, 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: To what extent will the individual Cores benefit the research base/users by providing opportunities not otherwise available to the members of the NORC? Are the professional or technical expertise (beyond the Core Director(s)) for specific cores/services appropriate for the NORC? How appropriate are the modes of operation and oversight for the Research Cores, including the funding model, quality control, prioritization of requests for services, and interaction with other institutional cores or Centers/CTSAs, etc.? If a research core leverages or resides within an institutional core, is there a plan for prioritization of access for NORC members, and do the NORC Core Director(s) play a leadership role in the institutional core?

In addition, for applications involving clinical trials

Does the application adequately address the following, if applicable

Study Design

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

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

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

Data Management and Statistical Analysis

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

Environment

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

In addition, for applications involving clinical trials

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

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

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

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

Scored Review Criteria - Admin. Core

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: How strong is the clinical element, are the proposed services appropriate and likely to be used, and will they advance clinical research? Will the internal and External Advisory Board contribute to the oversight and strength of the NORC? Will the Scientific Catalyst program further the overall aims and objectives of the NORC program as well as its cores?

In addition, for applications involving clinical trials

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

Investigator(s)

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

Specific to this NOFO: Are the members of the internal Advisory Board and the External Advisory Board (if identified) well-suited for the overall oversight and management of the Center? For Centers that do not name members of the External Advisory Board (i.e., new Centers), are the proposed areas of expertise for future members well-justified?

In addition, for applications involving clinical trials

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

Innovation

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

In addition, for applications involving clinical trials

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

Approach

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

If the project involves human subjects and/or NIH-defined clinical research, are the plans to address:

1) the protection of human subjects from research risks, and
2) inclusion (or exclusion) of individuals on the basis of sex, 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: How appropriate is the administrative organization proposed for the following: (a) coordination of ongoing research between the separately funded projects and the NORC, including mechanisms for internal monitoring; (b) establishment and maintenance of internal communication and cooperation among the Center investigators; (c) selecting and replacing professional or technical personnel within the Cores; and (d) managing resources, including fiscal administration, procurement, property and personnel management, planning, budgeting, and other appropriate capabilities? Are the research services provided as described in the Clinical Element and across the NORC holistically appropriate for the research base and likely to advance clinical research? How strong is the potential for scientific interactions as part of the Scientific Catalyst Program amongst the Center members, early career investigators, and trainees?

In addition, for applications involving clinical trials

Does the application adequately address the following, if applicable

Study Design

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

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

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

Data Management and Statistical Analysis

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

Environment

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

In addition, for applications involving clinical trials

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

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

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

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

Scored Review Criteria -P&F Program

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: Is the pool from which potential pilot and feasibility applications reasonable and well-justified? Are the metrics for assessing the productivity and success of the P&F program appropriate and reasonable? Are all aspects of the Center involved and able to assist the P and F Director in the management of the program? Will the P&F program invite and support projects across the full research spectrum from basic science and pre-clinical to implementation research? Is there a strong mentoring plan for P&F recipients?

In addition, for applications involving clinical trials

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

Investigator(s)

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

Specific to this NOFO: Is the P&F Program Director able to devote adequate time to provide effective management of the P&F Program? Does the P&F Program Director have a track record of mentoring junior investigators and/or P&F program recipients?

In addition, for applications involving clinical trials

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

Innovation

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Specific to this NOFO: Do the P&F Program leadership demonstrate the ability or have a plan to adapt to support investigators in emerging areas of nutrition and obesity research? How likely is the P&F program to support new investigators and encourage new research directions?

In addition, for applications involving clinical trials

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

Approach

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

If the project involves human subjects and/or NIH-defined clinical research, are the plans to address:

1) the protection of human subjects from research risks, and
2) inclusion (or exclusion) of individuals on the basis of sex, 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: How well does the P and F Program's vision or mission statement reflect the overall Center's goals and inform the Program's processes?How appropriate and transparent are the processes for soliciting, evaluating, and selecting the P and F projects? Is the solicitation process likely to reach the appropriate pool of potential candidates who have the potential to advance nutrition and obesity research? Are the evaluation and selection processes free of bias and likely to lead to awards for strong applications? Is a mentoring approach described, and if so, is it likely to benefit the P&F recipients? How appropriate is the administrative organization proposed for internal oversight, communication, tracking, and evaluation of the P&F program? Is the potential available funding for individual P&F projects well-justified and appropriate for the type of projects that the NORC is likely to fund? Is there a strong plan for mentoring P&F recipients?

In addition, for applications involving clinical trials

Does the application adequately address the following, if applicable

Study Design

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

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

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

Data Management and Statistical Analysis

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

Environment

Will the 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: How supportive is the leadership of the institution to the NORC P&F program, including recipients?

In addition, for applications involving clinical trials

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

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

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

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

Additional Review Criteria - Overall

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

Study Timeline

Specific to applications involving clinical trials

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

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

Protections for Human Subjects

For research that involves human subjects but does not involve one of the categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2)

adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the Guidelines for the Review of Human Subjects (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11175).

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).

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)

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.

Research Base: Does the Center show continued evidence of a strong research base with a consistent record of scientific excellence and achievement reflected in an outstanding level of productivity and success in securing peer-reviewed research funding? Does the Center show evidence of fostering multi-disciplinary collaborations among its Center investigators? Have such collaborations resulted in new research directions?

Biomedical Research Cores: Are the number and impact of research publications that acknowledge the Center sufficient to justify each core? Is there a significant fraction of papers that a) acknowledge the Center and b) do not have core personnel as co-authors? Are the number and listing of Center investigators who have used the core and resultant key advances consistent with the level of core investment? Do the number and listing of investigators who have used the core multiple times indicate satisfaction and continuing need for core services? Are there sufficient numbers of users who are not core personnel or their collaborators? Are the number and listing of users who are not Center personnel or members consistent with the best utilization of the core by the community? Are the numbers of services/tests completed by each core indicative of a growing need and sufficient to justify continued support? Is the capacity of each core with current resources sufficient to serve the needs of the Center community? Does the Center provide evidence of ability to evolve cores to meet changing needs of the research community? Does the Center provide evidence of Program Income and/or sufficient institutional support?

Administrative Core (including Scientific Catalyst Program and Clinical Component): Has the administrative structure proven effective? Has oversight of Center activities, including the P and F and Scientific Catalyst programs, been effective? Does the Center website show evidence of continuing maintenance and a high level of quality and usability? Has the Center fostered multidisciplinary approaches to nutrition/obesity research? Does the Center encourage and support high quality, productive clinical research? Has the Scientific Catalyst program fostered multidisciplinary approaches to nutrition/obesity research? Has the Scientific Catalyst Program attracted new investigators or trainees seeking to develop relevant expertise in nutrition/obesity research?

Pilot and Feasibility Program: Are the numbers and types of P and F awards well justified and related to the goals of the Center? Was the P and F program fully utilized during the previous project period? Were awards made to investigators who fully met the eligibility criteria (as described in the NOFO) for pilot and feasibility support? Is the oversight plan appropriate? Are data provided to document the outcome of all P and F projects completed in the last five years, including those that failed to lead to further funding? Has the P and F program led to publications of significant impact, subsequent independent peer-reviewed support, and/or attracted new and investigators into nutrition/obesity-related research? Are research papers generated under these awards, projects successfully funded with independent grants, and key advances linked to these awards well-documented and consistent with the level of support provided? For those Centers who provided P and F support to investigators new to nutrition/obesity research and/or to experienced nutrition/obesity researchers with innovative ideas, were the P and F recipients successful in their outcomes? If applicable, has the national/regional P and F program been effective as well as beneficial to both the Center and partnering institution(s)?

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)) 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) convened by CSR, in accordance with NIH peer review policies and practices (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11154), using the stated review criteria. Assignment to a Scientific Review Group will be shown in the eRA Commons.

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

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

Requests for reconsideration of initial peer review (https://grants.nih.gov/grants/policy/nihgps/html5/section_2/2.4.2_appeals_of_initial_scientific_review.htm) will not be accepted for applications submitted in response to this NOFO

Applications will be assigned on the basis of established PHS referral guidelines to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications submitted in response to this NOFO. Following initial peer review, recommended applications will receive a second level of review by the National Diabetes and Digestive and Kidney Disease Advisory Council. 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/url_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/url_redirect.htm?id=11123). Refer to Part 1 for dates for peer review, advisory council review, and earliest start date.

Information regarding the disposition of applications is available in the NIH Grants Policy Statement Section 2.4.4 Disposition of Applications (http://grants.nih.gov/grants/guide/url_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_the_notice_of_award.htm) and NIH Grants & Funding website, see Award Process. (https://grants.nih.gov/grants/pre-award-process.htm#award)

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

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

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

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

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

In accordance with NIH policy **http://grants.nih.gov/grants/policy/hs/index.htm** (https://grants.nih.gov/grants/policy/hs/index.htm)and the NIH Guide Announcement **NOT-OD-15-129** (https://grants.nih.gov/grants/guide/notice-files/not-od-15-129.html), the recipient institution is responsible for ensuring that all awarded P&F projects follow all relevant regulations and policies for Human Subjects Research. The following elements or procedures must be included in the recipient institution's P&F program oversight plan, as appropriate for all HS research inclusive of both clinical studies and clinical trials:

- Development and implementation of appropriate data and safety monitoring plans
- Documentation of IRB approval;

- Registration of all clinical trials in clinicaltrials.gov;
- Development and monitoring of appropriate milestones;
- Oversight of participant recruitment and retention;
- Results reporting in clincaltrials.gov, as appropriate; and
- Planning for dissemination of research results

Prior Approval of Pilot Projects

Recipient-selected projects that involve clinical trials or studies involving greater than minimal risk to human subjects require prior approval by NIH prior to initiation.

- 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).
- 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 (http://grants.nih.gov/grants/guide/url_redirect.htm?id=21600).

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), 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/url_redirect.htm?id=11120) 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/policy/nihgps/HTML5/part_ii_terms_and_conditions_of_nih_grant_awards.htm) and Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Recipients, and Activities (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11159).

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/policy/nihgps/HTML5/section_4/4_public_policy_requirements__objectives_and_other_appropriation_mandates.htm)

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-nihs-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), 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) 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 (cisa.gov) (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://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.samhsa.gov%2Fsites%2Fdefault%2Ffiles%2Fdear-colleague-letter-upated-hr-funding-guidance.pdf&data=05%7C02%7Cgary.marlowe%40nih.gov%7C0c3205f829f944888af908dea6141f06%7C14b77578977342d58507251ca2dc2b06%7C0%7C0%7C6391308025125161

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).

As of October 1, 2025, HHS has adopted 2 CFR 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://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.congress.gov%2Fbill%2F119th-congress%2Fhouse-bill%2F7148&data=05%7C02%7Cgary.marlowe%40nih.gov%7C65c08bc5f68f45573fec08deb06edc92%7C14b77578977342d58507251ca2dc2b06%7C0%7C0%7C6391421873455864 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.

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). 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) annually and financial statements as required in the NIH Grants Policy Statement Section 8.4.1 Reporting (http://grants.nih.gov/grants/guide/url_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/url_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). 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) - 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%7Cantoinette.caliman%40nih.gov%7Caf6dde64d644478d4e8b08dde6700581%7C14b77578977342d58507251ca2dc2b - Questions regarding Grants.gov registration and services (e.g., Workspace, subscriptions).

Scientific/Research Contact(s)

Division of Digestive Diseases and Nutrition
National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
Email:NIDDK_DDN@nih.gov (mailto:NIDDK_DDN@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)

Grants Management Branch
National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
Email:NIDDKGMBManagementTeam@niddk.nih.gov (mailto:NIDDKGMBManagementTeam@niddk.nih.gov)

Section VIII. Other Information

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

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.