Call for Proposals Checklist

RFP/RFA/FOA Title:

Sponsor:

Principal Investigator: Liz Lemon

☐ 1. Do you have the most recent guidelines? Is there more than one set to be referring to (call specific & several agency general guidelines are possible)?

☐ 2. Deadline date – electronic receipt, postmarked, or machine stamped (if a hard copy is hand-delivered)?

☐ 3. Time deadline – local time or sponsor’s time?

☐ 4. Electronic or paper submission? Optional? Mandatory? Both required?
   a. If electronic, is there any guidance about submission mechanism (e.g., FastLane, Grants.gov, email)?
   b. If paper, do multiple copies of proposal need to be sent to different addresses?

☐ 5. What type of funding instrument anticipated – Grant, Contract, subaward (if you are unsure what these are, please refer to the “Proposal Preparation & Submission” online course)? What type of terms (e.g. under the FDP)?

☐ 6. Is this a limited submission proposal (limit to the # of proposals that can be submitted by an institution)?

☐ 7. Is there more than one stage of proposal preparation (e.g. Letter of Intent or pre-proposal)? What are the deadlines for each?

☐ 8. Are there any Principal Investigator eligibility requirements? For UC Davis PI eligibility requirements, see PPM 230-02.

☐ 9. Technical requirements (e.g. collaboration between various scientific fields)?

☐ 10. Limit on how much funding can be requested?

☐ 11. Limit on project duration (e.g., one year – five years)?
12. Limit on number of PI's or Co-PI's?

13. Earliest start date for project?


15. Any specific budget requirements to be included within the budget? View the current Uniform Guidance

16. What is the F&A rate allowed by the sponsor? If it is different from UC Davis’ Federal Rate Agreement, does the sponsor have a written policy re: F&A restrictions?

17. Any time/effort commitments required? Any guidance regarding effort without compensation?

18. Any caps of any sort (e.g. salary, equipment)?

19. Page limitations?

20. Format restrictions (e.g. margins, font type and font size)?

21. Appendices allowed? Expected?

22. Subaward/Subcontract requirements and restrictions (e.g., FFRDC)?

23. Unusual considerations (e.g., conferences, alteration or renovation)?

24. What is SAM?
Department of Health and Human Services
Part 1. Overview Information

Participating Organization(s)
National Institutes of Health (NIH)

Components of Participating Organizations
Eunice Kennedy Shriver National Institute of Child Health Development (NICHD)
National Institute on Deafness and Other Communication Disorders (NIDCD)
National Institute of Environmental Health Sciences (NIEHS)
National Institute of Mental Health (NIMH)
National Institute of Neurological Disorders and Stroke (NINDS)

Funding Opportunity Title
Autism Centers of Excellence: Networks (R01)

Activity Code
R01 (Research Project Grant)

Announcement Type
Reissue of RFA-HD-12-196

Related Notices

Funding Opportunity Announcement (FOA) Number
RFA-HD-17-008

Companion Funding Opportunity
RFA-HD-17-009, P50 (Specialized Center)

Number of Applications
See Section III.3. Additional Information on Eligibility.

Catalog of Federal Domestic Assistance (CFDA) Number(s)
93.865, 93.173, 93.113, 93.242, 93.853

Funding Opportunity Purpose
The Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) and participating Institutes invite applications for the Autism Centers of Excellence: Networks Program, hereafter termed “ACE Networks”. Each ACE Network will consist of a multi-site project focusing on a specific topic of research for R01 support through this FOA. Each ACE Network will submit one R01 application that includes sub-awards to the collaborating sites. A companion FOA (RFA-HD-16-009) invites applications for ACE Centers supported by the P50 mechanism.

Key Dates

Posted Date
July 12, 2016

Open Date (Earliest Submission Date)
October 17, 2016

Letter of Intent Due Date(s)
30 days prior to the application due date
Background
Autism spectrum disorders (ASD) are complex neurodevelopmental disorders with early childhood onset. The prevalence of ASD may be increasing, and ASD is more common than previously thought. These disorders, for which there is presently no cure and only limited treatments, generally have lifelong effects.

The NIH historically has supported a vast array of projects in autism research. Beginning in 1997, the Collaborative Programs of Excellence in Autism (CPEA) focused on research related to the possible causes of autism, including genetic, immunological, and environmental factors. The CPEA program resulted from a congressionally mandated conference on the State of the Science in Autism. The attendees identified gaps in the understanding of autism and articulated directions for future research. Both NICHD and NIDCD sponsored the CPEA program. As a result of the efforts of researchers affiliated with the CPEA, data now exist on the genetics and phenotypic
characteristics of the largest group of well-diagnosed persons with autism in the world. After the establishment of the CPEA Centers program, Congress enacted the Children's Health Act of 2000. This legislation mandated the establishment of a new autism research program. In response, the five Institutes of the NIH Autism Coordinating Committee (NIH-ACC; represented by NICHD, NIDCD, NIEHS, NIMH, and NINDS) implemented the STAART (Studies to Advance Autism Research and Treatment) program in 2002. Each of the eight STAART centers contributed to the autism research base in the areas of causes, diagnosis, early detection, prevention, and treatment. In 2007, consolidation of funding from the CPEA and STAART programs resulted in autism centers and networks called the Autism Centers of Excellence or ACE program. In FY 2007 and 2008, five centers and six networks were funded. In FY 2012 and 2013, three centers and eight networks were funded.

**Purpose**

In response to the urgent public health significance of ASD, Congress passed the Combating Autism Act (CAA) of 2006. Through this Act, Congress intended to accelerate the pace, and improve the coordination of scientific discovery in ASD research. With the Autism Collaboration, Accountability, Research, Education and Support, or Autism CARES Act of 2014, Congress authorized the continuation of important investments in research, prevalence monitoring and services for both children and adults on the autism spectrum. This FOA is intended to build on the research progress and momentum of the past decade by funding research on innovative interventions and services for individuals with ASD across the lifespan, as well as cutting-edge research on the neurobiological basis and phenotypic characteristics of ASD that might lead to the identification of novel intervention strategies.

NIH will consider “centers” as well as “networks” in response to the ACE initiative. This funding opportunity invites applications for ACE Networks supported by the R01 mechanism. A companion FOA (RFA-HD-17-009) invites applications for ACE Centers supported by the P50 mechanism.

**Research Objectives**

This FOA invites applications for ACE Networks, which will consist of multiple sites focusing on a specific topic of research. Each network will submit one R01 application that includes subawards to the collaborating sites. An ACE Network application must require multiple sites for optimal design and conduct of the study. Given the heterogeneity of ASD, subgroups requiring large numbers of participants for each protocol may be studied best under a network because of enhanced recruitment and other benefits of multi-site subject accrual. The intent is to fund research that will address important gaps that take advantage of cutting edge technologies and methods for understanding the developmental trajectories, underlying mechanisms, biological pathways or signatures in ASD, including syndromic or monogenic disorders with ASD (as long as the research can lead to a better understanding of the broader ASDs).

**The minimal structural requirements of an ACE Network under this FOA are:**

- Research Project(s) -- An ACE Network application must include multiple sites for optimal design and conduct of one or more research studies. Each network will submit one R01 application that includes subawards to the collaborating sites. Those applying for a renewal of an ACE Network are encouraged to form new collaborations with investigators.

- Data Coordinating Center -- Each network must have a Data Coordinating Center (DCC) that is functionally separate from the data collection sites, with separate chains of command. The DCC must design and conduct data analyses and oversee all data management, including organizing and performing on-site monitoring. In addition, DCC staff must provide program support and generate standard operating procedures that include assisting in the design of protocols, data collection forms, manuals of operations, data collection/distribution systems, quality assurance (edit/query procedures) and monitoring systems, reliability assessment, data sharing, and generating reports. When relevant, medical monitoring and consultation regarding clinical data management (e.g., adverse events reporting, safety and protocol deviation monitoring), must also be provided. The DCC lead must supervise staff in accomplishing these activities, and direct the performance of the DCC. Dissemination and Outreach -- ACE Networks must disseminate research knowledge and information and provide educational and awareness experiences to relevant audiences including students, families, and researchers who wish to pursue ASD research to enhance clinical research and practice. Examples of activities that would address this important aspect of the Network could include a designated grand rounds series on the Network's theme, collaborative case conference sessions, development of a website for the scientific and lay communities that includes tutorials, fact sheets, and development of laboratory-based learning experiences. Seminars and workshops designed for the scientific and lay communities are also appropriate. The ACE Networks are expected to play leadership roles in disseminating research findings to the community. Involvement of junior and established researchers who are new to the field of autism is encouraged. Recruitment of investigators from underrepresented racial and ethnic groups and disadvantaged backgrounds is also encouraged. Each ACE Network must promote two-way communication between the investigators and the community of individuals with autism and caregivers. The purpose of the partnership is to lay the groundwork for successful recruitment and retention of study subjects. In addition, this partnership should inform investigators about patient concerns and feasibility of future studies in this population (such as risk/benefit determination, burden of visits and procedures, etc.) and inform the patient community about current research avenues and plans for future studies.

**The minimal data collection requirements of an ACE Network under this FOA are:**

Network studies must include collection of data using the following forms or a justification of why the forms are not appropriate. These are widely accepted and NIH-established common data elements for autism research. Additional modifications to these forms may occur periodically.

- Autism Diagnostic Interview-Revised (ADI-R) and the Autism Diagnostic Observation Schedule (ADOS-2), for use according to their published manuals
- Vineland Adaptive Behavior Scales, Second Edition
- An IQ or developmental assessment measure that includes both nonverbal and verbal components and results in standardized scores for both
- ACE Subject Physical Exam (where applicable to the purpose of a study) ([https://ndar.nih.gov/ndar_data_dictionary.html?short_name=ace_physexam01](https://ndar.nih.gov/ndar_data_dictionary.html?short_name=ace_physexam01))

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

**Section II. Award Information**

**Funding Instrument**

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

**Application Types Allowed**

- New
- Renewal

The [OER Glossary](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11116) and the SF424 (R&R) Application Guide provide details on these application types.

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[Funds Available and Anticipated Number of Awards](http://grants.nih.gov/grants/guide/rfa-files/RFA-HD-17-008.html)
The NICHD and participating Institutes intend to commit approximately $25 million total for the first year of funding for this funding opportunity and the companion FOA for ACE Centers (RFA-HD-17-009). The first year of funding will be in either FY2017 or FY2018. Approximately 8 to 11 ACE awards are anticipated in response to the two FOAs.

**Award Budget**

Applicants for an ACE Network may request up to $1.5 million in direct costs per year (excluding subaward F & A costs).

**Award Project Period**

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

NIH grants policies as described in the [NIH Grants Policy Statement](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11120) will apply to the applications submitted and awards made in response to this FOA.

**Section III. Eligibility Information**

**1. Eligible Applicants**

**Eligible Organizations**

**Higher Education Institutions**

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

The following types of Higher Education Institutions are always encouraged to apply for NIH support as Public or Private Institutions of Higher Education:

- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions
- Asian American Native American Pacific Islander Serving Institutions (AANAPISIs)

**Nonprofits Other Than Institutions of Higher Education**

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

**For-Profit Organizations**

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

**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)
- U.S. Territory or Possession

**Other**

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

**Foreign Institutions**

Non-domestic (non-U.S.) Entities (Foreign Institutions) are not eligible to apply. Non-domestic (non-U.S.) components of U.S. Organizations are not eligible to apply. Foreign components, as defined in the [NIH Grants Policy Statement](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11118), are allowed.

**Required Registrations**

**Applicant Organizations**

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

- [Dun and Bradstreet Universal Numbering System (DUNS)](http://fedgov.dnb.com/webform) - All registrations require that applicants be issued a DUNS number. After obtaining a DUNS number, applicants can begin both SAM and eRA Commons registrations. The same DUNS number must be used for all registrations, as well as on the grant application.
- [System for Award Management (SAM)](https://www.sam.gov/portal/public/SAM/) (formerly CCR) – 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.

eRA Commons (https://grants.nih.gov/grants/guide/url_redirect.htm?id=11123) – Applicants must have an active DUNS number and SAM registration in order to complete the eRA Commons registration. Organizations can register with the eRA Commons as they are working through their SAM or Grants.gov registration. 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://www.grants.gov/web/grants/applicants/organization-registration.html) – Applicants must have an active DUNS number and SAM registration in order to complete the Grants.gov registration.

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

All PD(s)/PI(s) must have an eRA Commons account. PD(s)/PI(s) should work with their organizational officials to either create a new account or to affiliate their existing account with the applicant organization in eRA Commons. If the PD/PI is also the organizational Signing Official, they must have two distinct eRA Commons accounts, one for each role. Obtaining an eRA Commons account can take up to 2 weeks.

Eligible Individuals (Program Director/Principal Investigator)

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)) is invited to work with his/her organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support.

For institutions/organizations proposing multiple PDs/Pis, visit the Multiple Program Director/Principal Investigator Policy and submission details in the Senior/Key Person Profile (Expanded) Component of the SF424 (R&R) Application Guide.

2. Cost Sharing

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

3. Additional Information on Eligibility

Number of Applications

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

The NIH will not accept duplicate or highly overlapping applications under review at the same time. This means that the NIH will not accept:

- A new (A0) application that is submitted before issuance of the summary statement from the review of an overlapping new (A0) or resubmission (A1) application.
- A resubmission (A1) application that is submitted before issuance of the summary statement from the review of the previous new (A0) application.
- An application that has substantial overlap with another application pending appeal of initial peer review (see NOT-OD-11-101 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-101.html)).

A PD/PI may submit only one application, either an ACE Center or an ACE Network. This does not exclude multiple applications from a single institution, provided each application is submitted by a different PD/PI.

Section IV. Application and Submission Information

1. Requesting an Application Package

Buttons to access the online ASSIST system or to download application forms are available in Part 1 of this FOA. See your administrative office for instructions if you plan to use an institutional system-to-system solution.

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the Research Instructions for the SF424 (R&R) Application Guide (https://grants.nih.gov/grants/guide/url_redirect.htm?id=12000), including Supplemental Grant Application Instructions (https://grants.nih.gov/grants/guide/url_redirect.htm?id=82216) except where instructed in this funding opportunity announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.


Letter of Intent

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

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

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

The letter of intent should be sent to:

Maribeth Champoux, Ph.D.
Center for Scientific Review (CSR)
Telephone: 301-594-3163
Email: Maribeth.Champoux@nih.gov (mailto:Maribeth.Champoux@nih.gov)

Page Limitations

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

Instructions for Application Submission

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

SF424(R&R) Project/Performance Site Locations
All instructions in the SF424 (R&R) Application Guide must be followed.

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

Facilities and Other Resources:

- **Overall Environment** -- Briefly describe the facilities and other resources relevant to the effective implementation of the proposed ACE network, such as clinical and laboratory facilities, participating and affiliated units, patient populations, geographical distribution of space and personnel, and consultative resources.
- **Research Sites** -- Provide a detailed description of each participating site within the Network, including the institution, departmental affiliations, resources, and role in the overall research project(s).
- **Organizational Chart** -- Provide an organizational chart for the entire Network, including the central administration, Network sites, and DCC.

SF424(R&R) Senior/Key Person Profile
All instructions in the SF424 (R&R) Application Guide must be followed.

The application must name one of the PD(s)/PI(s) as the overall Network Director.

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

The application must name one of the PD(s)/PI(s) as the overall Network Director. This individual must commit a minimum effort of 2.4 person-months per year overall effort to the Network.

Data Coordinating Center -- If the DCC will be located at the applicant organization, the DCC budget should be included as part of the overall R01 budget. If the DCC will be located at an organization distinct from the applicant organization and the network research sites, the DCC budget should be prepared as a subaward. If the DCC is located at one of the participating research sites, the DCC budget should be included as part of the subaward budget for that particular site. DCC budgets that are included as part of either the R01 or research site budgets should be explained and justified in the respective budget justification section.

ACE Network budgets and subaward budgets must include travel funds for key investigators to attend annual two-day ACE meetings in Bethesda, Maryland. Key investigators for this include: the Network PD(s)/PI(s), leaders of the various network sites, and the leader of the Data Coordinating Center (DCC) and all should plan to attend the annual meeting to share findings, research approaches, and information about core instrumentation.

To estimate the cost of data sharing, please visit [http://ndar.nih.gov/ndarpublicweb/Documents/NDAR_Data_Submission_Costs.xls](http://ndar.nih.gov/ndarpublicweb/Documents/NDAR_Data_Submission_Costs.xls)

Budget Justifications -- Describe the specific functions of all key personnel, consultants, collaborators, and support staff. For all years, explain and justify any unusual items such as major equipment or alterations and renovations. For additional years of support requested, justify any significant increases or decreases in any category over the first 12-month budget period.

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

PHS 398 Cover Page Supplement
All instructions in the SF424 (R&R) Application Guide must be followed.

PHS 398 Research Plan
All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions:

Research Strategy:

Applicants should describe the network research project(s) following instruction in the SF424 application guide. In addition, applicants should address the following subjects:

- **Purpose and Objectives of the ACE Network** -- Provide an overview of the entire proposed ACE Network, including the relevant history leading up to the ACE network application, the central theme, and the overall objectives. Describe how the network will achieve those objectives. The administrative arrangements and support necessary to effect the research should be carefully described in the application. In addition, provide detailed information on collaborations, subject recruitment, facilities, and any resources not described in the Facilities and Other Resources section. Provide documented evidence of subject recruitment capability specific to each study proposed. Discuss the philosophy and objectives of the ACE network and general plans for the proposed grant period.

- **Administration and Operation of the ACE Network** -- Include information on the support and commitment of the institution responsible for clinical coordination for the ACE network, the authority of the ACE Network Director, and the establishment of a Network Advisory Committee including external scientific and lay members (individuals should not be named in the application). Describe how the Network Advisory Committee will contribute to the proposed ACE network activities and research project. The Network Advisory Committee should meet approximately once a year virtually or in person, and brief reports of the proceedings of the meeting and recommendations of the committee should be included in the annual progress reports of the ACE network.

- For any investigators new to the field of autism (junior and/or established investigators), describe the role they will play in network activities. Include a plan for the dissemination and outreach requirement.

- **Data Coordinating Center (DCC)** -- Applications must provide a clearly defined Data Coordinating Center (DCC) section that describes the DCC's capabilities and functions in detail and explains how it will operate independently from data collection sites. Applicants must provide evidence that the data collection sites and DCC are functionally separate, with separate chains of command. The data management plan should take into account the interface with the National Database for Autism Research (NDAR). Describe how the DCC will design and conduct data analyses and oversee all data management, including organizing and performing on-site monitoring. In addition, describe how DCC staff will provide program support and generate standard operating procedures that include assisting in the design of protocols, data collection forms, manuals of operations, data collection/distribution systems, quality assurance (edit/query procedures) and monitoring systems, reliability assurance, data sharing, and generating reports. When relevant, describe how medical monitoring and consultation regarding clinical data management (e.g., adverse events reporting, safety and protocol deviation monitoring), will also be provided.

- **Network Preliminary Data/Progress Report** -- The application should present, in condensed form, previously published and/or preliminary data that support the rationale for the proposed ACE network activities and research project. Renewal applications must include a progress report detailing the activities/advances made on the project funded by the previous ACE FOA.

Protection of Human Subjects: Consent documents should include an explanation about whether participants' individual-level data will be shared through unrestricted- or controlled-access repositories.

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

- All applications, regardless of the amount of direct costs requested for any one year, should address a Data Sharing Plan.
- Sharing Human Data via the National Database for Autism Research:

In order to advance the goal of advancing autism research as broadly and effectively as possible, investigators funded under this FOA who are collecting data from humans are expected to share those data among ASD researchers through a broadly accessible repository addressing the needs of the autism research community, e.g., via the National Database for Autism Research (NDAR; http://ndar.nih.gov (http://ndar.nih.gov/)). Fulfilling this expectation by the awardee will be among the terms and conditions of the award. Established by the NIH, NDAR, for example, is a secure bioinformatics platform for scientific collaboration and data-sharing that enables the effective communication of detailed research data, tools, and supporting documentation. NDAR links data across research projects through its Global Unique Identifier (GUID) and Data Dictionary technology. Investigators funded under this FOA would be able to use these technologies to submit data to NDAR. To accomplish this objective, it will be important to formulate a) an enrollment strategy that will obtain the information necessary to generate a GUID for each participant, and b) a budget strategy that will cover the costs of data submission. The NDAR web site provides two tools to help investigators develop appropriate strategies: 1) the NDAR Data Sharing Checklist (http://ndar.nih.gov/NDAR_Data-Sharing_Checklist_10152009.pdf (http://ndar.nih.gov/NDAR_Data-Sharing_Checklist_10152009.pdf)) -- A list of critical steps in the data submission process, including informed consent language and GUID generation; and 2) the NDAR Data Submission Planning Cost and Effort Model (http://ndar.nih.gov/NDAR_Data Submission Costs.xls) -- A customizable Excel worksheet that includes tasks and hours for the Principal Investigator and Data Manager. Investigators are expected to certify the quality of all data generated by grants funded under this FOA prior to submission to the repository and to review their data for accuracy after submission. Submission of descriptive data is expected semi-annually (every January 15 and July 15); submission of all other experimental data is expected after the primary objectives of the grant have been met (the primary objectives of a grant will be determined in consultation with the investigator’s Program Officer prior to award). For reference, the NDAR Data Sharing Policy (http://ndar.nih.gov/NDAR_Data_Sharing_Policy) is available for review on the NDAR web site. NDAR staff will work with investigators to help them submit data types other than phenotypic, genetic, or imaging. For answers to frequently asked questions and how to contact the NDAR Manager, please see: http://ndar.nih.gov (http://ndar.nih.gov).

- Genetics and other Data Sharing in the ACE Program

The rapid dissemination of data and biomaterials is of increasing importance to the NIH for advancing research. The mission of the NIH and a goal of NIH policies are to promote discoveries to improve the health care and treatment of people, which is a mission that should be shared by the research community. The expedient sharing of data and biomaterials collected under scientific studies facilitates that mission. The NIH supports several databases through the NCBI, and the NIHM supports a repository for biospecimens of interest to mental health (http://nimhinformatics.org/NDAR/NDAR_Data_Submission_Costs.xls) to enable rapid sharing of data and biospecimens. These resources offer centralized sources of curated materials that are widely accessible to investigators in the international scientific community.

Investigators applying for awards under this FOA are encouraged to deposit data and biospecimens in NIH designated databases and appropriate repositories. However, depending on the nature of the data or biomaterials, there may not be an appropriate NIH supported resource for deposition. In such cases, alternative venues for data sharing can be considered. The sharing of data through NIH resources would not necessarily be exclusive and the data could be additionally shared through other investigator suggested venues.

It is expected that the investigator’s data sharing plan will specify the following elements: (1) description of what data will be collected including clinical data, diagnostic data, and physiological measurements such as MRI, (2) description of what biospecimens will be collected, (3) description of the data that will be derived from the biospecimens such as genotyping, sequence, metabolic measures, proteomic measures, etc., (4) what data and/or biospecimens will be made available for deposit in databases or in a repository accessible to the research community, (5) a timetable for deposition of the data and/or biomaterials, and a specified time interval after which those data and materials can be released to the research community.

Guidelines have evolved from extensive discussion within NIH Program staff, consultations with human genetics researchers and advocacy members, recommendations from the Genetics Workgroup of the National Advisory Mental Health Council (NAMHC), and requirements of the National Database for Autism Research recommending shortened timelines for data deposition and reduced proprietary periods before the data is released to the research community. The deposition of data is encouraged to occur at intervals throughout the period of the award and not be retained until the end of the award period. Similarly, the proprietary period for data release is encouraged to be short to facilitate rapid data release. Adherence to shortened time intervals for data deposition and release is highly desirable. This is expected to result in all data being released to the scientific community no later than the end of the award period, even if a competing renewal application is submitted. More rapid sharing is strongly encouraged. Requests for exemptions or extensions will require compelling justification and will be fully evaluated by program staff.

In order to meet the ethical obligations for human subjects protections, NIH expects investigators to obtain appropriate participants’ consent for their research data, including biospecimens, to be used for future research purposes and to be shared broadly.

Appendix: Do not use the Appendix to circumvent page limits. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

PHS Inclusion Enrollment Report

When conducting clinical research, follow all instructions for completing PHS Inclusion Enrollment Report as described in the SF424 (R&R) Application Guide.

PHS Assignment Request Form

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

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

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

4. Submission Dates and Times

Part I. Overview Information contains information about Key Dates and times. Applicants are encouraged to submit applications before the due date to ensure they have time to make any application corrections that might be necessary for successful submission. When a submission date falls on a weekend or Federal holiday (http://www.opm.gov/Operating_Status_Schedules/fedhol/2010.asp), the application deadline is automatically extended to the next business day.

Organizations must submit applications to Grants.gov (https:// Grants.gov/grants-guide/url_redirect.htm?dir=11120) (the online portal to find and apply for grants across all Federal agencies). Applicants must then complete the submission process by tracking the status of the application in the eRA Commons (https:// Grants.gov/grants-guide/url_redirect.htm?dir=1122), 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 subject to the NIH Policy on Late Application Submission.

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

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

5. Intergovernmental Review (E.O. 12372)
This initiative is not subject to intergovernmental review. (https://grants.nih.gov/grants/guide/url_redirect.htm?id=11142)

6. Funding Restrictions
All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement (https://grants.nih.gov/grants/guide/url_redirect.htm?id=11120).

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

7. Other Submission Requirements and Information
Applications must be submitted electronically following the instructions described in the SF424 (R&R) Application Guide. Paper applications will not be accepted.

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

For assistance with your electronic application or for more information on the electronic submission process, visit Applying Electronically (https://grants.nih.gov/grants/guide/url_redirect.htm?id=11144). If you encounter a system issue beyond your control that threatens your ability to complete the submission process on-time, you must follow the Guidelines for Applicants Experiencing System Issues (https://grants.nih.gov/grants/ElectronicReceipt/support.htm#guidelines). For assistance with application submission, contact the Application Submission Contacts in Section VII.

Important reminders:
All PD(s)/PI(s) must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile Component of the SF424 (R&R) Application Package. Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to NIH. See Section III of this FOA for information on registration requirements.

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

See more tips (https://grants.nih.gov/grants/guide/url_redirect.htm?id=11145) 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.

Post Submission Materials
Applicants are required to follow the instructions for post-submission materials, as described in NOT-OD-13-030 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-13-030.html).

Section V. Application Review Information

1. Criteria
Only the review criteria described below will be considered in the review process. As part of the NIH mission (https://grants.nih.gov/grants/guide/url_redirect.htm?id=11149), all applications submitted to the NIH in support of biomedical and behavioral research are evaluated for scientific and technical merit through the NIH peer review system.

For this particular announcement, note the following:
ACE Networks supported under this FOA will consist of multiple sites focusing on a specific topic of research. Each network R01 application will include subawards to the collaborating sites. An ACE Network application must include one or more collaborative research projects that require multiple sites for optimal design and conduct of studies. The scored review criteria outlined below will be considered in relation to all components of the network, including the various participating sites, investigators, and research project or projects.

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

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

Significance
Does the project address an important problem or a critical barrier to progress in the field? Is there a strong scientific premise for the project? 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? Will the ACE Network make an important contribution to the progress of autism research?

Investigator(s)
Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, or 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? Will the Network attract both established and junior investigators to autism research? Will new, junior faculty-level investigators be integrated within the structure of the ACE Network?

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?

**Approach**

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

If the project involves human subjects and/or NIH-defined clinical research, are the plans to address 1) the protection of human subjects from research risks, and 2) inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion or exclusion of children, justified in terms of the scientific goals and research strategy proposed?

How well-delineated and appropriate are the arrangements for internal quality control of ongoing research, allocation of funds, day-to-day management, contractual agreements, internal communication, external review, and cooperation among the investigators (including those new to the field of autism), in the network? How is the administrative and organizational structure conducive to attaining the specific aims of the proposed program? How appropriate is the plan for the dissemination and outreach requirement?

**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?

**Additional Review Criteria**

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

**Data Coordinating Center**

Evidence of Successful Past Performance -- What level of experience does the DCC Lead have in the design, conduct, data analysis, and data management of major collaborative clinical research projects? What is the evidence of successful performance as a DCC for multi-site studies?

Appropriate Staff Expertise and Capability -- How appropriate is the expertise of the DCC Lead and other staff? What are the capabilities of the DCC in biostatistics, developmental study design, development and support, data management, data analysis, and project management? If the network involves clinical trials, how appropriate is the clinical expertise for medical monitoring and consultation regarding clinical data management (e.g., adverse events reporting, safety and protocol deviation monitoring)?

Capacity and Ability to Manage Data and Communications -- How will the DCC provide data management and program support capabilities? How well-described are the standard operating procedures that include assisting in the design of protocols, data collection forms, manuals of operations, data collection/distribution systems, quality assurance (edit/query procedures) and monitoring systems, reliability assessment and generating reports? What is the evidence of the DCC's ability to organize and conduct on-site monitoring?

**Protections for Human Subjects**

For research that involves human subjects but does not involve one of the six 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 six 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 [here](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11175).

**Inclusion of Women, Minorities, and Children**

When the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of children to determine if it is justified in terms of the scientific goals and research strategy proposed. For additional information on review of the Inclusion section, please refer to the Guidelines for the Review of Inclusion in Clinical Research [here](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11174).

**Vertebrate Animals**

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following criteria: (1) description of proposed procedures involving animals, including species, strains, ages, sex, and total number to be used; (2) justifications for the use of animals versus alternative models and for the appropriateness of the species proposed; (3) interventions to minimize discomfort, distress, pain and injury; and (4) justification for euthanasia method if NOT consistent with the AVMA Guidelines for the Euthanasia of Animals. Reviewers will assess the use of chimpanzees as they would any other application proposing the use of vertebrate animals. For additional information on review of the Vertebbrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section [here](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11150).

**Biohazards**

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

**Resubmissions**

Not Applicable

**Renewals**

For Renewals, the committee will consider the progress made in the last funding period. For existing networks, how successful was the previous network grant in advancing progress in autism research?

**Revisions**

Not Applicable

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

**Applications from Foreign Organizations**
Not Applicable

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

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

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

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

# 2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s), convened by the Center for Scientific Review, in accordance with [NIH peer review policy and procedures](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11154), using the stated [review criteria](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11157). Assignment to a Scientific Review Group will be shown in the eRA Commons.

As part of the scientific peer review, all 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.
- Will receive a written critique.

[Appeals](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-064.html) of initial peer review will not be accepted for applications submitted in response to this FOA.

Applications will be assigned to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications submitted in response to this FOA. Following initial peer review, recommended applications will receive a second level of review by the appropriate national Advisory Council or Board. The following will be considered in making funding decisions:

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

# 3. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) via the [eRA Commons](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11123). Refer to Part I 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](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11156).

# Section VI. Award Administration Information

## 1. Award Notices

If the application is under consideration for funding, NIH will request “just-in-time” information from the applicant as described in the [NIH Grants Policy Statement](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11157).

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the grants management officer is the authorizing document and will be sent via email to the grantee’s business official.

Awardees must comply with any funding restrictions described in [Section IV.5. Funding Restrictions](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11158). Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs.

Any application awarded in response to this FOA will be subject to terms and conditions found on the [Award Conditions and Information for NIH Grants](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11158) website. This includes any recent legislation and policy applicable to awards that is highlighted on this website.

## 2. Administrative and National Policy Requirements

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

Recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights laws. This means that recipients of HHS funds must ensure equal access to their programs without regard to a person’s race, color, national origin, disability, age, and, in some circumstances, sex and religion. This includes ensuring your programs are accessible to persons with limited English proficiency. HHS recognizes that research projects are often limited in scope for many reasons that are nondiscriminatory, such as the principal investigator’s scientific interest, funding limitations, recruitment requirements, and other considerations.

Thus, criteria in research protocols that target or exclude certain populations are warranted where nondiscriminatory justifications establish that such criteria are appropriate with respect to the health or safety of the subjects, the scientific study design, or the purpose of the research.
In accordance with the statutory provisions contained in Section 872 of the Duncan Hunter National Defense Authorization Act of Fiscal Year 2009 (Public Law 110-417), NIH awards will be subject to the Federal Awardee Performance and Integrity Information System (FAPIIS) requirements. FAPIIS requires Federal award making officials to review and consider information about an applicant in the designated integrity and performance system (currently FAPIIS) prior to making an award. An applicant, at its option, may review information in the designated integrity and performance systems accessible through FAPIIS and comment on any information about itself that a Federal agency previously entered and is currently in FAPIIS. The Federal awarding agency will consider any comments by the applicant, in addition to other information in FAPIIS, in making a judgement about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in 45 CFR Part 75.205 “Federal awarding agency review of risk posed by applicants.” This provision will apply to all NIH grants and cooperative agreements except fellowships.

For additional guidance regarding how the provisions apply to NIH grant programs, please contact the Scientific/Research Contact that is identified in Section VII under Agency Contacts of this FOA. HHS provides general guidance to recipients of FFA on meeting their legal obligation to take reasonable steps to provide meaningful access to their programs by persons with limited English proficiency. Please see http://www.hhs.gov/ocr/civilrights/resources/laws/revisedlep.html. The HHS Office for Civil Rights also provides guidance on complying with civil rights laws enforced by HHS. Please see http://www.hhs.gov/ocr/civilrights/understanding/section1557/index.html and http://www.hhs.gov/ocr/civilrights/understanding/index.html. Recipients of FFA also have specific legal obligations for serving qualified individuals with disabilities. Please see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html. Please contact the HHS Office for Civil Rights for more information about obligations and prohibitions under federal civil rights laws at http://www.hhs.gov/ocr/office/about/ocr­hqaddresses.html or call 1-800-504-0027 for TTY or 1-800-504-0877 for Teletype. Also note it is an HHS Departmental goal to ensure access to quality, culturally competent care, including long-term services and supports, for vulnerable populations. For further guidance on providing culturally and linguistically appropriate services, recipients should review the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care at http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53.

Cooperative Agreement Terms and Conditions of Award
Not Applicable

3. Reporting
When multiple years are involved, awardees will be required to submit the Research Performance Progress Report (RPPR) annually and financial statements as required in the NIH Grants Policy Statement. A final progress report, 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.

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All awardees of NIH grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov for all subawards over $25,000. See the NIH Grants Policy Statement for additional information on this reporting requirement.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts from all Federal awarding agencies with a cumulative total value greater than $10,000,000 for any period of time during the period of performance of a Federal award, must report and maintain the currency of information reported in the System for Award Management (SAM) about obligations and other information required for Federal procurement contracts, will be publicly available. Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75 – Award Term and Conditions for Recipient Integrity and Performance Matters.

Section VII. Agency Contacts
We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

Application Submission Contacts
eRA Service Desk (Questions regarding ASSIST, eRA Commons registration, submitting and tracking an application, documenting system problems that threaten submission by the due date, post submission issues)
Finding Help Online: https://grants.nih.gov/support/ (preferred method of contact)
Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

Grants.gov Customer Support (Questions regarding Grants.gov registration and submission, downloading forms and application packages)
Contact Center Telephone: 800-518-4726
Email: support@grants.gov

GrantsInfo (Questions regarding application instructions and process, finding NIH grant resources)
Email: GrantsInfo@nih.gov (preferred method of contact)
Telephone: 301-954-7573

Scientific/Research Contact(s)
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Section VIII. Other Information  

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

Weekly TOC for this Announcement (//grants/guide/WeeklyIndex.cfm?07-15-16)  
NIH Funding Opportunities and Notices (//grants/guide/index.html)