

Part 1. Overview Information

Participating Organization(s)	National Institutes of Health (NIH (http://www.nih.gov))
Components of Participating Organizations	National Institute of Mental Health (NIMH (https://www.nimh.nih.gov/index.shtml)) National Institute on Alcohol Abuse and Alcoholism (NIAAA (http://www.niaaa.nih.gov/))
Funding Opportunity Title	Development and Optimization of Tasks and Measures for Functional Domains of Behavior (R01 Clinical Trial Not Allowed)
Activity Code	R01 (/grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=r01&Search.x=0&Search.y=0&Search_Type=Activity) Research Project Grant
Announcement Type	New
Related Notices	None
Funding Opportunity Announcement (FOA) Number	PAR-18-930
Companion Funding Opportunity	None
Number of Applications	See Section III. 3. Additional Information on Eligibility.
Catalog of Federal Domestic Assistance (CFDA) Number(s)	93.242; 93.273
Funding Opportunity Purpose	The purpose of this Funding Opportunity Announcement (FOA) is to support the development and optimization of tasks and/or measures for constructs pertaining to functional aspects of

behavior or cognitive/affective processes, for use in laboratory or population-based studies, clinical trials outcomes, or related research. This FOA encourages research that will result in the availability of tasks and measures that demonstrate: (1) good validity as a measure of a specific construct; (2) robust measurement properties; and (3) suitability for use across diverse participants.

Key Dates

Posted Date	September 21, 2018
Open Date (Earliest Submission Date)	January 05, 2019
Letter of Intent Due Date(s)	January 5, 2019
Application Due Date(s)	<p>Standard dates (//grants.nih.gov/grants/guide/url_redirect.htm?id=11111) apply, by 5:00 PM local time of applicant organization. All types of non-AIDS applications allowed for this funding opportunity announcement are due on these dates.</p> <p>The first standard application due date for this FOA is February 5, 2019.</p> <p>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.</p>
AIDS Application Due Date(s)	Not Applicable
Scientific Merit Review	Standard dates (//grants.nih.gov/grants/guide/url_redirect.htm?id=11113) apply
Advisory Council Review	Standard dates (//grants.nih.gov/grants/guide/url_redirect.htm?id=11113)
Earliest Start Date	Standard dates (//grants.nih.gov/grants/guide/url_redirect.htm?id=11113)
Expiration Date	January 08, 2022

Due Dates for E.O. 12372

Not Applicable

Required Application Instructions

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

Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in [Section IV](#). When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions.

Applications that do not comply with these instructions may be delayed or not accepted for review.

There are several options available to submit your application through Grants.gov to NIH and Department of Health and Human Services partners. You **must** use one of these submission options to access the application forms for this opportunity.

1. Use the NIH ASSIST system to prepare, submit and track your application online.

[Apply Online Using ASSIST](#)

2. Use an institutional system-to-system (S2S) solution to prepare and submit your application to Grants.gov and [eRA Commons](#) (<http://public.era.nih.gov/commons/>) to track your application. Check with your institutional officials regarding availability.
3. Use [Grants.gov](#) (<http://www.grants.gov/web/grants/applicants/download-application-package.html#search=true&oppNum=PAR-18-930>) Workspace to prepare and submit your application and [eRA Commons](#) (<http://public.era.nih.gov/commons/>) to track your application.

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Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

Purpose

The purpose of this Funding Opportunity Announcement (FOA) is to support the development and optimization of tasks and/or measures for constructs pertaining to functional domains of behavior or cognitive/affective processes, for use in laboratory or population-based studies and clinical trials outcomes. This FOA encourages research that will result in the availability of tasks and measures of constructs that demonstrate: (1) good validity as a measure of a specific construct; (2) robust measurement properties; and (3) suitability for use with individuals who vary widely in age, ability, and/or severity of disorder. Because there are some constructs for which there are well-validated tasks/measures already available and others for which there are few standardized tasks/measures, candidate tasks/measures should be selected based on an analysis of the existing tools for assessing the construct(s) of interest and an assessment of the methodological and psychometric issues that are in need of further empirical work. Highest priority will be given to applications that target constructs with the greatest need for optimized measurement tools. In addition to the inherent value of having validated and psychometrically sound measurements, the tasks and measures will be evaluated for their potential to serve as common data elements for sharing and harmonizing data across multiple studies and data sets.

Research Objectives and Scope

This FOA encourages research projects to develop new tasks and measures or to optimize existing tasks and measures for functional behavioral constructs. Tasks and measures could include self-report tools, behavioral tasks, physiological measures, or neuroimaging protocols. Their properties should allow use with diverse research participants in a consistent manner. Optimally, tasks should provide a behavioral output, but for some constructs, a physiological or neuroimaging paradigm that does not involve behavioral responses may be appropriate. A single task/measure may yield multiple outputs or data elements, which may be associated with different constructs or units of analysis. It is important, however, that the specific relationship between individual outputs or data elements and the constructs be defined and determined. Because the development status of different tasks and measures varies, the nature and scope of proposed projects is expected to vary, with some projects focused on early stage development of novel tasks/measures and other focused on optimizing existing tasks. The intended use of the test should be considered in designing research projects; some tasks may be intended for use in high-throughput phenotyping or screening purposes, and others may require specialized equipment and procedures. Stages of measurement development covered in this announcement include validation, assessment of measurement characteristics, standardization of administration procedures/parameters, and collection of normative data.

Given the primary importance of validity in assessment methods, applications must provide either a review of existing evidence of strong validity for the task as a measure of an indicated construct or should include plans to test the construct validity of the task. This may be accomplished by tests of convergent, divergent, concurrent, and/or predictive validity. Evidence of validity can also be provided by data from relevant clinical

populations, imaging studies with normal and clinical samples, and/or pharmacological or behavioral manipulation studies involving animal or human models.

Task parameters should be empirically tested in order to optimize measurement characteristics (i.e., psychometric properties), including such considerations as internal reliability, test-retest reliability, alternate forms reliability, stability, practice effects, ceiling/floor (i.e., range) effects, and optimal task length and difficulty. The degree to which these characteristics vary in clinical versus healthy populations is also relevant.

Standardization of administration procedures and parameters (e.g., number of trials, stimulus characteristics) enables examiners in diverse settings to implement tasks in a consistent manner. Applicants should address any administration and scoring difficulties that may limit usability. The standardization process should include considerations of burden and practicality and may include establishing specific stimulus or item sets and administration procedures including response options and presentation parameters, with appropriate attention to potential variation needed as a function of population, setting, or stimulus presentation hardware. Any modifications needed to allow use of tasks across different age groups and ability levels should be standardized. Documentation and ?instructions should allow implementation of the task(s) by new users.

Normative data are necessary for the interpretation of performance/scores across administration settings. For the purposes of establishing normative data, the participant sample should be diverse with regard to age, gender, ethnicity, education, and socioeconomic status. In particular, applicants should power studies to evaluate sex differences and sex-specific effects, in accord with current NIH priorities on sex as a biological variable (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-102.html>).

Successful applications will identify a true gap in measurement tools for a specific construct or ?constructs. Applications proposing to study a measure for a construct that already has several useable tasks will not be considered high priority for funding. Applicants should explain the details of the gap in available methods and how the proposed work will address the shortcoming. This should be accompanied by specific descriptions of the data that will be collected and what criteria will be used to evaluate if the characteristics are considered robust enough for use. An application may focus on a single task/measure or more than one task/measure.

Interests of Participating NIH Institutes, Centers and Offices

NIMH

The National Institute of Mental Health (NIMH) is interested in applications that pertain to the Research Domain Criteria (RDoC) initiative (<https://www.nimh.nih.gov/research-priorities/rdoc/index.shtml> (<https://www.nimh.nih.gov/research-priorities/rdoc/index.shtml>)). The RDoC matrix includes five major domains of function (Negative Valence Systems, Positive Valence Systems, Cognitive Systems, Systems for Social Processes, and Arousal/Regulatory Systems), each with several inter-related constructs (<https://www.nimh.nih.gov/research-priorities/rdoc/constructs/rdoc-matrix.shtml> (<https://www.nimh.nih.gov/research-priorities/rdoc/constructs/rdoc-matrix.shtml>)). There are some constructs for which standardized tasks and measures have been identified and others for which no standardized task or measure exists. A workgroup of the National Advisory Mental Health Council (NAMHC) was convened in April, 2016 to evaluate tasks and measures for each RDoC construct (see the workgroup's

final report, https://www.nimh.nih.gov/about/advisory-boards-and-groups/namhc/reports/rdoc_council_workgroup_report_153440.pdf (https://www.nimh.nih.gov/about/advisory-boards-and-groups/namhc/reports/rdoc_council_workgroup_report_153440.pdf). While this document is not a comprehensive review of RDoC-related tasks and measures, it does contain information regarding the gaps in the current recommendations for tasks and measures, as well as specific examples of tasks that require further evaluation. Applicants to this FOA are encouraged to consult the report as they formulate their research plans.

As RDoC is considered to be an evolving research framework that supports continual updating on the basis of new information, investigators are encouraged to submit applications intended to develop tasks/measures that assess current RDoC constructs or modified conceptions of current constructs. For modified constructs, applicants should provide supportive information consistent with the established criteria for developing RDoC constructs, i.e., (1) evidence for a functional dimension of behavior/cognition, (2) evidence for a neural circuit/system predominantly involved in implementing the behavior, and (3) relevance for psychopathology. These three construct criteria are particularly relevant for applications which will use computational approaches that employ data-driven methods to assess current or modified constructs.

Tasks/measures may be developed either for traditional laboratory/clinic settings, or for population-based studies that involve self-administration via mobile or web-based apps. Priority will be given to tasks for which versions can be developed that show potential validity in either type of setting, although applicants may focus on one or the other setting for initial task development.

The RDoC framework includes an emphasis upon neurodevelopmental factors that affect psychopathology, and also the broad range of environmental influences, both harmful and protective, that interact with neurodevelopment to confer risk or resilience. Given this emphasis, the development and/or validation of tasks/measures that can be scaled for appropriate use across a broad range of development, or that target critical periods of development, are of high priority. (For example, many measures in the NIH Toolbox, <http://www.nihtoolbox.org/Pages/default.aspx> (<http://www.nihtoolbox.org/Pages/default.aspx>) , are standardized from ages 3 to 85.) However, it is recognized that for many RDoC constructs (e.g., for assessing fear or reward-related behavior), it is not possible to develop scaled version of the same task across age ranges; further, it is highly expensive to validate the scaling of a task across the entire life span. For these reasons, applicants may confine the focus of the research plan to a particular, justifiable age range. However, applicants should address the potential age range for which a task/measure might be scaled and address any future plans to expand the age range of validation. Development of tasks that target children of particular ages, or that could readily be scaled across the range of childhood, is particularly encouraged.

Relevant research topics include, but are not limited to:

- Development of variants of existing task(s)/measure(s) that are optimized for use in a novel setting or for a new clinical research purpose; for example, development and testing of parallel versions of a task that can be used for high-throughput phenotyping for screening purposes and for intensive, lab-based research.

- Development of tasks/measures for realms of behavior that are computationally definable, and conducted within the scope of a theoretical framework that is sufficiently precise to make quantitative predictions about how computational processes (neural and/or psychological) can result in particular aspects of behavior;
- Direct comparisons of a range of administration parameters and analysis of the effects on the test's measurement characteristics.
- Development of standardized stimuli for an existing task in order to enhance usability across age groups or level of ability and/or as a repeated measure with psychometrically equivalent alternate forms.
- The collection of normative data from a broad population and development of methods to convert raw scores into a common scale that can be interpreted in a standardized way. This stage of task development is most appropriate for tasks and measures for which reliability and validity have been established

Projects that would not be supported by NIMH under this announcement include:

- Development or optimization of tests that are only suitable for animal research; however, development of tasks that have animal analogs is encouraged.
- Applications that propose to modify the current structure of the RDOC matrix by suggesting new RDoC constructs, subconstructs, domains, or units of analysis. Please note that suggested changes to the RDoC matrix may be submitted to the RDoC Unit via RDocAdmin@mail.nih.gov (<mailto:RDocAdmin@mail.nih.gov>) and that investigators may submit investigator-initiated applications to study new constructs. Criteria for RDoC constructs are detailed [here](http://www.nimh.nih.gov/research-priorities/rdoc/rdoc-frequently-asked-questions-faq.shtml) (<http://www.nimh.nih.gov/research-priorities/rdoc/rdoc-frequently-asked-questions-faq.shtml>).
- Applications that propose to study tests that are designed only for use with specific DSM or ICD diagnostic categories.
- Projects that ONLY use existing data; while it would be appropriate, and encouraged, to include aims that involve aggregation and/or reanalysis of existing data, analysis of existing data should not be the sole focus of the application.

NIAAA

The National Institute on Alcohol Abuse and Alcoholism (NIAAA) is interested in tasks and measures of functional domains that are pertinent to alcohol use. NIAAA has established the Addictions Neuroclinical Assessment (ANA) as a package of tests and measures that are grounded in three neuroscience domains relevant for addictions, and which share significant overlap with RDoC. These domains comprise Incentive Salience, Negative Emotionality, and Executive Function. The NAMHC workgroup report described above identifies tasks that are relevant for these domains and for studying alcohol use disorder (AUD) and related constructs. For example, measures to assess Executive Function and Negative Emotionality overlap with Cognitive Systems and Negative Valence Systems, respectively. Because the NAMHC report did not include AUD, it does not identify aspects directly related to Incentive Salience, i.e., increased salience for alcohol and related cues. Thus, tasks that measure this domain are of specific relevance to the NIAAA.

In addition to measures focused on Incentive Saliency, and the relevant research topics described under point 2 above, NIAAA is particularly interested in the following:

- Projects focused on existing measures that have not been evaluated in patients with AUD and that test these measures in this population. For example, there may be different clinical considerations or normative data for use among patients with AUD as compared to healthy volunteer groups or patients with psychotic disease.
- Identification of tasks that may be used repeatedly over time, i.e., are less sensitive to practice effects, and which are relevant for understanding changes in the ANA domains during acute and protracted withdrawal and recovery from AUD.
- Additional testing of tasks that may be used in different age groups, e.g., with children, adolescents, and finally, adults, to understand risk factors for development and maintenance of AUD as measured by the same tasks. If using the same tasks is not feasible, direct comparison of tasks that assess the same domains/subdomains of function, e.g., visuospatial functioning, hypohedonia, etc. in different age groups would also be useful.
- Evaluation of measures that may be used to predict recovery and relapse among patients with AUD, and measures that may be used to determine clinical trials outcomes.

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

Clinical Trial?

Not Allowed: Only accepting applications that do not propose clinical trials
[Need help determining whether you are doing a clinical trial? \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82370\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82370)

Funds Available and Anticipated Number of Awards

The number of awards is contingent upon NIH appropriations and the submission of a sufficient number of meritorious applications.

Award Budget

Application budgets are not limited but need to reflect the actual needs of the proposed project.

Award Project Period

The scope of the proposed project should determine the project period. The total project period may not exceed 5 years.

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

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

Higher Education Institutions

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

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

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

Nonprofits Other Than Institutions of Higher Education

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

For-Profit Organizations

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

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)
- 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
- Non-domestic (non-U.S.) Entities (Foreign Institutions)

Foreign Institutions

Non-domestic (non-U.S.) Entities (Foreign Institutions) **are** eligible to apply

Non-domestic (non-U.S.) components of U.S. Organizations **are** eligible to apply.

Foreign components, as [defined in the NIH Grants Policy Statement \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11118\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11118), **are** allowed.

Required Registrations

Applicant organizations

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

- [Dun and Bradstreet Universal Numbering System \(DUNS\) \(http://fedgov.dnb.com/webform\)](http://fedgov.dnb.com/webform) - All registrations require that applicants be issued a DUNS number. After obtaining a DUNS number, applicants can begin both SAM and eRA Commons registrations. The same DUNS number must be used for all registrations, as well as on the grant application.
- [System for Award Management \(SAM\) \(https://www.sam.gov/portal/public/SAM/\)](https://www.sam.gov/portal/public/SAM/) (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.
 - [NATO Commercial and Government Entity \(NCAGE\) Code \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11176\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11176) – Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
- [eRA Commons \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11123\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11123) - Applicants must have an active DUNS number 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 – 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 \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11126\)NIH Grants Policy Statement. \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11126\)](http://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 \(//grants.nih.gov/grants/guide/notice-files/NOT-OD-11-101.html\)](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-101.html))

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

For information on Application Submission and Receipt, visit [Frequently Asked Questions – Application Guide, Electronic Submission of Grant Applications \(//grants.nih.gov/grants/guide/url_redirect.htm?id=41137\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=41137).

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:

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

Page Limitations

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

SF424(R&R) Senior/Key Person Profile

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

The investigative team should include individuals with expertise in assessment development, psychometrics, and, where relevant, computational modeling and/or neurocircuitry.

R&R or Modular Budget

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

R&R Subaward Budget

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

PHS 398 Cover Page Supplement

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

PHS 398 Research Plan

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

Significance: Applicants should provide a strong rationale for the selection of task(s)/measure(s) to be developed and a description of how the proposed project will increase the availability of high-quality measures of construct(s) or that pertain to high-quality measures of Functional Brain Processes (FBP).

Investigators: The investigative team should include individuals with expertise in assessment development, psychometrics, and, where relevant, computational modeling and/or neurocircuitry.

Innovation: The application should propose to develop a task/measure that addresses a true gap in measurement tools for a specific construct or constructs.?

Approach: The application should focus on optimization of selected task(s)/measures(s) for use in a diverse patient group and/or in individuals who span the illness/health dimension. While studies focused on the initial development of innovative new tasks/measures may recruit primarily healthy subjects, the sample must include a sufficient range of performance to provide evidence for the feasibility of the task in studies of patients with mental or substance-use disorders. Task(s)/measure(s) should have a strong theoretical and/or empirical relationship to one or more functional behavioral construct(s). The application should include a summary of existing evidence for construct validity or a plan to test for construct validity

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.

The following modifications also apply:

- All applications, regardless of the amount of direct costs requested for any one year, should address a Data Sharing Plan.

Appendix:

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

PHS Human Subjects and Clinical Trials Information

When involving NIH-defined human subjects research, clinical research, and/or clinical trials (and when

applicable, clinical trials research experience) follow all instructions for the PHS Human Subjects and Clinical Trials Information form in the SF424 (R&R) Application Guide, with the following additional instructions:

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

Study Record: PHS Human Subjects and Clinical Trials Information

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

Delayed Onset Study

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

PHS Assignment Request Form

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

Foreign Institutions

Foreign (non-U.S.) institutions must follow policies described in the [NIH Grants Policy Statement \(//grants.nih.gov/grants/guide/redirect.htm?id=11137\)](https://grants.nih.gov/grants/guide/redirect.htm?id=11137), and procedures for foreign institutions described throughout the SF424 (R&R) Application Guide.

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

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

4. Submission Dates and Times

[Part I. Overview Information](#) contains information about Key Dates and times. Applicants are encouraged to submit applications before the due date to ensure they have time to make any application corrections that might be necessary for successful submission. When a submission date falls on a weekend or [Federal holiday \(https://grants.nih.gov/grants/guide/redirect.html?id=82380\)](https://grants.nih.gov/grants/guide/redirect.html?id=82380), the application deadline is automatically extended to the next business day.

Organizations must submit applications to [Grants.gov \(//grants.nih.gov/grants/guide/redirect.htm?id=11128\)](https://grants.nih.gov/grants/guide/redirect.htm?id=11128) (the online portal to find and apply for grants across all Federal agencies). Applicants must then complete the submission process by tracking the status of the application in the [eRA Commons \(//grants.nih.gov/grants/guide/redirect.htm?id=11123\)](https://grants.nih.gov/grants/guide/redirect.htm?id=11123), NIH’s electronic system for grants administration. NIH and Grants.gov systems check the application against many of the application instructions upon submission. Errors must be corrected and a changed/corrected application must be submitted to Grants.gov on or before the application due date and time. If a Changed/Corrected application is submitted after the deadline, the application will be considered late. Applications that miss the due date and time are subjected to the NIH Policy on Late Application Submission.

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

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

5. Intergovernmental Review (E.O. 12372)

This initiative is not subject to (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11142)intergovernmental review. (http://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 \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11120\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11120) .

Pre-award costs are allowable only as described in the [NIH Grants Policy Statement \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11143\)](http://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 \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11144\)](http://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 \(http://grants.nih.gov/grants/ElectronicReceipt/support.htm#guidelines\)](http://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 \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11146\)](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, NIH. Applications that are incomplete or non-compliant will not be reviewed.

Requests of \$500,000 or more for direct costs in any year

Applicants requesting \$500,000 or more in direct costs in any year (excluding consortium F&A) must contact a Scientific/ Research Contact at least 6 weeks before submitting the application and follow the

Policy on the Acceptance for Review of Unsolicited Applications that Request \$500,000 or More in Direct Costs as described in the SF424 (R&R) Application Guide.

Post Submission Materials

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

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process. As part of the [NIH mission \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11149\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11149), 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.

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 proposed study increase the availability of high-quality assessment tools for functional behavioral constructs? Will the proposed task(s)/measure(s) be suitable to serve as common data elements for sharing of data across multiple studies and data sets?

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?

Does the investigative team possess adequate expertise in the areas of assessment development, psychometrics, and where relevant, computational modeling and/or neurocircuitry?

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?

Does the application propose to develop a task/measure that addresses a true gap in measurement tools for a specific construct or constructs?

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?

Does the application include a plan for optimizing the task for use in diverse settings and in diverse patient groups and/or across the health-illness spectrum? Is there compelling evidence of a relationship between the task/measure and one or more functional behavioral constructs? Is there existing evidence of construct validity or a plan to evaluate construct validity for the task/measure that is to be developed? Does the application include a plan for optimizing measurement characteristics of the task/measure?

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?

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.

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 \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11175\)](https://grants.nih.gov/grants/guide/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 \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11174\)](https://grants.nih.gov/grants/guide/redirect.htm?id=11174).

Vertebrate Animals

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

Not Applicable

Revisions

For Revisions, 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

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

Reviewers will assess whether the project presents special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions that exist in other countries and either are not readily available in the United States or augment existing U.S. resources.

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) (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) (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) (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 Center for Scientific Review, in accordance with [NIH peer review policy and procedures \(//grants.nih.gov/grants/guide/uri_redirect.htm?id=11154\)](https://grants.nih.gov/grants/guide/uri_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:

- 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.

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. 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 \(//grants.nih.gov/grants/guide/uri_redirect.htm?id=11123\)](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=11123). Refer to Part 1 for dates for peer review, advisory council review, and earliest start date. Information regarding the disposition of applications is available in the [NIH Grants Policy Statement \(//grants.nih.gov/grants/guide/uri_redirect.htm?id=11156\)](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=11156).

Section VI. Award Administration Information

1. Award Notices

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

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

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

considered allowable pre-award costs.

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

2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the [NIH Grants Policy Statement \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11120\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11120) as part of the NoA. For these terms of award, see the [NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11157\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11157) and [Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Grantees, and Activities \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11159\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11159). More information is provided at [Award Conditions and Information for NIH Grants \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11158\)](http://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 law. 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 (FAPIS) requirements. FAPIS requires Federal award making officials to review and consider information about an applicant in the designated integrity and performance system (currently FAPIS) prior to making an award. An applicant, at its option, may review information in the designated integrity and performance systems accessible through FAPIS and comment on any information about itself that a Federal agency previously entered and is currently in FAPIS. The Federal awarding agency will consider any comments by the applicant, in addition to other information in FAPIS, 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> (<http://www.hhs.gov/ocr/civilrights/understanding/section1557/index.html>); and <http://www.hhs.gov/ocr/civilrights/understanding/index.html> (<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> (<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/rgn-hqaddresses.html> (<http://www.hhs.gov/ocr/office/about/rgn-hqaddresses.html>) or call 1-800-368-1019 or TDD 1-800-537-7697. 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> (<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 \(RPPR\)](#) (<http://grants.nih.gov/grants/rppr/index.htm>) annually and financial statements as required in the [NIH Grants Policy Statement](#). (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11161)

A final RPPR, invention statement, and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the [NIH Grants Policy Statement](#) (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11161).

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All awardees of applicable NIH grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11170) on all subawards over \$25,000. See the [NIH Grants Policy Statement](#) (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11171) for additional information on this reporting requirement.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts from all Federal awarding agencies with a cumulative total value greater than \$10,000,000 for any period of time during the period of performance of a Federal award, must report and maintain the currency of information reported in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and

performance system (currently FAPIIS). This is a statutory requirement under section 872 of Public Law 110-417, as amended (41 U.S.C. 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available. Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75 – Award Term and Conditions for Recipient Integrity and Performance Matters.

Section VII. Agency Contacts

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

Application Submission Contacts

eRA Service Desk (Questions regarding ASSIST, eRA Commons registration, submitting and tracking an application, documenting system problems that threaten submission by the due date, post submission issues)

Finding Help Online: <http://grants.nih.gov/support/> ([//grants.nih.gov/support/](http://grants.nih.gov/support/)) (preferred method of contact)

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

[Grants.gov Customer Support](http://grants.nih.gov/grants/guide/url_redirect.htm?id=82301) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=82301](http://grants.nih.gov/grants/guide/url_redirect.htm?id=82301)) (Questions regarding Grants.gov registration and submission, downloading forms and application packages)

Contact Center Telephone: 800-518-4726

Email: support@grants.gov (<mailto:support@grants.gov>)

GrantsInfo (Questions regarding application instructions and process, finding NIH grant resources)

Email: GrantsInfo@nih.gov (<mailto:GrantsInfo@nih.gov>) (preferred method of contact)

Telephone: 301-710-0267

Scientific/Research Contact(s)

Sarah Morris, Ph.D.

National Institute of Mental Health ([NIMH](https://www.nimh.nih.gov/index.shtml) (<https://www.nimh.nih.gov/index.shtml>))

Telephone: 301-443-9233

Email: sarah.morris@nih.gov (<mailto:sarah.morris@nih.gov>)

Ivana Grakalic, Ph.D.

National Institute on Alcohol Abuse and Alcoholism ([NIAAA](http://www.niaaa.nih.gov) (<http://www.niaaa.nih.gov>))

Telephone: 301-443-7600

Email: igrakalic@mail.nih.gov (<mailto:igrakalic@mail.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)

Rita Sisco

National Institute of Mental Health (NIMH (<https://www.nimh.nih.gov/index.shtml>))

Telephone: 301-443-2805

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

Jeff Thurston

National Institute of Alcohol Abuse and Alcoholism (NIAAA (<http://www.niaaa.nih.gov>))

Telephone: 301-443-9801

Email: jeffrey.thurston@nih.gov (<mailto:jeffrey.thurston@nih.gov>)

Section VIII. Other Information

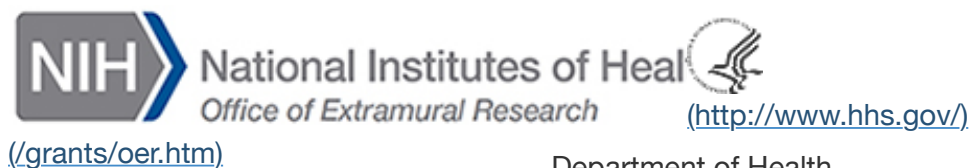
Recently issued trans-NIH [policy notices](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11163) (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11163) may affect your application submission. A full list of policy notices published by NIH is provided in the [NIH Guide for Grants and Contracts](http://grants.nih.gov/grants/guide/url_redirect.htm?i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

Authority and Regulations

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

[Weekly TOC for this Announcement](http://grants/guide/WeeklyIndex.cfm?09-21-18) (<http://grants/guide/WeeklyIndex.cfm?09-21-18>)

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



Department of Health
and Human Services (HHS)



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Note: For help accessing PDF, RTF, MS Word, Excel, PowerPoint, Audio or Video files, see [Help Downloading Files](http://grants/edocs.htm) ([/grants/edocs.htm](http://grants/edocs.htm)).