



# PRE-APPLICATION TECHNICAL ASSISTANCE WEBINAR AND CONFERENCE CALL

**HRSA-19-090: R41 Autism Secondary Data Analysis Research (SDAR)  
Program – Fiscal Year 2019 Competition**

**November 5, 2018**



# Presenter



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# Presentation Outline

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- Staff Introductions
- Overview of HRSA and MCHB
- Overview of Autism SDAR Program
- Key Changes in Fiscal Year 2018 and 2019
- Program Goals
- Eligibility Requirements
- Application Process & Deadlines
- Getting Help
- Questions and Answers



# Health Resources and Services Administration (HRSA)

- HRSA is the primary federal agency focused on improving health care for geographically isolated, economically or medically vulnerable populations.
- HRSA programs assist:
  - Those in need of high quality primary health care,
  - People living with HIV/AIDS,
  - Pregnant women and mothers, and
  - The training of health professionals.



# Maternal and Child Health Bureau (MCHB)

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- **HRSA's MCHB focuses on improving the health of America's mothers, children, and families.**
  - MCHB programs serve more than 50 million women, children, and families each year.
  - Our programs rely upon evidence-based strategies and are data-driven.

# Office of Epidemiology and Research (OER)

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- OER supports and conducts maternal and child health (MCH) research by providing national leadership around the development, advancement, and utilization of scientific knowledge.
- OER comprises of:
  - Division of Epidemiology (intramural research) and
  - Division of Research (extramural research).

# Division of Research (DoR)

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- Provides leadership and funding that supports innovative research which informs:
  - Practitioners,
  - The scientific community, and
  - The public.
- DoR's research programs help advance the MCH field improving the health and well-being of women, children, and families.

# MCHB Research Grant Competitions

MCH Focused Grants	Autism-Focused Grants
<b>Research Network (RN) Program</b>	
MCH RN Grant competitions	Autism RN Grant Competitions
<b>Field-Initiated Innovative Research Studies (FIRST) Program</b>	
MCH FIRST Grant Competitions	Autism FIRST Grant Competitions
<b>Secondary Data Analysis Research (SDAR) Studies Program</b>	
MCH SDAR Grant Competitions	<b>→ Autism SDAR Grant Competition</b>
<b>Single Investigator Innovation Program (SIIP)</b>	
MCH SIIP Grant Competitions	Autism SIIP Grant Competitions



# R41 Autism Secondary Data Analysis Research Program (SDAR)

- The R41 Autism SDAR Program is authorized by **Public Health Service Act, § 399BB(f) (42 U.S.C. § 280i-1(f))**, as amended.
  - (1) to increase awareness, reduce barriers to screening and diagnosis, promote evidence-based interventions for individuals with autism spectrum disorder or other developmental disabilities
  - (2) to conduct activities under this section with a focus on an interdisciplinary approach that will focus on specific issues for children who are not receiving an early diagnosis and subsequent interventions
- The R41 Autism SDAR program supports applied Autism research that **exclusively** utilizes secondary analysis of existing national databases and/or administrative records.



# Overview of R41 Autism SDAR Program

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- R41 Autism SDAR Program will provide funding for one (1) year
- Project Period will be September 1, 2019 – August 31, 2020.
  - Will fund four (4) grants for one (1)-year project period.
  - Award ceiling amount up to \$100,000 per grant/per year.
  - Funding is dependent upon satisfactory performance, availability of funding, and the continued interests of the federal government.



# Key Changes in Fiscal Year 2018 and 2019

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- The funding opportunity announcement is no longer called **FOA** but **Notice of Funding Opportunity, NOFO**.
- **Review score amounts** were added to the Crosswalk between the narrative and review criteria section of the NOFO to assist applicants.

# Program Goals (p.1 of the NOFO)

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Findings from the research supported by the program are expected to:

- Generate new evidence to address the needs of underserved populations
- Contribute to the broad public health impact to improve patient engagement and care delivery through studies
- Address the U.S. Department of Health and Human Services' (HHS) and Health Resources and Services Administration (HRSA) priority areas as they relate to ASD/DD populations and align with the research and surveillance activities identified in the Autism Cares Act of 2014



# Grantee Activities (p. 2)

**HRSA expects each Autism SDAR award recipient to complete the following major activities:**

- Conduct applied or translational research on critical and emerging ASD/DD issues through appropriate secondary data analyses of existing national databases and/or administrative records, that are aligned with research goals;
- Write and publish several peer-reviewed research articles about your project.
- Distribute research findings and products to scientific, professional, and lay audiences, including HRSA and other HHS agencies; and
- Report target population study sample with regards to diversity (i.e., ethnicity, race, gender/sex, geographic location, and socioeconomic status).



## National Databases (p. 2)

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Innovative secondary use of existing data from national datasets, administrative records and other publicly available datasets from a variety of sources are encouraged.

- Innovative analytic methods are encouraged.
- Dataset might consist of state or local administrative records, which would typically represent universal participation within a program among a particular population (e.g., Medicaid records for the population of children within a state who receive Medicaid.).

## Autism Cares Act, 2014, (p. 3)

In carrying out the provisions of the Autism CARES Act, HRSA supports programs to improve the quality of care among those diagnosed with ASD/DD through **education**, early **detection**, and **intervention**. Specifically, these activities are designed to:

- **Increase awareness** of ASD/DD;
- **Reduce barriers** to screening and diagnosis;
- **Support research** on evidence-based interventions for individuals with ASD/DD;
- **Promote guideline development** for interventions; and
- **Train professionals to utilize valid screening tools, to diagnose and to provide research-informed interventions** through an interdisciplinary approach that will also focus on specific issues for children who are not receiving an early diagnosis and subsequent interventions.
- The **four program areas** supported by HRSA include (1) Training for Professionals, (2) Autism Research Programs (3) Autism Policy Programs and (4) National Evaluation. For additional details, please see <https://mchb.hrsa.gov/maternal-child-health-initiatives/autism>.



# Eligibility Requirements: Institutions (p. 4)

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- Eligible applicants include
  - Any domestic public or private entity, including research centers or networks.
  - Domestic faith-based and community-based organizations,
  - Tribes, and tribal organizations.

# Application Responsiveness Criteria (p.4-5)

- In order to diversify our research grant portfolio, and ensure that investigators devote adequate time and expertise to funded research programs, a current PD/PI of an active HRSA/MCHB Research award:
  - Cannot be named as the Project Director (PD) or Principal Investigator (PI) on more than one application for the HRSA-19-090 competition; and serve for no more than 10 percent time on a new proposal;
- Applications to analyze publicly available and accessible longitudinal data are allowed;
- Analysis of secondary data previously collected by the applicant PD/PI will not be considered for funding;
- **NOTE:** Multiple applications from an organization with the same DUNS number **are** allowable if the applications propose separate and distinct projects.



# Application Responsiveness Criteria: Continued (p.4-5)

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Applications cannot propose to analyze linked datasets where one of the datasets proposed for analysis is not publicly available and accessible as all proposed datasets must be publicly available and accessible;

Applications must propose the use of existing publicly available and accessible national datasets and/or administrative records;

All secondary analyses, including those that involve the linkage of multiple datasets, cannot exceed 1 year in length; and

Projects that include the collection of biological specimens will not be considered, as this program funds only applied or translational research on ASD/DD populations and allows the use of existing databases and administrative data.



# Eligibility Requirements: Suspension & Debarment (S&D) (p. 6)

- An organization that is suspended, debarred, declared ineligible, or voluntarily excluded from eligibility for covered transactions by any Federal department or agency cannot, during the period of suspension, debarment, or exclusion, receive HHS grants or be paid from HHS grant funds.
- Failure to make required disclosures can result in any of the remedies described in 45 CFR § 75.371, including suspension or debarment. (See also 2 CFR parts 180 and 376, and 31 U.S.C. 3321).



# Budget (p. 6)

Section 4 of HRSA's *SF-424 R&R Application Guide* provides instructions for the budget, budget justification, staffing plan and personnel requirements, assurances, certifications, and abstract.

- Indirect cost rate: Each applicant organization has an indirect cost rate negotiated with HHS. Check with your sponsored programs office.
- Cap of \$100,000 total cost/year for up to 1 year.
- Funding restriction: foreign travel is not allowed
- You must include a budget justification explaining your budget.
- Links for SF-424 application guide are on page 6 of the NOFO:  
<https://www.hrsa.gov/sites/default/files/hrsa/grants/apply/applicationguide/sf-424-rr-guide-v2.pdf>



# Application Page Limits (p.6)

- Total **80 page limit**, includes all attachments. Only Standard Office of Management and Budget (OMB)-approved forms (application package) are not included in this page limit and others as specified in NOFO.
- Section C. Methodology/Research Strategy/Work Plan/Approach:
  - Limited to **6 pages** in length
  - Applications that exceed these page limits will be deemed non-responsive and will not be considered for funding under this notice.
- Font/Margin requirements: See SF-424 R&R Application Guide:
  - <https://www.hrsa.gov/sites/default/files/hrsa/grants/apply/applicationguide/sf-424-rr-guide-v2.pdf>



# Application Resubmissions (p. 7)

For a resubmission of a previously reviewed proposal, begin the Introduction by specifying that it is a resubmission; state the application/tracking number of the prior submission, its title, and HRSA notice number of the prior submission.

- **Example: This is a resubmission of application #, ‘Determinants of Racial Disparities in Access to Screening Services for Autism,’ that was submitted for HRSA-15-032.** (There is no limitation to the amount of time lapsed from initial submission of an application to resubmission.)

The following requirements pertain to a resubmission:

- Resubmitted applications will not be reviewed by the prior reviewers/review panel;
- The PD/PI must make significant changes to the application;
- This section must summarize the substantial additions, deletions, and changes to the application. It must also include a response to the issues and criticism raised in the Summary Statement of the previous application.
- The Introduction **should not exceed three pages in length;** and



# Application Resubmissions Continued (p. 7)

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- The substantial scientific changes must be marked in the text of the application by bracketing, indenting, or changing the typography. Do not underline or shade the changes. Deleted sections should be described but not marked as deletions.
- If the changes are so extensive that essentially all of the text would be marked, explain this in the Introduction. The Preliminary Studies/Progress Report section should incorporate work completed since the prior version of the application was submitted. Resubmissions must address all of the current NOFO requirements.

# Project Narrative Sections (p. 7-15)

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- A. Introduction
- B. Specific Aims
- C. Methodology/Research Strategy (important page limits)
- D. Impact and Dissemination
- E. Resources and Capabilities
- F. Feasibility
- G. Evaluation and Technical Support Capacity
- H. Protection of Human Subjects



# Other Application Materials

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- Abstract
- Staffing Plan: include in budget justification and personnel costs
- Biographical Sketches of Key Personnel
- Attachments:
  - Letters of Agreement/Support
  - Key Publications/Condensed citations
  - *Surveys, Questionnaires, Data Collection Instruments, Clinical Protocols*
  - Information regarding the database(s) you propose to use
  - Explanation on Delinquent Federal Debt, if applicable
  - Other relevant documents

# R41 Autism SDAR Review Criteria (p. 20)

Criteria	Description	Evaluative Points
Criterion 1	Need	10 points
Criterion 2	Response	20 points
Criterion 3	Evaluative Measures	20 points
Criterion 4	Impact	20 points
Criterion 5	Resources/Capabilities	10 points
Criterion 6	Support Requested	10 points
Criterion 7	Program Assurances	10 points

**These criteria are the basis upon which reviewers will evaluate the application during the objective review.**

# Crosswalk between Narrative and Review Criteria (p. 15-16)

Criteria	Corresponding Program Narrative Section	Points
N/A	<ul style="list-style-type: none"> <li>Introduction (for resubmission only)</li> </ul>	N/A
1. Need	<ul style="list-style-type: none"> <li>Section B - Specific Aims: Needs Assessment</li> </ul>	<b>10</b>
2. Response	<ul style="list-style-type: none"> <li>Section B - Specific Aims: Significance</li> <li>Section B - Specific Aims: Goals and Hypotheses</li> </ul>	<b>20</b>
3. Evaluative Measures	<ul style="list-style-type: none"> <li>Section C - Methodology/Research Strategy: Work Plan/Approach</li> <li>Section C - Methodology/Research Strategy: Scientific Innovation</li> </ul>	<b>20</b>
4. Impact	<ul style="list-style-type: none"> <li>Section D - Impact and Dissemination</li> </ul>	<b>20</b>



# Crosswalk between Narrative and Review Criteria (p. 15-16)

Review Criteria	Corresponding Program Narrative Section	Points
5. Resources/Capabilities	<ul style="list-style-type: none"> <li>Section E – Resources and Capabilities</li> </ul>	<b>10</b>
6. Support Requested	<ul style="list-style-type: none"> <li>Budget and Budget Justification</li> </ul>	<b>10</b>
7. Program Assurances	<ul style="list-style-type: none"> <li>Section F - Feasibility;</li> <li>Section G - Evaluation and Technical Support Capacity;</li> <li>Section H - Protection of Human Subjects</li> </ul>	<b>10</b>

# Appendix E: Grant Application Completeness Checklist (p. 42)

Requirement	Yes	No	Comments
Are you applying to the correct funding opportunity?			
Does this application propose a secondary data analysis project?			If no, you are applying to the wrong application.
Do you meet the eligibility criteria?			
Did you read the R&R Application Guide?			HRSA's SF-424 R&R Application Guide: <a href="https://www.hrsa.gov/grants/apply/application_guide/sf424rrguidev2.pdf">https://www.hrsa.gov/grants/apply/application_guide/sf424rrguidev2.pdf</a>
Do you have a DUNS number?			Dun and Bradstreet number: <a href="http://www.dnb.com/duns-number.html">http://www.dnb.com/duns-number.html</a>
Did your Authorized Organization Representative register in SAM <u>and</u> Grants.gov?			<ul style="list-style-type: none"> <li>This process can take up to 1 month to complete.</li> <li>System for Award Management (SAM:): <a href="https://www.sam.gov/">https://www.sam.gov/</a></li> <li>Grants.gov: <a href="http://www.grants.gov/">http://www.grants.gov/</a></li> </ul>
In the NEED Section, did you fully address how the proposal will address an unmet need?			
In the RESPONSE Section, did you fully address: <ul style="list-style-type: none"> <li>Goals and Hypotheses?</li> <li>Significance of Methodology/Research Strategy?</li> </ul>			



# First Things First!

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- **IMPORTANT:** Registration with **SAM.GOV** and **GRANTS.GOV** is required in order to submit your application for this competition. These registrations are mandatory.
  - If you have accounts, ensure your SAM.gov and Grants.gov registrations and passwords are current
  - If not, register with SAM.gov and Grants.gov immediately!
  - Registrations may take up to one month to complete.
  - Deadline extensions will not be granted due to a lack of registration.

# Electronic Submission

- Applications to this NOFO must be submitted electronically through **Grants.GOV**. There are **no** exceptions.
- Applications must be complete, within the specified page limit, and validated by Grants.gov under the correct funding opportunity number prior to the deadline to be considered under the announcement.
- Download SF-424 Research and Related (R&R) Application Guide associated with this NOFO following the directions provided at Grants.gov.
- Contact the Grants.GOV support center for assistance in downloading the application package.
- Familiarize yourself with SAM.Gov and Grants.Gov and obtain all the requirements that you need to make an application.

# SAM.GOV

View assistance for SAM.gov



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### CREATE USER ACCOUNT

Your CCR username will not work in SAM. You will need a new SAM User Account to register or update your entity records. You will also need to create a SAM User Account if you are a government official and need to create Exclusions or search for FOUO information.

[Create User Account](#)

### REGISTER/UPDATE ENTITY

You can register your Entity (business, individual, or government agency) to do business with the Federal Government. If you are interested in registering or updating your Entity, you must first create a user account.

[Register/Update Entity](#)

**New!** Use the SAM Status Tracker to: [Check Status](#)

### SEARCH RECORDS

All entity records from CCR/FedReg and ORCA and exclusion records from EPLS, active or expired, were moved to SAM. You can search these records and new ones created in SAM. If you are a government user logged in with your SAM user account, you will automatically have access to FOUO information.

[Search Records](#)

[WHAT IS SAM?](#) [Need Help?](#)

The **System for Award Management (SAM)** is the Official U.S. Government system that consolidated the capabilities of CCR/FedReg, ORCA, and EPLS. There is NO fee to register for this site. Entities may register at no cost directly from this page. User guides and webinars are available under the Help tab.

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Funding Opportunity Number	Opportunity Title	Agency
RFA-367-15-000002	Health and Hygiene Activity	Nepal USAID-Kathmandu
CDC-RFA-PS14-141202CONT16	World Health Organization: Expanding Efforts and Strategies to Prevent and Control TB Including Multidrug-Resistant TB, and TB in Vulnerable Populations	Centers for Disease Control and Prevention
N00014-15-R-SN16	Stand-Off and Remote Improvised Explosive Device Detection and Neutralization	Office of Naval Research

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### Grants.gov Updates

- Grants.gov Calendar**  
Check out our calendar to get the latest updates about our upcoming releases, maintenance, and outages.
- Grants.gov Scheduled Maintenance Outage: September 19-21, 2015**
- Grants.gov Notices - Updated June 25, 2015**  
For more information on upcoming changes with user impacts, please visit the Grants.gov notices page for the latest information.
- Grants.gov Releases**  
For information about recent changes and enhancements to Grants.gov, review the latest release notes.
- Grants.gov Blog**  
Visit the Grants.gov Blog to get up-to-date status of upcoming maintenance and outages.
- DATA Act Section 5 Pilot Program Presentation**  
The Department of Health and Human Services (DHHS) recently organized a webinar about the DATA Act Section 5 Pilot Program.

Grants.gov Support Center Contact Info:

Phone: 1-800-518-4726, Email: [support@grants.gov](mailto:support@grants.gov)



# Application Deadline

- All applications are due on **Monday, January 22, 2019 by 11:59 PM ET**
- Apply in advance.
- Extensions are not allowed.
- Sign-up for alerts on [Grants.gov](https://www.grants.gov)



# Review of Applications

- HRSA has instituted procedures to provide for an objective scientific review of applications.
- Procedures allow for independent assessment of the scientific merit and potential impact of applications.
- Applications are reviewed by HRSA's Division of Independent Review using rigorous peer-review mechanisms.
- Applicants should understand the standards of evaluation and follow these as guidelines while preparing applications.
- HRSA does not institute pay lines.
- The highest ranked applications will receive consideration for award within available funding ranges, depending on availability of funds.
- Funding ranges vary for each competition.



# Outcome Notifications

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- After the independent review, all applicants will receive:
  - A review critique (summary statements); and
  - An email notice regarding the outcome of their proposals.

# Application Process Reminders - Summary

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- Review the entire Notice of Funding Opportunity (NOFO)
- Use the completeness checklist for your planning
- Review the Frequently Asked Questions (FAQ)
- Review the eligibility requirements and application criteria
- Register with [www.SAM.gov](http://www.SAM.gov)
- Familiarize yourself with [www.Grants.gov](http://www.Grants.gov)
- Plan to apply early – do not wait for the last minute
- Program staff are here to assist.



# Getting Help: Key Resources

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- [www.Grants.gov](http://www.Grants.gov)
- [www.Sam.gov](http://www.Sam.gov)
- NOFO Frequently Asked Questions (Appendix D)
- [www.HRSA.gov](http://www.HRSA.gov)
- [www.mchb.hrsa.gov](http://www.mchb.hrsa.gov)
- [www.mchb.hrsa.gov/research](http://www.mchb.hrsa.gov/research)

# Getting Help - Key Contacts

## Programmatic Questions

Sylvia Sosa, MSc  
[ssosa@hrsa.gov](mailto:ssosa@hrsa.gov)

## Budget/Financial Questions

Stanley Gordon  
[SGordon2@hrsa.gov](mailto:SGordon2@hrsa.gov)

## Issues Downloading/Submitting Applications

Grants.gov Support Center 1-800-518-4726  
[support@grants.gov](mailto:support@grants.gov)



# Questions and Answers

