

Data Access Request Instructions

Access to data contained in the NDAR Central Repository is guided by [SOP-04 Data Access Permission Request](#). Access to data contained in federated repositories can be requested through NDAR, but will be adjudicated by the Data Access Committee for the federated resource. Such federated resources have their own data access procedures and policies which must be complied with separate and apart from those utilized by NDAR.

For permission to query and access shared data stored in the NDAR Central Repository, an investigator is required to complete:

1. The [simplified SF-424 \(R&R\) form](#) and
2. The Data Use Certification contained in the [NDAR Data Access Request information packet](#).

Instructions for completing these forms are provided below.

For permission to query and access shared data stored in data sources that are federated with NDAR, an investigator will be expected to complete access agreements specific to these data sources in addition to the SF-424(R&R) and Data Use Certification.

Approved access requests are valid for one year at which time the investigator must re-apply using the same forms and process.

SF 424 R&R Application for Federal Assistance

Instructions: The SF 424 is comprised of two parts. The first part is the application. The second part is the additional information about the proposed research and the use of human subjects in the proposed research; only the highlighted fields need to be completed.

Application

1. **Type of Submission:** This field does not need to be completed.
2. **Date Submitted:** Record the date on which the application is completed.
3. **Date Received:** This field does not need to be completed.
4. **Federal Identifier and Agency Routing Number:** This field does not need to be completed.
5. **Applicant Information:** Complete the following information for the applicant.
 - **Organizational DUNS:** This field does not need to be completed.
 - **Legal Name:** Record the legal name of the organization with which the applicant is affiliated. This is the organization that has registered with the Central Contractor Registry (CCR). Information on registering with CCR may be obtained by visiting www.Grants.gov.
 - **Department:** Enter the name of primary organizational department, service, laboratory, or equivalent level within the organization which will undertake the assistance activity.
 - **Division:** Enter the name of primary organizational division, office, or major subdivision which will undertake the assistance activity.
 - **Complete Address:** Record the complete mailing address for the applicant.
 - **Street1** - Enter first line of the street address for the applicant in "Street1" field. This field is required.
 - **Street2** - Enter second line of the street address for the applicant in "Street2" field. This field is optional.
 - **City** - Enter the city for address of applicant. This field is required.
 - **County/Parish** - Enter the county or parish for address of applicant.
 - **State** - Enter the State where the applicant is located. This field is required if the applicant is located in the United States.
 - **Province** – Enter the Province.
 - **Country** - Enter the country for the applicant address. This field is required.

- ZIP / Postal Code - Enter the nine-digit Postal Code (e.g., ZIP code) of applicant. This field is required if the applicant is located in the United States. This field is required if a State is selected; optional for Province.
- Person to be Contacted: This field does not need to be completed.

6. Employer Identification: This field does not need to be completed.

7. Type of Applicant: This field does not need to be completed.

8. Type of Application: Record the type of application. Only two options are available for NDAR Access requests (New or Renewal). Only the type of application needs to be marked. No other information is needed in this section.

- New: Check 'New' if this is the initial application for access to NDAR.
- Renewal: Check 'Renewal' if you have already had access to NDAR and you are submitting an annual renewal application.
- Resubmission: Do not use.
- Continuation: Do not use.
- Revision: Do not use.

9. Name of Federal Agency: This field does not need to be completed.

10. Catalog of Federal Domestic Assistance Number: This field does not need to be completed.

11. Descriptive Title of Applicant's Project: Provide a title for the project that will utilize data accessed in NDAR. More information on the details of the project should be provided in "Box 7. Project Summary/Abstract" on page 3.

12. Proposed Project Dates: Enter the dates proposed for the project. While you may enter in a range of time more than one year, be advised that access to NDAR must be renewed every 12 months.

13. Congressional District of Application: This field does not need to be completed.

14. Project Director/Principal Investigator Contact Information: Provide complete contact information for the Project Director/Principal Investigator of the proposed project. Required elements are listed below.

- First Name
- Last Name
- Organization Name
- Complete Address (Street, City, State, Country and Zip/Postal Code)

- Phone Number
- Email Address

15. Estimated Project Funding: This field does not need to be completed.

16. Is Application Subject to Review by State Executive Order 12372 Process?: This field does not need to be completed.

17. Certification and Signature:

- I Agree: After reading the acknowledgements related to the SF 424 (R&R), the Project Director/Principal Investigator should mark the 'I Agree' check box to indicate acceptance of the terms specified above. Applications that do not have this box checked will not be accepted for review.
- Signature: The signature of the person listed as Project Director/Principal Investigator in question 14 must be provided. **An actual signature must be provided. Stamped names or electronic signatures will not be accepted.**
- Date: The date on which the document was signed must also be included for the application to be reviewed.

18. SFLL or Other Explanatory Documentation: This field does not need to be completed.

19. Authorized Representative: It is the organization's responsibility to assure that only properly authorized individuals sign in this capacity. Provide complete contact information for an authorized individual at the institution with signature authority. Information must be supplied for the authorized institutional business official who also counter-signs the Data Use Agreement. The authorized institutional business official is defined as an individual at the institution which has signature authority as denoted in the Electronic Research Administration database also known as eRA Commons (<https://public.era.nih.gov>). **It is important to note that individuals authorized to sign the form are listed with a Role of 'SO'. Individuals listed with the role of 'AA' or 'AO' are not authorized to sign the document.** Required elements are listed below.

- First and Last Name
- Position/Title
- Organization Name
- Complete Address (Street, City, State, Country and Zip/Postal Code)
- Phone Number
- Email Address

- Signature: The signature of the person listed as the Authorized Representative in question 19 must be provided. **An actual signature must be provided. Stamped names or electronic signatures will not be accepted.**
- Date: Enter the date that the Authorized Representative signed the document.

20. Pre-Application: This field does not need to be completed.

SF 424 Research and Related - Other Project Information

1. Are Human Subjects Involved?:

- No: Check “No” if research activities involving human subjects are not planned at any time during the proposed project period.
- Yes: Check “Yes” if research activities involving human subjects are planned at any time during the proposed project period, either at the applicant organization or at any other performance site or collaborating institution. Check “Yes” even if the research is exempt from the regulations for the protection of human subjects. **Since data related to human subjects will be accessed, investigators should check “Yes”.
- 1a. Is the Project Exempt from Federal Regulations?:
 - No – Check No if the project is not exempt from Federal regulations.
 - Yes - Check “Yes” if all the research activities proposed are designated to be exempt from Federal regulations. Insert the exemption number(s) corresponding to one or more of the six exemption categories listed in I. B. “Exemptions.”
- **Exemption Number:** Select the appropriate exemption number from 1, 2, 3, 4, 5, 6. If human subject activities are exempt from Federal regulations, provide the exemption numbers corresponding to one or more of the exemption categories. The six categories of research that qualify for exemption from coverage by the regulations are defined in the Common Rule for the Protection of Human Subjects. Definitions of the exemptions can be found at: <http://grants.nih.gov/grants/policy/hs/glossary.htm>. ** It should be noted that most exemptions will be exemption #4. Exemption 4, as it pertains to research involving human subjects, is defined in 46.101(b). In order for proposed research to be exempt from the requirement of continuing IRB review and approval under Exemption 4, investigators must propose the use of data or samples that are either: existing and publicly available OR existing and unidentifiable to the research team.
- If no, is the IRB review Pending?: Check “Yes” or “No” to indicate whether an IRB review is pending.

- **IRB Approval Date:** If the IRB has already reviewed and approved your proposed research, record the date on which the IRB approved the research plan.
- **Human Subject Assurance Number:** All investigators seeking access to data in NDAR must be affiliated with an institution with a Federalwide Assurance Number. The numbers provided on the Data Access Agreement (EIN and DUNS) are not acceptable to meet this requirement. Enter the approved Federalwide Assurance (FWA) that the applicant has on file with the Office for Human Research Protections. If the applicant has a FWA number, enter the 8-digit number. If your organization does not have a Federalwide Assurance, you can request one through the following link. <http://www.hhs.gov/ohrp/assurances/assurances/file/index.html>. Applications for access to NDAR data without a Federalwide Assurance number that can be verified will not be accepted for review by the Data Access Committee.

2. **Are Vertebrate Animals Used:** This field is not applicable and should not be completed.
3. **Is proprietary/privileged information included in the application?:** This field is not applicable and should not be completed.
4. **Does this project have an actual or potential impact on the environment?:** This field is not applicable and should not be completed.
5. **Is the research performance site designated, or eligible to be designated, as a historic place?:** This field is not applicable and should not be completed.
6. **Does this project involve activities outside the U.S. or partnership with International Collaborators?** This field is not applicable and should not be completed.
7. **Project Summary/Abstract:** Provide a short description of the proposed research that will utilize data in NDAR. The project does not need to be thoroughly described as this is not an application for research funding, however it should sufficiently demonstrate the type of data that is planned to be accessed and the general research question related to the project.
8. **Project Narrative:** This field is not applicable and should not be completed.
9. **Bibliography & References Cited:** This field is not applicable and should not be completed.
10. **Facilities & Other Resources:** This field is not applicable and should not be completed.
11. **Equipment:** This field is not applicable and should not be completed.
12. **Other Attachments:** This field is not applicable and should not be completed.

Research and Related Senior/Key Person Profile

The data access request process also allows for multiple members of a research team to be provided with access to the NDAR Central Repository in addition to the Project Director/Principal Investigator. Each additional person for whom complete information is provided will also be provided automatic access NDAR if the request is approved once they request an NDAR account. An unlimited number of people can be added to the application using additional sheets of this page. Any team member not listed on the initial application will not be provided access until an addendum is completed and submitted to NDAR. The addendum requires the following:

- A new, fully completed SF 424 adding the new team members is required.
- The new SF 424 must be signed by both the PI and an authorized institutional business official.
- Dates on the addendum should be current dates. The signatures and dates from the original application will not be accepted.
- An updated Data Use Certification is not required.

If additional team members are approved using this addendum method, the expiration date of the access will not be extended, rather it will remain the one year from the approval date of the original application and standard re-application procedures will need to be followed.

For each additional person added, the following information is required and is indicated by the highlighted areas on the form:

- Prefix
- Last Name
- First Name
- Street Address
- City
- State
- Country
- Zip/Postal Code
- Phone Number
- Email Address
- Project Role

Data Use Certification - Central Repository Access Request

Instructions: The Data Use Certification is a required document for review of a data access request to the NDAR Central Repository. After reading the policy on the preceding pages, the final Recipient Information and Certifications page must be completed and provided as part of the data access request package sent to NDAR.

All information should be PRINTED clearly and legibly.

- **First Name:** Print the first name of the Project Director/Principal Investigator.
- **Last Name:** Print the last name of the Project Director/Principal Investigator.
- **Degree:** Print the degree(s) of the Project Director/Principal Investigator.
- **Academic Position or Title:** Print the position or title of the Project Director/Principal Investigator.
- **Institution:** Print the institution with which the Project Director/Principal Investigator is affiliated.
- **Department:** Print the department if applicable.
- **Address:** Print the complete mailing address for the Project Director/Principal Investigator including the street address, city, state/province, zip/postal code and country.
- **Telephone:** Provide the telephone number for the Project Director/Principal Investigator.
- **Fax:** Provide the fax number for the Project Director/Principal Investigator.
- **Email address:** Print the email address for the Project Director/Principal Investigator.
- **Research Project (title):** Print a title for the research project. Details do not need to be provided in this area as they are provided on the SF-424.
- **Certification Signature:** The Project Director/Principal Investigator must sign and date the document. An original signature must be used. A stamp of the Project Director/Principal Investigator name or electronic signature is not acceptable.
- **Authorized Institutional Business Official Information:**
 - **Name:** Print the complete name of the authorized institutional business official. It is the organization's responsibility to assure that only properly authorized individuals sign in this capacity. The same person who signs the SF 424 must sign this

document. The authorized institutional business official is defined as an individual at the institution which has signature authority as denoted in the Electronic Research Administration database also known as eRA Commons (<https://public.era.nih.gov>). **It is important to note that individuals authorized to sign the form are listed with a Role of 'SO'. Individuals listed with the role of 'AA' or 'AO' are not authorized to sign the document.**

- **Title:** The title of the authorized institutional business official must be printed.
- **FWA#:** All investigators seeking access to data in NDAR must be affiliated with an institution with a Federalwide Assurance Number. Enter the approved Federalwide Assurance (FWA) that the applicant has on file with the Office for Human Research Protections. If the applicant has a FWA number, enter the 8-digit number. If your organization does not have a Federalwide Assurance, you can request one through the following link: <http://www.hhs.gov/ohrp/assurances/assurances/file/index.html>. Applications for access to NDAR data without a Federalwide Assurance number that can be verified will not be accepted for review by the Data Access Committee.
- **Signature:** The authorized institutional business official with signature authority must sign the document. **An original signature must be provided. Stamped names or electronic signatures are not acceptable.**
- **Date:** Record the date on which the authorized institutional business official signed the document.

Glossary

Authorized Institutional Signing Official - The Signing Official (SO) has institutional authority to legally bind the institution in grants administration matters. The individual fulfilling this role may have any number of titles in the grantee organization. The label "Signing Official" is used in conjunction with the eRA Commons. The SO can register the institution, and create and modify the institutional profile and user accounts. The SO also can view all grants within the institution, including status and award information. An SO can create additional SO accounts as well as accounts with any other role or combination of roles. For most institutions, the Signing Official (SO) is located in its Office of Sponsored Research or equivalent. The list of Signing Officials can also be found in the Institution Profile.

- Log in to eRA Commons
- Select Institution Profile tab followed by the Basic tab
- The list of Signing Officials is listed at the bottom under Signing Officials

If you are unable to identify the SO at your institution, contact the NIH eRA Commons Help Desk at commons@od.nih.gov.

Data Access Committee (DAC) - NDAR Data Access Committee (DAC) has been established to objectively and systematically review the requests for data submission and access to NDAR resources. Collectively, the NDAR DAC has overall responsibility for ensuring compliance with the NDAR Policy. Specifically, the NDAR DAC is responsible for the following:

1. Reviewing and approving of data submissions to the NDAR Central Repository in compliance with the NDAR policies.
2. Reviewing and approving of individuals requesting access to controlled NDAR resources (e.g. NDAR Central Repository) for broad access or for NDAR's Ongoing Study capability.
3. Agreeing to Memoranda of Understanding (MOUs) or agreements with entities interacting with NDAR, such as federated data resources.
4. Authorizing other groups, such as NDAR Staff, to perform specific tasks defined within this document (e.g. QA/QC procedures, security compliance, granting of access in NDAR based upon DAC decisions, etc.).
5. Approving the NDAR standard operating procedures (SOPs).

Each repository that is federated with NDAR has established a separate DAC and associated policies and procedures.

Federalwide Assurance (FWA) – The Federalwide Assurance (FWA) is the only type of assurance currently accepted and approved by Office for Human Research Protections (OHRP). Through the FWA, an institution commits to Department of Health and Human Services (HHS) that it will comply with the requirements in the HHS Protection of Human Subjects regulations at 45 CFR part 46. AN FWA is a requirement for access to data in NDAR.

Federated Resource - An autism-relevant data repository that has agreed to federate and make their data available through NDAR. Access to the NDAR Central Repository is separate from access to any data contained in a federated resource.

Human Subjects - The Department of Health and Human Services (HHS) regulations "Protection of Human Subjects" (45 CFR 46, administered by Office for Human Research Protections (OHRP) define a human subject as a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or identifiable private information. Certain protections for human subject in research have been established and must be followed in the conduct of research activities.