NIMH Data Repositories

Data Access Request/Use Certification

Last updated: TBD

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NIMH Data Repositories Access Request

The NIMH Data Repositories are a group of Federal data repositories based on an informatics platform for human-subjects research domains related to mental health, initially established as the National Database for Autism Research to support autism-related research. As of June 2014, the system has expanded to include the following repositories:

- National Database for Autism Research (NDAR)—data submission and access
- National Database for Clinical Trials Related to Mental Illness (NDCT)—data submission and access
- Research Domain Criteria Database (RDoCdb)—data submission and access
  NIH Pediatric MRI Database (PedsMRI)—data access only

The appropriate Data Access Committee (DAC) reviews and approves requests to access data and/or images from their respective data repositories for research purposes only. The DAC(s) will review the NIMH Data Repositories Data Access Request/Use Certification of each Recipient requesting data and provide access based on the expectations outlined in the NDAR Policy and the NIH Guide Notice, Data Sharing Expectations for NIMH-funded Clinical Trials (NOT-MH-14-015). These expectations include the protection of data privacy, confidentiality, and security. In the event that requests raise concerns related to privacy and confidentiality, risks to populations or groups, or other concerns, the DAC(s) will consult with other experts as appropriate.

Recipients seeking access to data or images from any of the NIMH Data Repositories are expected to submit their Data Access Request/Use Certification (DUC) certified and co-signed by the Principal Investigator and the designated Institutional Official(s). Completing this Data Access Request/Use Certification is a necessary step to access data or images from any of the NIMH Data Repositories. Submission of data to any of the NIMH Data Repositories may be subject to the NIMH Data Repositories Submission Request and procedures.

Steps to Request General Data Access to the NIMH Data Repositories

1. Read the Data Access Request/Use Certification (DUC).
2. Complete the Recipient Information and Certifications pages, provide the institution's Federal-wide Assurance number, and include a Research Use Statement/Project Summary. Indicate the NIMH Data Repositories to which you are applying for access. The Research Use Statement/Project Summary should provide a brief description of the Research Project in the text box provided stating the objectives, design, and analysis plan. Provide a statement as to whether you have/will apply for, obtain, or do not have a Certificate of Confidentiality for the Research Project. List all the collaborating investigators at your organization. By submitting an individual's name on the form, you and your Institutional Official affirm that the collaborators have read and agreed to the terms and conditions within the Data Access Request/Use Certification (DUC). Collaborators at different organizations/institutions must complete separate requests for the data sponsored by their own organization/institution. Coordinated requests by collaborating organizations should all use the same title in their request and each should reference the others in the Research Use Statement.
3. Sign the Recipient Information and Certifications page, and obtain your Institutional Official's signature and date. Signatures will be accepted by institutional officials listed as a signing official (SO) in the eRA Commons system.

4. Provide a scanned copy of this complete document including the instructions and Data Access Request/Use Certification pages, with appropriate signatures, when requesting an account or requesting additional access to the NIMH Data Repositories
5. Access Request Review: The appropriate DAC will review requests to access the appropriate data repository. Such reviews are generally completed within 10 business days.
6. The DAC(s) will notify NIMH Data Repositories staff if the access request has been approved, and an account will then be provided. The user will receive an automated notification of their account update with any modified user name, passwords, or instructions for accessing the appropriate data.
7. Optional: System Training (if request approved): Contact NIMH Data Repositories Staff through NIMHDRHelp@mail.nih.gov to discuss specific training needs the user may have and schedule the training.

Data Use Certification for the NIMH Data Repositories—Introduction

The National Institutes of Health (NIH) and the National Institute of Mental Health (NIMH) have developed a federation of data repositories to store the collection of data from participants in research studies related to mental health, regardless of the source of funding. The extensive information collected by these studies, and subsequently stored in the National Database for Autism Research (NDAR), the NIH Pediatric MRI Repository (PedsMRI), the National Database for Clinical Trials Related to Mental Illness (NDCT), and the Research Domain Criteria Database (RDoCdb) provides a rare and valuable scientific resource. Promoting optimal use on a national scale of this resource will require a large and concerted effort, which may exceed the research capacity of currently available investigators. NIH and NIMH have responsibility to the public in general, and to the scientific community in particular, to encourage the use of these resources to achieve rapid scientific progress. In order to take full advantage of such resources and maximize their research value, it is important that data be made available, on appropriate terms and conditions, to the largest possible number of qualified investigators in a timely manner.

Data collected by the Submitters have been stripped of all individual identifiers, but the unique and intrinsically personal nature of DNA, derivative data of which are included in these repositories, combined with the recent increase in the accessibility of conducting genotype and other sequence analyses (in terms of technological capacity and cost), has altered the framework through which "identify-ability" can be defined. To protect and assure the confidentiality and privacy of all participants, the Recipient who is granted access to these data is expected to adhere to the specifications of this DUC. Failure to do so could result in denial of further access to data.

Submitters have made a substantial long-term contribution to NDAR, PedsMRI, NDCT, and RDoCdb by submitting data to the NIMH Data Repositories. NIH seeks to encourage appropriate data use and collaborative relationships by outside investigators with the Submitters and to ensure that the contribution of the Submitters is appropriately acknowledged.

National Database for Autism Research (NDAR)

The National Database for Autism Research (NDAR) is an NIH-funded research data repository that aims to accelerate progress in autism spectrum disorder (ASD) research through data sharing, data harmonization, and the reporting of research results. NDAR also serves as a scientific community platform and portal to multiple other research repositories, allowing for aggregation and secondary analysis of data.

NIH Pediatric MRI Data Repository (PedsMRI)

The goal of the NIH MRI Study of Normal Brain Development and the resulting Pediatric MRI Data Repository (PedsMRI) is to generate data that can help foster a better understanding of normal brain maturation as a basis for understanding atypical brain development associated with a variety of developmental, neurological, and neuropsychiatric disorders affecting children and adults. PedsMRI contains data from seven-year longitudinal study using magnetic resonance technologies to track brain maturation in healthy, typically developing infants, children, and adolescents, and to correlate brain development with cognitive and behavioral development.

National Database for Clinical Trials Related to Mental Illness (NDCT)

NIMH has made data sharing an expectation for all future clinical trials funded by NIMH (see NOT-MH-14-015). Researchers are expected to submit both positive and negative data and results from NIMH-funded clinical trials to the National Database for Clinical Trials Related to Mental Illness (NDCT) which will use the NDAR model. NDCT will provide a system to support the submission, sharing and access of relevant data at all levels of biological and behavioral organization and for all data types. At present, data submitted to NDCT will be the result of grants funded through a series of NIMH funding opportunity announcements (FOAs).

Research Domain Criteria Database (RDoCdb)

The Research Domain Criteria (RDoC) project aligns research in genetics, neuroscience, and behavioral science to develop a precision-medicine approach for classifying mental illnesses. In contrast to current symptom-based diagnostic systems for mental illnesses, precision medicine integrates many levels of information for each patient to define a precise diagnosis. Data submitted to the RDoC Database (RDoCdb) will include the results of grants funded through a series of NIMH FOAs in support of the RDoC project, as well as relevant data submitted by other interested investigators, regardless of funding source. More information on the RDoC project and related FOAs can be found on the RDoC webpage.

Definitions

For purposes of this agreement, "data" refers to the information that has been collected and recorded from participants in any study, regardless of the source of funding. Data from study participants were collected through the periodic examinations and follow-up contacts conducted pursuant to the Submitters' Cooperative Agreement grants, other grants, contracts, and other studies of mental illness conducted independent of NIH.

A "Submitter" is defined as a researcher with a past or current/active grant, contract, or consulting agreement with NIH, one of its contractors, or any other funding source, who has submitted data to the NIMH Data Repositories, according to the policies laid out in the NIMH Data Repositories Submission Agreement.

The "Recipient" Principal Investigator and his/her Organization may be a researcher at a non-profit or for-profit organization or corporation with an approved assurance from the Department of Health and Human Services Office for Human Research Protections. The Recipient Principal Investigator requests access to study data at his or her sole risk and at no expense to the study or NIH.

Terms and Conditions

I request approval to access data and/or images from one or more of the datasets within the NIMH Data Repositories for the purpose of scientific investigation or the planning of clinical research studies as described in the following Data Use Certification (DUC). I agree to the following terms:

1. Research Project/Research Use

These data will be used by Recipient Principal Investigator solely in connection with the "Research Project", specifically indicated and described in the Research Use Statement on the DUC. If the Project does involve Submitter(s), their names and the work they will perform is also included in the Recipient Information and Certifications section.

This DUC covers only the Research Project contemplated in the Research Use Statement section. Access is granted only to those datasets of the NIMH Data Repositories specified on the DUC. Recipient agrees that data will not be used in any research that is not disclosed and approved as part of the Research Project. Recipient will submit a completed DUC (this document) for each research project for which data are requested. This applies to all versions of NDAR data, all versions PedsMRI data, all versions of NDCT data, and all versions of RDoCdb data.

2. Non-transferability of Agreement

This DUC is not transferable. Recipient agrees that any substantive change Recipient makes to the Research Project requires execution of a new DUC, in which the new Research Project is designated. If the Recipient appoints another Principal Investigator to complete the Research Project, a new DUC in which the new Recipient is designated is necessary. If the Recipient changes institutions and wishes to retain access to NIMH Data Repositories, a new DUC in which the new institution acknowledges and agrees to the provisions of the DUC is necessary. If the Recipient changes Institutions and does not complete a new DUC, the Recipient agrees to destroy all copies of NIMH Data Repositories dataset(s) obtained under this DUC, including backup or working copies at the original site.

3. Non-Identification of Subjects

Recipient agrees that data will not be used, either alone or in conjunction with any other information, in any effort whatsoever to establish the individual identities of any of the study participants from whom data were obtained and/or contact the individual study participant, except as permitted by law (e.g., in connection with a separately negotiated collaboration with the original research team). Recipient agrees to notify NIH as soon as possible if, upon use of NIMH Data Repositories data, the Recipient discovers identifying information in that data.

4. GUID and Access to Submitted Data

The Global Unique Identifier (GUID) is a computer-generated alphanumeric code that is unique to each research participant. The GUID allows NIMH Data Repositories to link together all submitted information on a single participant, giving researchers access to information even if the data were collected at different locations or through different studies. If Recipients request access to data on individuals for whom they themselves have previously submitted data to NIMH Data Repositories, they may gain access to more data about an individual participant than they themselves collected. Consequently, these research activities may be considered "human subjects research" within the scope of 45 C.F.R. 46. Recipients must comply with the requirements contained in 45 C.F.R. 46, as applicable, which may require that they obtain IRB approval of their Research Project.

5. Data Disclaimers

Recipient agrees that NIH does not and cannot warrant the results that may be obtained by using any data included therein. NIH disclaims all warranties as to the accuracy of the data in NIMH Data Repositories or the performance or fitness of the data for any particular purpose.

6. Notification of NIH of Publication

Prompt publication or other public disclosure of the results of the Research Project is encouraged. Recipient agrees to notify NIH via email at NIMHDRHelp@mail.nih.gov as to when and where a publication (or other public disclosure) of a report from the Research Project will appear. Notification of such publications can occur by sending an email to NIMHDRHelp@mail.nih.gov with the title, authors, place of publication, and publication date. Notification of such publications can also occur by sending to NIH an updated biographical sketch or CV of the publishing author.

7. Data Access for Research

Data from completed studies are eligible for restricted "Controlled Access" by qualified researchers pursuant to the terms set forth in this agreement. Recipients of Controlled Access data acknowledge that other researchers have access to the data and that downloading, utilization, and duplication of research is a distinct possibility.

Data from ongoing studies may be eligible for restricted "Ongoing Study Access" following coordination and consultation with the Submitter and pursuant to the Additional Standards for Accessing Data While a Study is Ongoing (see http://ndar.nih.gov/ndarpublicweb/Documents/NDAR%20Ongoing%20Study%20Policy%20Addendum.PDF). This Ongoing Study Access policy pertains to NDAR, NDCT, and RDoCdb datasets.

8. No Distribution of Data

Recipient agrees to retain control over data, and further agrees not to transfer data, with or without charge, to any other entity or any individual. Recipient agrees not to sell the data in any form to any entity or individual or to distribute the data to anyone other than his/her research staff who will also agree to the terms within this DUC. This applies to all versions of NDAR data, all versions of PedsMRI data, all versions of NDCT data, and all versions of RDoCdb data.

9. Acknowledgments

Recipient agrees to acknowledge the contribution of the NIMH Data Repositories informatics platform; the appropriate repository (National Database for Autism Research (NDAR), and/or Pediatric MRI Data Repository (PedsMRI), and/or National Database for Clinical Trials (NDCT), and/or Research Domain Criteria Database (RDoCdb); the relevant dataset identifier(s) (e.g., a serial number generated via the NDAR Study feature [http://ndar.nih.gov/access_ndar_study.html or similar feature to be made available on the NDCT and RDoCdb Websites]); and, the Submitter(s) in any and all oral and written presentations, disclosures, and publications resulting from any and all analyses of data using the NIMH Data Repositories tools, whether or not Recipient is collaborating with Submitter(s). The manuscript should include the following acknowledgement or other similar language, as appropriate:

> **NDAR Acknowledgement**
> Data and/or research tools used in the preparation of this manuscript were obtained and analyzed from the controlled access datasets distributed from the NIH-supported National Database for Autism Research (NDAR). NDAR is a collaborative informatics system created by the National Institutes of Health to provide a national resource to support and accelerate

research in autism. Dataset identifier(s): [provide]. This manuscript reflects the views of the authors and may not reflect the opinions or views of the NIH or of the Submitters submitting original data to NDAR.

Pediatric MRI Acknowledgement
Data used in the preparation of this article were obtained from the NIH Pediatric MRI Data Repository created by the NIH MRI Study of Normal Brain Development. This is a multisite, longitudinal study of typically developing children from ages newborn through young adulthood conducted by the Brain Development Cooperative Group and supported by the National Institute of Child Health and Human Development, the National Institute on Drug Abuse, the National Institute of Mental Health, and the National Institute of Neurological Disorders and Stroke (Contract #s N01-HD02-3343, N01-MH9-0002, and N01-NS-9-2314, -2315, -2316, -2317, -2319 and -2320). A listing of the participating sites and a complete listing of the study investigators can be found at http://www.bic.mni.mcgill.ca/nihpd/info/participating_centers.html. This manuscript reflects the views of the authors and may not reflect the opinions or views of the NIH.

NDCT Acknowledgement
Data and/or research tools used in the preparation of this manuscript were obtained and analyzed from the controlled access datasets distributed from the NIMH-supported National Database for Clinical Trials (NDCT). NDCT is a collaborative informatics system created by the National Institute of Mental Health to provide a national resource to support and accelerate discovery related to clinical trial research in mental health. Dataset identifier(s): [provide]. This manuscript reflects the views of the authors and may not reflect the opinions or views of the NIMH or of the Submitters submitting original data to NDCT.

RDoCdb Acknowledgement
Data and/or research tools used in the preparation of this manuscript were obtained and analyzed from the controlled access datasets distributed from the NIMH-supported Research Domain Criteria Database (RDoCdb). RDoCdb is a collaborative informatics system created by the National Institute of Mental Health to store and share data resulting from grants funded through the Research Domain Criteria (RDoC) project. Dataset identifier(s): [provide]. This manuscript reflects the views of the authors and may not reflect the opinions or views of the NIH or of the Submitters submitting original data to RDoCdb.

If the Research Project involves collaboration with Submitters or NIH staff (as indicated in the DUC), then Recipient will acknowledge Submitters or NIH staff as co-authors, if appropriate, on any publication.

10. Non-Governmental Endorsement; Liability
Recipient agrees not to claim, infer, or imply endorsement by the United States Government, the Department of Health & Human Services, the National Institute of Health, or the National Institute of Mental Health of the Research Project, the entity, or personnel conducting the Research Project or any resulting commercial product(s). The United States Government assumes no liability except to the extent provided under the Federal Tort Claims Act (28 U.S.C. § 2671-2680).

11. Recipient's Compliance with Institutional Requirements.
Recipient acknowledges that access, if provided, is for research that is approved by the Institution, which must be operating under an Office of Human Research Protections-approved Federal-wide

Assurance. Furthermore, Recipient agrees to comply with all applicable rules for the protection of human subjects, which may include Department of Health and Human Services regulations at 45 C.F.R. Part 46, and other federal and state laws for the use of this data. Recipient agrees to report promptly to NIH any proposed change in the research project and any unanticipated problems involving risks to subjects or others. This DUC is made in addition to, and does not supersede, any of Recipient's institutional policies or any local, State, and/or Federal laws and regulations that provide additional protections for human subjects.

12. Recipient's Permission to Post Information Publicly

Recipient agrees to permit the NIH to summarize on the appropriate NIMH Data Repositories Web site the Recipient's research use of data along with the Recipient's name and organizational/institutional affiliation.

13. Privacy Act Notification

The Recipient agrees that information collected from the Recipient, as part of the Data Access Request, may be made public in part or in whole for tracking and reporting purposes. This Privacy Act Notification is provided pursuant to Public Law 93-579, Privacy Act of 1974, 5 U.S.C. Section 552a. Authority for the collection of the information requested below from the recipient comes from the authorities regarding the establishment of the National Institutes of Health, its general authority to conduct and fund research and to provide training assistance, and its general authority to maintain records in connection with these and its other functions (42 U.S.C. 203, 241, 289l-1 and 44 U.S.C. 3101), and Section 301 and 493 of the Public Health Service Act. These records will be maintained in accordance with the Privacy Act System of Record Notice 09-25-0156 (http://oma.od.nih.gov/public/ms/privacy/pafiles/0156.htm) covering "Records of Participants in Programs and Respondents in Surveys Used to Evaluate Programs of the Public Health Service, HHS/PHS/NIH/OD." The primary uses of this information are to document, track, and monitor and evaluate the use of the NIMH Data Repositories datasets, as well as to notify interested recipients of updates, corrections or other changes to the database.

The Federal Privacy Act protects the confidentiality of the Recipient's NIH records. The NIH and any sites that are provided access to the datasets will have access to the data collected from the Recipient for the purposes described above. In addition, the Act allows the release of some information in the Recipient's records without his/her permission; for example, if it is required by members of Congress or other authorized individuals. The information requested is voluntary, but necessary for obtaining access to data in the NIMH Data Repositories.

14. *Security*

Recipient acknowledges the expectations set forth by the attached "Information Technology Security Best Practices" for the use and security of data.

15. Annual Update/Research Use Reporting

When requested, Recipient will provide to NIMHDRHelp@mail.nih.gov, as applicable, an annual summary of research accomplishments from using NIMH Data Repositories data in an updated biographical sketch or CV. This annual summary may also be submitted via an NIMH Data Repositories Web site link if the function is available. NIH encourages Recipients who publish manuscripts based on a combination of NIMH Data Repositories data and data collected independent of the NIMH Data Repositories to consider submitting the complete analyzed dataset to the NIMH Data Repositories if possible.

16. Amendments

Amendments to this DUC must be made in writing and signed by authorized representatives of all parties.

17. Termination

Either party may terminate this DUC, without cause, provided 30 days' written notice to the other party. Recipients agree to immediately report violations of NDAR Policy and/or NOT-MH-14-015 to the appropriate NIMH Data Repositories DAC. Additionally, NIH may terminate this agreement with 5 days' written notice if the NIH determines, in its sole discretion, that the Recipient has committed a material breach of this DUC. NIH may, in its sole discretion, provide Recipient with 30 days' notice to remedy a breach before termination. Closed accounts may be reactivated upon submission of an updated Central Repository Access Request and DUC.

18. One-Year Term and Access Period

Recipients who are granted permission to access data from any of the NIMH Data Repositories receive an account with permission to access the data from a specified repository that is valid for a period of one year. This DUC will automatically terminate at the end of one year. An account may be renewed upon recertification of a new DUC. Accounts that remain inactive for 12 consecutive months may be closed at the discretion of NIH.

19. Accurate Representations

Recipient expressly certifies that the contents of any statements made or reflected in this document are truthful and accurate.

Information Technology Security Best Practices

The purpose of these Security Best Practices, which are subject to applicable law, is to provide minimum security standards and best practices for individuals who use the to submit, access, and analyze data. Keeping information from the NIMH Data Repositories secure through these best practices is important. Subject to applicable law, Recipients agree to immediately report breaches of data confidentiality to the NIMH Data Repositories DAC(s).

Best Practices

We suggest that you:

- Do not attempt to override technical or management controls to access data for which you have not been expressly authorized.
- Do not use your trusted position and access rights to exploit system controls or access data for any reason other than in the performance of the proposed research.
- Ensure that anyone directed to use the system has access to, and is aware of, Information Security Best Practices and all existing policies and procedures relevant to the use of the NIMH Data Repositories, including but not limited to, the NDAR Policy at http://ndar.nih.gov and 45 C.F.R. Part 46.
- Follow the password policy which includes:
  - Choose passwords of at least seven characters including at least three of the following types of characters: capital letters, lower case letters, numeric characters and other special characters.
  - Change your passwords every six months.
  - Protect your password from access by other individuals—for example, store it electronically in a secure location.
- Notify NIMH Data Repositories staff, as permitted by law, at nimhdrhelp@mail.nih.gov of security incidents, or any incidents of suspected fraud, waste or misuse of NIMH Data Repositories or when access to NIMH Data Repositories is no longer required.

Security Standards

- Protect the data, providing access solely to authorized researchers permitted access to such data by your institution or to others as required by law.
- When you download NIMH Data Repositories data, download the data to a secured computer or server with strong password protection.
- For the computers hosting NIMH Data Repositories data, ensure that they have the latest security patches and are running virus protection software.
- Make sure the data are not exposed to the Internet or posted to a website that may be discovered by Internet search engines such as Google or MSN.
- If you leave your office, close out of data files or lock your computer. Consider the installation of a timed screen saver with password protection.
- Avoid storing data on a laptop or other portable medium. If storing data on such a device, encrypt the data. Most operating systems have the ability to natively run an encrypted file system or encrypt portions of the file system. (Windows = EFS or Pointsec and Mac OSX = File Vault)
- When finished using the data, destroy the data or otherwise dispose of it properly, as permitted by law.

Burden Disclosure Statement

Public reporting burden for this collection of information is estimated to average 95 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-xxxx*). Do not return the completed form to this address

NIMH Data Repositories Data Access Request/Use Certification

Date: _____

Application Type		Data Requested
NEW	RENEWAL	
●	●	National Database for Autism Research (NDAR)
●	●	Pediatric MRI Data Repository (PedsMRI)
●	●	National Database for Clinical Trials (NDCT)
●	●	Research Domain Criteria Database (RDoCdb)

First Name: _____ Last Name: _____

Degree: _____ Academic Position (or Title): _____

Institution: _____ Department: _____

Street Address: _____

City: _____ State/Province: _____ Zip/Postal Code: _____

Country: _____ Phone: _____ FAX: _____

Institutional E-mail Address: _____

Research Project (title): _____

_____

_____

By signing and dating this DUC as part of requesting access to data in the NIMH Data Repositories, my Institutional Officials and I certify that we will abide by the DUC and the NIH principles, policies and procedures for the use of the NIMH Data Repositories. I further acknowledge that I have shared this document and the NIH policies and procedures with any research staff who will participate in the use of the NIMH Data Repositories. My Institutional Business Official(s) also acknowledges that they have shared this document and the relevant NIH policies and procedures with appropriate institutional organizations.

Signature: _____ Date: _____

Authorized Institutional Business Official (as registered in the NIH eRA Commons: https://commons.era.nih.gov/commons/*)*

Name: _____

Title: _____

FWA#:_____ Signature: _____ Date: _____

Inquiries and requests to Access Data in NIMH Data Repositories should be sent to:
Office of Technology Development and Coordination (OTDC), Program Director
National Institute of Mental Health, National Institutes of Health
6001 Executive Boulevard, Room 7202, MSC 9645
Rockville, MD 20892-9649 (if overnight delivery): Rockville, Maryland 20852
Telephone: 301-443-3265 Email: NIMHDRHelp@mail.nih.gov

Project Director/Principal Investigator Contact Information (if different from above)

First Name: _____ Last Name: _____

Degree: _____ Academic Position (or Title): _____

Institution: _____ Department: _____

Street Address: _____

City: _____ State/Province: _____ Zip/Postal Code: _____

Country: _____ Phone: _____ FAX: _____

Institutional E-mail Address: _____

Authorized Representative (Institutional Official)

First Name: _____ Last Name: _____

Degree: _____ Academic Position (or Title): _____

Institution: _____ Department: _____

Street Address: _____

City: _____ State/Province: _____ Zip/Postal Code: _____

Country: _____ Phone: _____ FAX: _____

Institutional E-mail Address: _____

Other Project Information:

1. Are Human Subjects involved? __ Yes __ No

If YES to Human Subjects

Is the Project Exempt from Federal regulations? __ Yes __ No

If yes, check appropriate exemption number. __1 __2 __3 __4 __5 __6

If no, is the IRB review pending? __ Yes __ No

IRB Approval Date: _____

2. Research Use Statement/Project Summary:

Senior/Key Person Profile (Collaborating Investigator)

First Name: ____________________ Last Name: ____________________

Degree: __________ Academic Position (or Title): ____________________

Institution: ____________________ Department: ____________________

Street Address: ____

City: ______________ State/Province: ______________ Zip/Postal Code: ________

Country: ______________ Phone: ______________ FAX: ______________

Institutional E-mail Address: ____

Project Role: ____________________ Other Project Role Category: ______________

Senior/Key Person Profile (Collaborating Investigator)

First Name: ____________________ Last Name: ____________________

Degree: __________ Academic Position (or Title): ____________________

Institution: ____________________ Department: ____________________

Street Address: ____

City: ______________ State/Province: ______________ Zip/Postal Code: ________

Country: ______________ Phone: ______________ FAX: ______________

Institutional E-mail Address: ____

Project Role: ____________________ Other Project Role Category: ______________

Senior/Key Person Profile (Collaborating Investigator)

First Name: ____________________ Last Name: ____________________

Degree: __________ Academic Position (or Title): ____________________

Institution: ____________________ Department: ____________________

Street Address: ____

City: ______________ State/Province: ______________ Zip/Postal Code: ________

Country: ______________ Phone: ______________ FAX: ______________

Institutional E-mail Address: ____

Project Role: ____________________ Other Project Role Category: ______________

Senior/Key Person Profile (Collaborating Investigator)

First Name: ____________________ Last Name: ____________________

Degree: __________ Academic Position (or Title): ____________________

Institution: ____________________ Department: ____________________

Street Address: ____

City: ______________ State/Province: ______________ Zip/Postal Code: ________

Country: ______________ Phone: ______________ FAX: ______________

Institutional E-mail Address: ____

Project Role: ____________________ Other Project Role Category: ______________

Use additional sheets for additional profiles as needed.