Federal Interagency Traumatic Brain Injury Research (FITBIR)

National Trauma Research Repository (NTRR)

Data Submission Request

Contents

Informatics System Data Submission Request

From here on, the Federal Interagency Traumatic Brain Injury Research (FITBIR) and the National Trauma Research Repository (NTRR) will collectively be referred to as "the Informatics System." The Data Access Committee (DAC) approves the submission of data and/or images to the Informatics System. The DAC will review the Informatics System Data Submission Request (DSR) and will decide whether to permit the submission based on the expectations outlined in the Informatics System policy. In the event that submissions raise concerns related to privacy and confidentiality, risks to populations or groups, or other concerns, the DAC will consult with other experts as appropriate. In unusual circumstances, when people are denied approval to submit data, appeals may be sent to the Policy Committee.

Submitters may use this DSR to 1) only submit data or 2) submit data for subsequent analysis with the Informatics System tools by the Submitter. Both types of requests are subject to approval by the DAC. Completing this DSR is a necessary step to submit data to the Informatics System. Access to other data within the Informatics System for analysis purposes may be subject to the Informatics System Data Access Request and procedures.

Steps to Request to Submit Data and/or Images

1. Contact the Operations staff through email, FITBIR: FITBIR-help@mail.nih.gov or NTRR: NTRR-ops@list.nih.gov to schedule an introductory call to begin planning for data submission. The Operations staff will discuss with the Data Submitter a) data submission expectations; b) supporting materials submission expectations; c) data access preferences; d) technical specifications; and e) data accuracy. Contacting the NIH two months before the desired date of submission is recommended to provide ample time to resolve technical and other issues.
2. Review the capabilities of FITBIR at https://fitbir.nih.gov/ or NTRR at https://ntrr.nih.gov/.
3. If the Informatics System can accommodate the data per the discussion with the Operations staff, read the Informatics System Data Submission Agreement below.
4. Identify individuals from your institution to serve as:
    - Data Submitter
        - Must be a permanent employee of their institution at a level equivalent to, but not limited to, a tenure-track professor or senior researcher. **Data Submitters cannot be post-doctoral fellows, trainees, or lab technicians.**
        - Must have oversight responsibility for others named on the data submission request who will be granted submission privileges to the study.
        - Can be accountable for ensuring that all aspects of data submission align with the terms of the DSR and institutional policy.
        - Must have an institutional email (no public emails will be accepted, e.g., Gmail)
    - Institutional Signing Official (SO)

    Note: The Institutional Signing Official CANNOT also serve as the Data Submitter

    Both the Data Submitter and Institutional Signing Official must provide an email address affiliated with their same self-identified institution corporation (NO personal email addresses will be accepted, e.g., Gmail).

    Any request submitted with a public-domain email address will be rejected.
5. Complete the Data Submitter Information and Certifications page and digitally sign it using a digital certificate. In addition, complete and digitally sign the signature page associated with the applicable certification form. Both signed documents should be uploaded when requesting an account.
6. Request an account by using the Research Auth Service (RAS) for single-sign on. Detailed instructions are available here: FITBIR: https://fitbir.nih.gov/access-with-ras or NTRR: https://ntrr.nih.gov/access-with-ras. When creating an account, request access to submit data (Study Privilege) at FITBIR: https://fitbir.nih.gov/ or NTRR: https://ntrr.nih.gov/. Requests for access to the Global Unique Identifier (GUID) client software may be submitted at this time.

7. Include your completed Data Submission Request (DSR) document with your request to create a new Study in the system.
8. Data submission review: The DAC will review requests to submit data to the Informatics System. Such reviews are generally completed within 15-20 business days.
9. The DAC will notify the Operations staff if the submission request has been approved. Users will receive an automated notification confirming their account access has been granted or updated.

Once a Submitter has been granted data submission permissions, they should follow the data submission steps outlined on FITBIR: https://fitbir.nih.gov/content/contribute-data or NTRR: https://ntrr.nih.gov/contribute-data.

Data Submission Agreement for the Informatics System

I request approval to submit data and/or images to the Informatics system for the purpose of sharing data for research purposes. I agree with the following terms:

1. **Research Project:** These data will be submitted solely in connection with the "Research Project", specifically indicated and described in the Submitter Information and Certifications section.

Data submitted to the Informatics System may be made available by the National Institutes of Health (NIH), the Department of War (DoW), and the Department of Veteran Affairs (VA) for either collaborative research (i.e., to accelerate research on ongoing studies) or general research purposes (i.e., meta-analyses and other secondary uses of the data). This agreement covers only the Research Project as contemplated in the Submitter Information and Certifications section. The Submitter must submit a completed DSR (this document) for each research project for which submission is requested.

2. **Non-transferability of Agreement:** This agreement is not transferable. The submitter agrees that substantive changes the Submitter makes to the Research Project require execution of a new DSR, in which the new Research Project is designated. If the Submitter changes institutions and wishes to retain submission privileges to the Informatics System, a new DSR in which the new institution acknowledges and agrees to the provisions of the DSR is necessary.

3. **Use of NIH Global Unique Identifier Client and Common Data Elements:** The Submitter has used the software program provided free-of-charge by NIH to assign GUIDs to each participant as described in the Policy for the Informatics System (Informatics System Policy) and has re-sorted the data according to the GUID. Submitter also agrees to use the Interagency TBI Common Data Elements or Trauma Common Data Elements as appropriate for their research. Operations staff will work with researchers to map their study variables to specific CDEs.

4. **Non-Identification of Subjects:** The Submitter agrees that the data and/or images have been 'de-identified' according to the following criterion: the identities of subjects cannot be readily ascertained or otherwise associated with the data by the repository staff or secondary data users. Submitter further agrees not to disclose the identities of research participants to the Informatics System in the future and to verify that data and/or images lack identifiers after submission. Submitter agrees to notify the Informatics System as soon as possible if, upon review of Informatics System data, the Submitter discovers identifying information in that data.

5. **Data Disclaimers:** The Submitter agrees that the DoW, NIH, and VA do not and cannot warrant the results that may be obtained by using any data or data analysis tools included in the Informatics System. The DoW, NIH, and VA disclaim all warranties as to the accuracy of the data in the Informatics System or the performance or fitness of the data or data analysis tools for any particular purpose.

6. **Supporting Materials:** The Submitter agrees to provide the Operations team with supporting information and documentation ("Supporting Materials") to enable efficient use of the submitted data by other researchers unfamiliar with the data. For example:

- Research protocol(s)
- Questionnaire(s)
- Study manuals
- Description of variable measures
- Other supporting documentation, as appropriate

7. **Data Accuracy:** The Submitter certifies to the best of his/her knowledge and belief that the data submitted to the Informatics System are accurate. Submitter also agrees to perform the specified quality control activities within a timeframe specified by the Informatics System Policy (see above). Submitter further agrees to notify the Informatics System as soon as possible if, upon review of Informatics System data, the Submitter discovers data quality concerns.

8. **Notification to DoW and NIH of Publication:** Prompt publication or other public disclosure of the results of the Research Project is required. Submitter agrees to notify the DoW, NIH, and VA 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 FITBIR: FITBIR-help@mail.nih.gov or NTRR: NTRR-ops@list.nih.gov with the title, authors, place of publication, and publication date. Notification of such publications can also occur by sending to the Informatics System an updated biographical sketch or CV of the publishing author.

9. **Data Access for Research:** The Submitter agrees that data and Supporting Materials submitted to the Informatics System may be accessed and used broadly by qualified researchers for research and other activities as authorized by and consistent with law. This access may result in duplication of research data.

10. **Non-Research Access:** The Submitter acknowledges that data and Supporting Materials submitted to the Informatics System become U.S. Government records that are subject to the Freedom of Information Act (FOIA). DoW and NIH are required to release Government records in response to FOIA requests unless they are exempt from release under one of the FOIA exemptions. Submitter further acknowledges that data and Submitting Materials may be used or released consistent with the law.

11. **Acknowledgments:** In any and all publications based upon dataset(s) submitted to the Informatics System, Submitter agrees to cite the Informatics System, the relevant Informatics System dataset identifier (a serial number), and the Submitter's federal research funding sources in each publication to which such datasets contribute (for abstracts, as space allows). The publication should include the following acknowledgement:

> *Data used in the preparation of this article reside in the Department of War (DoW) and National Institutes of Health (NIH)-supported **[specify FITBIR or NTRR]** Informatics System in **[specify dataset identifier].** This manuscript reflects the views of the authors and does not reflect the opinions or views of the DoW or the NIH.*

The Submitter agrees to acknowledge the contribution of the bioinformatics platform, the relevant Informatics System dataset identifier(s) (a serial number), 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 Informatics System tools, whether or not Recipient is collaborating with Submitter(s). The manuscript should include the following acknowledgement or other similar language:

> *Data and/or research tools used in the preparation of this manuscript were obtained and analyzed from the controlled access datasets distributed from the DoW, VA, and NIH-supported Informatics Systems. The **[specify FITBIR or NTRR]** Informatics System, created by the Department of War, the Department of Veteran Affairs, and the National Institutes of Health, is a national resource to support and accelerate research in TBI and trauma. Dataset identifier(s): **[provide]**. This manuscript reflects the views of the authors and may not reflect the opinions or views of the DoW, VA, NIH, or of the Submitters submitting original data to the Informatics System.*

12. **Non-Endorsement; Liability:** The Submitter agrees not to claim, infer, or imply endorsement by the United States Government, the Department of War, the Department of Health & Human Services, or the National Institutes of 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).

13. **Submitter's Compliance with Institutional Requirements:** The Submitter acknowledges that these data were collected in a manner consistent with all applicable laws and regulations, as well as institutional policies. Submitter further acknowledges that the data were collected pursuant to an informed consent that is not inconsistent with the data submission, and that the data submitted were collected in accordance with the NIH, DoW, and VA regulations, or applicable foreign law concerning the protection of human subjects, and other applicable U.S. federal and state laws, if any.

14. **Submitter's Permission to Post Information Publicly:** The Submitter agrees to permit the DoW, NIH, and VA to summarize and release for public use on the Informatics System Web site the Supporting Materials, along with the Submitter's name and organizations/institutional affiliation.

15. **Privacy Act Notification:** The Submitter agrees that information collected from the Submitter, as part of the SA, 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 Submitter 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 09-25-0200 covering "Clinical, Basic and Population-based Research Studies of the National Institutes of Health (NIH), HHS/NIH/OD." The primary uses of this information are to document, track, and monitor and evaluate the submission of data from clinical, basic, and population-based research activities and to notify Submitters in the event of a potential error in the dataset is identified or in the event of updates or other changes to the database.

The Federal Privacy Act protects the confidentiality of the Submitter's NIH, DoW, and VA records. The DoW, NIH, and VA will use the data collected for the purposes described above. In addition, the Act allows the release of some information in the Submitter's records without the Submitter's permission; for example, if it is required by members of Congress or other authorized individuals. The information requested is voluntary, but necessary for submitting data to the Informatics System.

16. **Security:** The Submitter acknowledges the expectations set forth by the attached "Information Security Best Practices" for the use and security of data.

17. **Amendments:** Amendments to this DSR must be made in writing and signed by authorized representatives of all parties.

18. **Termination:** Either party may terminate this DSR without cause, provided 30 days written notice to the other party. The Informatics System will retain a copy of all data already submitted for which data quality activities have been completed, except in the event that research participants withdraw consent for sharing of their data through the Informatics System repository and the DoW, NIH, and VA are informed by the Submitter to withdraw the data. Submitters agree to immediately report violations of the Informatics System Policy to the DAC. Additionally, the DoW, NIH, and VA may terminate this agreement with 5 days written notice if the agencies determine, in their sole discretion, that the Submitter has committed a material breach of this DSR. The agencies may, in their sole discretion, provide Submitter with 30 days' notice to remedy a breach before termination. Closed accounts may be reactivated upon submission of an updated Data Submission Request and DSR.

19. **One-Year Term and Access Period:** Researchers who are granted permission to submit data to the Informatics System receive an account that is valid for a period of one year. This DSR will automatically terminate at the end of one year. An account may be renewed upon recertification of a new DSR. Accounts that remain inactive for 12 consecutive months may be closed at the discretion of the DoW, NIH, and VA.

Information 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 Informatics System to submit, access, and analyze data. Keeping the Informatics System information secure through these best practices is important. Subject to applicable law, Submitters agree to immediately report breaches of data confidentiality to the DAC.

Best Practices

- 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 Informatics System, including but not limited to the FITBIR or NTRR policy at FITBIR: https://fitbir.nih.gov/content/policies-and-procedures or NTRR: https://ntrr.nih.gov/policies-and-procedures.
- Notify the Operations team at FITBIR: FITBIR-help@mail.nih.gov or NTRR: NTRR-ops@list.nih.gov of security incidents, or any incidents of suspected fraud, waste, or misuse of the Informatics System, or when access to the Informatics System is no longer required.

Security Standards

- Protect the data, providing access solely to authorized researchers permitted access to such data by your institution.
- Neither store nor transmit links between personally identifiable information and GUIDs.
- When you download Informatics System data, download the data to a secure computer or server with strong password protection.
- For the computers hosting Informatics System 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.

Submitter Information and Certifications

NOTE: Upload the document as a PDF. E-signatures with a digital certificate are required.

Date: _____

Select one: ◯ FITBIR ◯ NTRR

Type of Application: ◯ New ◯ Renewal

Data Submitter Information (Click Link for more information)

First Name:_____ Last Name:_____

Degree:_____ Academic Position (or Title): _____

Institution: _____ Department:_____

Street Address: _____

City: _____ State/Province:_____

Zip/Postal Code:_____ Country: _____

Telephone:_____ E-mail Address:_____

Note: public emails will be automatically rejected – please use your institutional email

Controlled-Access Data Submission

Is this submission subject to the NIH Genomic Data Sharing (GDS) Policy? ◯ Yes ◯ No

◯ Yes – Complete the Institutional Certification section

◯ No – Complete the Data Submission Certification section

Type of Data Submission:

Please indicate the category that best describes your data submission:

◯ **Primary Analysis Data**
Data generated and analyzed by the submitting research team as part of the original study objectives. This includes data collected directly from study participants and used to address the primary aims outlined in the approved study protocol.

◯ **Secondary Analysis Data**
Data derived from the analysis of existing datasets (e.g., previously collected study data or shared data resources) to address new or additional research questions beyond the original study objectives.

Research Project (Grant #): _____ Funding Agency:_____

Research Project (title and brief description): _____

_____

_____

_____

Certificate of Confidentiality: ◯ applied ◯ obtained ◯ does not have

Signatures:

By signing and dating this DSR as part of submitting data to the Informatics System, I certify that I will abide by the DSR and the DoW, NIH, and VA principles, policies, and procedures for the use of the Informatics System. I further acknowledge that I have shared this document and the DoW, NIH, and VA policies and procedures with any research staff who will participate in the use of the Informatics System.

Signature:_____Date: _____

IRB Approval #:_____Expiration Date:_____

Submitter's Authorized Institutional Signing Official (SO) Information and Signature:

Name:_____

Title:_____

Email:_____

By signing and dating this DSR as part of submitting data to the Informatics System, I certify that I will abide by the DSR, and the DoW, NIH, and VA principles, policies, and procedures for the use of the Informatics System. As the SO, I confirm that the listed Data Submitter is affiliated with their listed institution and meets the minimum requirements to qualify as a Data Submitter. I also confirm that each listed Collaborator is affiliated with their indicated institution.

Signature:_____Date: _____

The Institutional 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. For most institutions, the Signing Official (SO) is located in its Office of Sponsored Research or equivalent.

If you are unable to identify your SO, contact the NIH eRA Commons Service Desk.

Inquiries about requests to Submit Data to the Informatics Systems should be sent to:

FITBIR: FITBIR-help@mail.nih.gov
NTRR: NTRR-help@mail.nih.gov

Information on Other Key Personnel Requiring Data Submission Privileges:

Please list ALL individuals on the project that will need submission privileges to the repository, including graduate students, post-doctoral fellows, technicians, internal collaborators, etc.

Note: Collaborators MUST be from the same institution as the Data Submission Requester and SO. List each Collaborator below. External Collaborators are required to submit a separate DSR.

Collaborator is an individual whose identity has been validated and who is a permanent employee of their institution at a level equivalent to a tenure-track professor or senior scientist equivalent, but who is not under the direct supervision of the Data Submission Requester submitting the Request, who assists with the research project involving controlled-access data.

- **Internal collaborators** are employees of the Institutional Requester and work at the same institution as the Data Submission Requester.
- **External collaborators** are not employees of the Requester and/or do not work at the same location as the Data Submission Requester and consequently must be independently approved to submit data. If the Data Submission Requester plans to collaborate with researchers outside of their Requesting institution, then each external collaborator must submit a separate DSR with the exact title and wording as the Data Submission Requester and be approved by the DAC.

Additional Participant Information (Must be from the same institution as the Data Submitter and SO):

First Name:________________________________ Last Name: ____________________________

Degree:_________________Academic Position (or Title): __________________________________

Institution:__________________________________Department: ____________________________

Street Address: ____

City:___________________________________State/Province: ______________________________

Zip/Postal Code:____________________Country: ________________________________

Telephone:______________________________FAX: ______________________________

E-mail Address: _______________________________________(institutional emails only, no Gmail etc)

Project Role:________________________________Other Project Role Category: _______________________

Additional Participant Information (Must be from the same institution as the Data Submitter and SO):

First Name:________________________________ Last Name: ____________________________

Degree:_________________Academic Position (or Title): __________________________________

Institution:__________________________________Department: ____________________________

Street Address: ____

City:___________________________________State/Province: ______________________________

Zip/Postal Code:____________________Country: ________________________________

Telephone:______________________________FAX: ______________________________

E-mail Address: _______________________________________(institutional emails only, no Gmail etc)

Project Role:________________________________Other Project Role Category: _______________________

Additional Participant Information (Must be from the same institution as the Data Submitter and SO):

First Name:________________________________ Last Name: ____________________________

Degree:_________________Academic Position (or Title): __________________________________

Institution:__________________________________Department: ____________________________

Street Address: ____

City:___________________________________State/Province: ______________________________

Zip/Postal Code:____________________Country: ________________________________

Telephone:______________________________FAX: ______________________________

E-mail Address: _______________________________________(institutional emails only, no Gmail etc)

Project Role:________________________________Other Project Role Category: _______________________

Additional Participant Information (Must be from the same institution as the Data Submitter and SO):

First Name:_______________________________ Last Name: ___________________________

Degree:________________Academic Position (or Title): _________________________________

Institution:________________________________Department: ____________________________

Street Address: ____

City:__________________________________State/Province: _____________________________

Zip/Postal Code:___________________Country: ______________________________

Telephone:_____________________________FAX: ____________________________

E-mail Address: _____________________________________(institutional emails only, no Gmail etc)

Project Role:______________________________Other Project Role Category: ______________________

Additional Participant Information (Must be from the same institution as the Data Submitter and SO):

First Name:_______________________________ Last Name: ___________________________

Degree:________________Academic Position (or Title): _________________________________

Institution:________________________________Department: ____________________________

Street Address: ____

City:__________________________________State/Province: _____________________________

Zip/Postal Code:___________________Country: ______________________________

Telephone:_____________________________FAX: ____________________________

E-mail Address: _____________________________________(institutional emails only, no Gmail etc)

Project Role:______________________________Other Project Role Category: ______________________

Additional Participant Information (Must be from the same institution as the Data Submitter and SO):

First Name:_______________________________ Last Name: ___________________________

Degree:________________Academic Position (or Title): _________________________________

Institution:________________________________Department: ____________________________

Street Address: ____

City:__________________________________State/Province: _____________________________

Zip/Postal Code:___________________Country: ______________________________

Telephone:_____________________________FAX: ____________________________

E-mail Address: _____________________________________(institutional emails only, no Gmail etc)

Project Role:______________________________Other Project Role Category: ______________________

Use additional sheets for additional profiles as needed.

Data Submission Provisions and Certifications

Institutional Certification

I hereby assure that submission of data from the study entitled _____ _____ to the Informatics System data repository meets the following expectations, as defined in the NIH Genomic Data Sharing (GDS) Policy (NIH Guide Notice Number NOT-OD-14-124):

- The data submission is consistent, as appropriate, with applicable national, tribal, and state laws and regulations as well as relevant institutional policies.
- Any limitations on the research use of the data, as expressed in the informed consent documents, are delineated in the table for Institutional Certification Data Use Limitations (DUL) in this document.
- The identities of research participants will not be disclosed to the Informatics System data repository.
- An Institutional Review Board (IRB), and/or Privacy Board, and/or equivalent body, as applicable, has reviewed the Submitter's proposal for data submission and assures that:
    - The protocol for the collection of genomic and phenotypic data is consistent with 45 CFR Part 46. (45 CFR Part 46. Protection of Human Subjects);
    - Data submission and subsequent data sharing for research purposes are consistent with the informed consent of study participants from whom the data were obtained;
    - Consideration was given to risks to individual participants and their families associated with data submitted to the Informatics System data repository and subsequent sharing, including unrestricted access to genomic summary results;
    - To the extent relevant and possible, consideration was given to risks to groups or populations associated with submitting data to the Informatics System data repository and subsequent sharing, including unrestricted access to genomic summary results; and
    - The Submitter's plan for de-identifying datasets is consistent with the standards outlined in the NIH Genomic Data Sharing (GDS) Policy (See section IV.C.1).

Availability of Individual-Level Human Data

1. The individual-level data are to be made available through (check one)

    ◯ Controlled-access

    ◯ Unrestricted access

2. Is the individual-level, human genomic data to be submitted funded in whole or in part by NIH?

    ◯ Yes ◯ No

    IMPORTANT: If your research involves the generation of individual-level, human genomic data and is funded in whole or in part by NIH, your research is automatically deemed to be issued a Certificate of Confidentiality (CoC). For more information, see the NIH Certificates of Confidentiality webpage.

3. Is the individual-level, human genomic data to be submitted covered by a CoC?

    ◯ Yes ◯ No

Availability of Genomic Summary Results (GSR)

NIH provides genomic summary results (GSR) from most studies submitted to the Informatics System data repository through unrestricted access. However, data from data sets considered to have particular "sensitivities" related to individual privacy or potential for group harm (e.g., those with populations from isolated geographic regions, or with rare or potentially stigmatizing traits) may be designated as "sensitive" by _____ and public posting would be prohibited.

In such cases, "controlled access" should be checked below, and a brief explanation for the sensitive designation should be provided. GSR from any such study will only be available through controlled access, and public posting would be prohibited.

☐ Controlled access

If "controlled access" is checked, include a brief explanation for the sensitive designation.

If GSR are designated as sensitive and "controlled access" is checked above, are the GSR covered under (or have been issued) a CoC?

◯ Yes ◯ No

Note: If GSR are designated as sensitive and available only via controlled access, they may be subject to the NIH Certificates of Confidentiality Policy if there is at least a very small risk the individuals included in the summary results may be re-identified.

Institutional Certification Data Use Limitations (DUL)

NIH expects the submitting institution(s) to select one of the three standard Data Use Limitations (DULs) for appropriate secondary use, or, if necessary, create a customized DUL. DULs are developed based on the original informed consent of the participant(s).

Data Use Limitations

General Research Use	GRU	Use of the data is limited only by the terms of the Data Use Certification: these data will be added to the dbGaP Collection.
Health/Medical/Biomedical	HMB	Use of the data is limited to health/medical/biomedical purposes and does not include the study of population origins or ancestry.
Disease-specific [list disease]	DS	Use of the data must be related to the specified disease.
Other		[ENTER CUSTOMIZED TEXT, IF APPLICABLE]

Additional modifiers to the standard DULs (e.g., not-for-profit use only) can be indicated, if appropriate. Use of the modifiers should have a basis in the informed consent from the participants or in special knowledge of the preferences of the original study population.

Data Use Limitations Modifiers (Optional)

IRB Approval Required	IRB	Requestor must provide documentation of local IRB approval.
Publication Required	PUB	Requestor agrees to make the results of studies using the data available to the larger scientific community.
Collaboration Required	COL	Requestor must provide a letter of collaboration with the primary study investigator(s).
Not-for-profit Use Only	NPU	Use of the data is limited to not-for-profit organizations.
Methods	MDS	Use of the data includes methods development research (e.g., development and testing of software or algorithms.
Genetic Studies Only	GSO	Use of the data is limited to genetic studies only.

Using the tables above, please indicate in the table below the consent group(s) for each collaborating study site. Use one row per consent group.

Collaborating Site Name	**Data Use Limitation**		**Data Use Limitation Modifiers (optional)**
			IRB ☐ PUB ☐ COL ☐ NPU ☐ MDS ☐ GSO ☐
			IRB ☐ PUB ☐ COL ☐ NPU ☐ MDS ☐ GSO ☐
			IRB ☐ PUB ☐ COL ☐ NPU ☐ MDS ☐ GSO ☐
			IRB ☐ PUB ☐ COL ☐ NPU ☐ MDS ☐ GSO ☐
			IRB ☐ PUB ☐ COL ☐ NPU ☐ MDS ☐ GSO ☐

SIGNATURE PAGE – INSTITUTIONAL CERTIFICATION

SUBMITTED AND AGREED TO BY:

Data Submitter:

Name:_____

Title:_____

Signature:_____ Date:_____

Institutional Signing Official:

By signing below, I certify on behalf of _____ that, in addition to myself, an IRB or Privacy Board or equivalent body, and other relevant senior-level institutional staff (e.g., Dean, Vice-President/Provost for Research, Chief Science Officer) have reviewed the requirements in this certification and agree that the submission meets them.

Name:_____

Title:_____

Signature:_____ Date:_____

Any false or misleading statements made, presented, or submitted to the Government, including any relevant omissions, under this Certification are subject to all applicable civil and criminal statues including Federal statutes 31 U.S.C. §§3801-3812 (civil liability) and 18 U.S.C. §1001 (criminal liability including fine(s) and/or imprisonment).

Data Submission Certification

I hereby attest that the data submitted from the study entitled _____ _____to the Informatics System data repository are not subject to the requirements of the NIH Genomic Data Sharing (GDS) Policy.

- The data was collected in a manner consistent with all applicable national, Tribal, and state laws and regulations, as well as relevant institutional policies.
- The submission of the data is consistent with applicable national, Tribal, and state laws and regulations, as well as relevant institutional policies.
- Explicit limitations on subsequent use, such as those imposed by laws, regulations, policies, informed consent, and agreements, as applicable, or as otherwise determined by the Submitting Institution, will be delineated at submission.
- The metadata and supporting information, materials, and documentation to adequately describe and facilitate interpretation will be submitted to the Informatics System data repository at submission.
- The appropriate office(s) or component(s) of the institution, with relevant roles and expertise (such as an Institutional Review Board (IRB), Privacy Board, Human Research Protection Program (HRPP), or equivalent body), have reviewed the Submitter's proposal for data submission and confirm that:
    - Submission for subsequent sharing and use of the data for research purposes is consistent with explicit limitations on subsequent use, such as those imposed by laws, regulations, policies, informed consent, and agreements, or as otherwise determined by the Submitting Institution.
    - The submitted data have been de-identified to the extent required by the Informatics System data repository, applicable laws, regulations, and NIH policies.
    - Consideration has been given to risks to individual participants and their families associated with data submitted to the Informatics System data repository and subsequent sharing.
    - Consideration has been given to risks to groups or populations associated with submitting datasets to the Informatics System data repository and subsequent sharing.

1. Does the information to be submitted include identifiable, sensitive information?

◯ Yes ◯ No

IMPORTANT: Research in which identifiable, sensitive information is collected or used includes research that:

- Meets the definition of human subjects' research as defined in the Federal Policy for the Protection of Human Subjects (45 CFR 46), including exempt research in which participant information cannot be identified or their identity cannot readily be ascertained, directly or through identifiers;
- Is collecting or using human biospecimens that are identifiable or that have at least a very small risk of being used to deduce the identity of an individual;
- Involves the generation or use of individual-level human genomic data from biospecimens, regardless of identifiability; or
- Involves any other information where there is at least a very small risk that a person could be identified.

2. Is the identifiable, sensitive information to be submitted covered by a CoC?

◯ Yes ◯ No

IMPORTANT: Note that research subject to the NIH Certificates of Confidentiality Policy that involves the generation, collection, or use of identifiable, sensitive information that is funded in whole or in part by NIH is automatically deemed to be issued a Certificate of Confidentiality (CoC). For more information, see the NIH Certificates of Confidentiality webpage.

SIGNATURE PAGE - DATA SUBMISSION CERTIFICATION

SUBMITTED AND AGREED TO BY:

Data Submitter:

Name:_____

Title:_____

Signature:_____ Date:_____

Institutional Signing Official:

By signing below, I certify on behalf of _____ that, in addition to myself, an IRB or Privacy Board or equivalent body, and other relevant senior-level institutional staff (e.g., Dean, Vice-President/Provost for Research, Chief Science Officer) have reviewed the requirements in this certification and agree that the submission meets them.

Name:_____

Title:_____

Signature:_____ Date:_____

Any false or misleading statements made, presented, or submitted to the Government, including any relevant omissions, under this Certification are subject to all applicable civil and criminal statues including Federal statutes 31 U.S.C. §§3801-3812 (civil liability) and 18 U.S.C. §1001 (criminal liability including fine(s) and/or imprisonment).