Wisconsin Longitudinal Study

Instructions for Requesting Genetic Data

The Wisconsin Longitudinal Study is committed to the privacy of its study participants and WLS staff takes great care to maintain their confidentiality.

Genetic Data are available to researchers who:

1. Submit a short proposal (5 pages maximum) describing the research question and study design to carol.roan@wisc.edu. NOTE: Researchers should also indicate whether they want to work with the first or second wave of genetic data. Those wishing to work with the second wave of data should specify whether they want imputed or non-imputed data. For more information on the differences between the waves of genetic data see: http://www.ssc.wisc.edu/wlsresearch/documentation/
2. Send Curriculum Vitae (CV) of **every researcher** who will work with the genetic data to carol.roan@wisc.edu. NOTE: Students and Post-Docs are eligible to receive the data but only if they also submit the name and CV of a faculty sponsor.
3. Receive approval from the WLS PI.
4. Provide documentation of IRB approval from home institution[1].
5. Enter into a fully-executed Data Use Agreement (DUA) between the researcher's home institution and UW-Madison. A template of that agreement is attached.

Accessing the Data

Approved researchers who are not at UW- Madison will receive a link to download the genetic and phenotypic data files. Geographic measures and dates will not be included in the phenotypic files. Any researcher needing these measures in conjunction with genetic data should email carol.roan@wisc.edu.

[1] Researchers from UW –Madison should contact Joe Savard (joe.savard@wisc.edu) before submitting to IRB.

DATA USE AGREEMENT RESTRICTING DISCLOSURE AND USE OF RESTRICTED DATA FROM THE WISCONSIN LONGITUDINAL STUDY

This Data Use Agreement (DUA) is entered into the ________ day of ________, 20__ between the Board of Regents of the University of Wisconsin System on behalf of the University of Wisconsin-Madison, Wisconsin Longitudinal Study (WLS) and the

____ (Receiving Agency) wherein

____ (Investigator) is the researcher responsible for the projects using the WLS Restricted Data files.

Whereas, WLS has a data bank containing confidential information (the WLS Restricted Data including the WLS Genetic Data), and

Whereas, Investigator has an IRB or equivalent Ethics Committee-reviewed study requiring access to one or more files of the said data bank, and has submitted that plan to WLS (the Research Plan), and

Whereas, the Investigator and all other employees or agents of Receiving Agency having access to WLS Restricted Data under this Agreement (Supplemental Users) (collectively Researchers) acknowledge that this Restricted Data was obtained by WLS under representations that the identity of the individuals participating in the WLS would be kept absolutely confidential, acknowledge that the WLS Restricted Data is being provided to the Investigator and Supplemental Users under a strict pledge of confidentiality and non-disclosure as further described in this Agreement, and agree to take all necessary steps to ensure the continuing security and confidentiality of the WLS Restricted Data, as further described in this Agreement.

In consideration of the WLS providing access to the WLS Restricted Data, the Receiving Agency, its Investigator(s), and Supplemental Users, agree:

1. The WLS Restricted Data under this Agreement includes both the original WLS Restricted Data files provided by WLS, and any variables and fields derived from them.

2. No attempt shall be made to identify the individual person, family or household, employer, or benefit provider (except sole source providers of public benefits), either directly or inferentially in this or other WLS datasets.

3. If the identity of any person, family or household, employer, or benefit provider, or establishment in this file is inadvertently discovered, then (a) no use will be make of this knowledge, (b) the Director of WLS will be advised of this incident immediately, (c) the information that would identify any individual or establishment will be safeguarded or destroyed, as requested by WLS, and (d) no one else will be informed of the discovered identity.

4. The following guidelines will be employed when producing tabulations for distribution:
    - Magnitude Data: Ensure that no cells/strata with n < 5 are produced

- Frequency Data: Apply a marginal threshold of n >= 5 and cell threshold of n >= 5 to all tabulations
- Protection against complementary disclosure: additional cells may be suppressed, i.e., complementary disclosure, to make sure the primary suppressions cannot be derived by subtraction from published marginal totals.

5. Only aggregate statistical summaries of the data and analyses (frequency tabulations, magnitude tabulations, means, variances, regression coefficients, and correlation coefficients), shall be published, subject to the provisions above.

6. WLS shall be cited as the data source in any publications or research based upon these data, and a copy of any publications shall be provided to the WLS. The following citation should in included in any research reports, papers, or publications based on these data:

   In text: "The Wisconsin Longitudinal Study genetic data is sponsored by the National Institute on Aging (grant numbers R01AG009775, R01AG033285, and R01AG041868) and was conducted by the University of Wisconsin."

   In references: "Wisconsin Longitudinal Study. Produced and distributed by the University of Wisconsin with funding from the National Institute on Aging (grant numbers R01AG009775, R01AG033285, and R01AG041868), Madison, WI."

7. The Restricted Data and any data sets derived from it shall be stored and used in a secure computing environment as described in Exhibit B.

8. To the extent permitted by law, Receiving Agency shall hold harmless and indemnify the University of Wisconsin, its agents and employees, for any claims of breaches of confidentiality arising out of the Receiving Entity's, its Investigators and Supplemental Users use of the data provided under this Agreement including failure to abide by any section of this Agreement or any accidental or intentional violation of privacy of any contributor to any WLS data resource.

9. Access to Restricted Data will be limited solely to the Investigator(s) who are signatories to this Agreement, and to Supplemental Users (research assistant/associate, postdoctoral scholar, graduate student, undergraduate student, or other individual working on the research project and who are employees or agents of Receiving Agency). All Investigators and Supplemental Users agree not to share or provide copies of any files received by this Agreement to any other person or organization.

10. Receiving Agency and its Investigator shall ensure that any Supplemental Users granted access to the Restricted Data shall first agree to the same terms of confidentiality and non-disclosure as set forth in this Agreement through a written acknowledgement such as that included in Exhibit A. Such acknowledgements shall be made available to WLS upon request.

11. Receiving Agency shall return or destroy the data, and any derivative data files, upon request from WLS.

12. WLS Restricted Data will be used solely for scientific and public policy statistical research, and not for any administrative or law enforcement purpose.

13. Qualitative analysis of audio files that require printed transcriptions are not considered to be WLS Restricted Data. Such information may be freely published by the Investigator and may be used for ongoing research programs approved under this Agreement. When producing transcriptions for distribution, the following guidelines are to be employed:
    a) All first and last names, employers or company names must be removed from the transcription
    b) All mentions of locations must be removed from the transcription.

14. Researchers are prohibited from publishing results that identify geographic areas below the level of Census Division. Under certain circumstances, Researchers using WLS Restricted Data who have access to state-level geographic information may wish to report state-level summary information. In such cases, analysis results must be submitted to the WLS for review and approval prior to presentation or publication.

15. All public representations of WLS Restricted Data involving geographic identifiers below Census Division must be submitted to WLS for review and approval. WLS will confirm receipt of materials via email to the Investigator, and will make every effort to review the materials within 10 business days of confirmed receipt. Investigator(s) agree to modify representations as suggested by WLS before public presentation.

16. No attempt will be made to link WLS Restricted Data with any other dataset, except as specified in the approved Research Plan; specifically, there may be no linkages of:
    a) the WLS Restricted Data with any other WLS research datasets; or
    b) any WLS Restricted Dataset containing information derived from Social Security Administration records, with any dataset containing geographic information at a level of aggregation more detailed than Census Division, except with explicit written permission from the Social Security Administration; or
    c) any of the WLS Restricted Data with any other dataset without written approval from WLS.

17. The WLS Restricted Data are and remain the sole property of the University of Wisconsin, and the Receiving Agency, Investigator(s) and Supplemental Users will not disclose them to any third party. The Receiving Agency agrees that in response to any request for WLS Restricted Data under the federal Freedom of Information Act, 5 U.S.C. 552 or similar state sunshine law, it will refuse to disclose the WLS Restricted Data on grounds that it is not a Receiving Agency record subject to disclosure under that Act or is alternatively exempt from disclosure under that Act. Receiving Agency will immediately notify WLS of any such requests and will provide WLS with sufficient opportunity to seek a protective order.

18. Use of WLS Restricted Data provided by WLS to the Investigator will be confined to the research described in the Research Plan submitted to and approved by WLS; the approved Research Plan is incorporated by reference into this Agreement.

19. The Receiving Agency will ensure that all originals and copies of Restricted Data, on whatever media, will be either returned to WLS, or destroyed, within 24 months of the date that the original Restricted Data is shipped to the Investigator (or such other date as is specified in the approved Research Plan), or within 5 days of a written demand from WLS; and the Receiving Agency will certify to WLS that this return/destruction has occurred. Extensions to this agreement may be granted by WLS upon review of a written request from the Investigator(s), and providing all other approval conditions remain in effect.

20. The Investigator(s) will provide annually within 30 calendar days of the anniversary of this Agreement the following:
    a) Project title, Investigator(s), and current contact information
    b) Progress report, including a summary of current work, project titles, and brief justification for continued access to the data
    c) Detail of changes or modifications in the research
    d) Citations for any papers, publications or presentations using the WLS Restricted Data
    e) Proof of current IRB or equivalent Ethics Committee review for projects using WLS Restricted Data, which must be renewed annually.
    f) Updated list of authorized users under this agreement. A new Supplemental User Agreement must be completed and signed for each new user. The list should include access termination dates for those no longer requiring access to the WLS Restricted Data.

21. The Investigator shall have a permanent, faculty-level or scientist-level appointment at the Receiving Agency, and the Co-Investigator(s), if any, shall have faculty-level or scientist-level appointments at the Receiving Agency.

22. All Supplemental Users signing Supplemental Agreements have an employment or agency relationship with the Receiving Agency and are listed as personnel on the research project described in the Research Plan, and will have access to WLS Restricted Data only under the supervision of the Investigator(s). The Supplemental Agreements with Supplemental Users are incorporated by reference into this Agreement.

23. The Research Plan shall be reviewed by the Receiving Agency's Institutional Review Board/or equivalent Ethics Committee, using the standards and procedures for live human subjects, and a certification of that approval or determination that the study is exempt has been provided to WLS.

24. The Receiving Agency represents that it has in place a Code of Ethics governing its employees that prohibits and provides sanctions for the unauthorized disclosure of confidential information, and policies and procedures on scientific integrity and misconduct. The Receiving Agency recognizes that certain violations of this agreement might constitute actions covered by such policies and procedures and Code of Ethics, as well as constituting violations of applicable federal or state laws protecting individual privacy. If the WLS notifies the Receiving Agency that a violation of this agreement has occurred and alleges that the violation constitutes an ethical breach or scientific misconduct, the Receiving Agency will handle the allegation according to its policies and procedures applicable to ethical behavior, scientific integrity and misconduct.

25. The representative signatory of the Receiving Agency is a person authorized to enter into contractual agreements on behalf of the Receiving Agency.

26. If WLS determines that this Agreement has been violated, WLS may:
    a) prohibit any of the signatories of this Agreement, and of any Supplemental Agreements from obtaining access to any WLS restricted data
    b) report the violation(s) to the Receiving Agency and request that sanctions be imposed on the person(s) responsible for the violations
    c) where the violation pertains to data obtained from a federal agency or used in connection with a federally-funded project, report directly or indirectly the violation(s) to funding agencies with a recommendation that current funding be terminated, and future funding denied, to the Investigator(s), the Researchers and any other person implicated in the violation(s)
    d) utilize such other remedies as may be available to it under law

Signature Page for Investigator and Co-Investigator

By signing this Agreement, I certify that I have reviewed the Agreement and that I agree to abide by its terms:

______________________________	______________________________
Investigator Signature & Date	Co-Investigator Signature & Date
______________________________	______________________________
Typed/Printed Name	Typed/Printed Name
______________________________	______________________________
Title	Title
______________________________	______________________________
Phone	Phone
______________________________	______________________________
Email	Email

Signature Page for Receiving Entity Signatory, WLS Representative, and
University of Wisconsin System Signatory

______________________________________	______________________________________
Receiving Entity Signatory	Wisconsin Longitudinal Study Representative
______________________________________	______________________________________
Typed/Printed Name	Carol Roan Study Director Department of Sociology, Room 4412 1180 Observatory Drive Madison, WI 53706 Phone: 608.265.6196 Carol.Roan@wisc.edu
______________________________________	
Title	
______________________________________	
Institution	
______________________________________	______________________________________
Building Address	Board of Regents of the UW System Signatory
______________________________________	______________________________________
Street Address	Typed/Printed Name
______________________________________	
City, State, Zip	
______________________________________	
Phone	
______________________________________	
Email	

Exhibit A: Supplemental User Agreement

By signing this Exhibit A, I certify that I have reviewed the Agreement and that I agree to not use or disclose the WLS Restricted Data except as authorized in this Agreement. I understand that any unauthorized use or disclosure may result in further access to the WLS Restricted Data being denied and may further result in discipline or other sanctions as outlined in the Agreement.

____
Supplemental User Name and Date

____
Typed/Printed Name

____
Title

Exhibit B

Secure Computing Environment Requirements

General Information Security Requirements

- When using local infrastructure, make sure these files are never exposed to the Internet with the exception of such connections as are required to download data from source repositories. Infrastructure should be behind local and/or institutional firewalls that block access from outside of the institution.

- Data must never be posted on servers in any fashion that will make them publically accessible, such as an investigator's (or institution's) website, because the files can be "discovered" by Internet search engines, e.g., Google, Bing.

- Receiving Agency must not set up web or other electronic services that host data publicly, or that provide access to other individuals that are not Investigators or Supplemental Users

- Utilize strong authentication technology for access control. Two factor authentication technologies (smart cards, hard or soft token, etc.) are preferred. When using single factor passwords, set policies that mandate the following requirements:

    - Minimum length of 8 characters
    - Does not contain user names, real names or company names
    - o Does not contain a complete dictionary word
    - Contains characters from each of the following groups: lowercase letters, uppercase letters, numerals, and special characters

- WLS Restricted Data may not be stored on mobile devices (e.g. laptops, smartphones, tablets, mp3 players) or removable media such as USB thumb drives (except where such media are used as backups and follow appropriate physical security controls).

- WLS Restricted Data may not be stored on a Cloud Service Provider.

- Keep all software patches up-to-date.

Physical Security Requirements

- Data that are in hard copy or reside on portable media, e.g., on a USB stick, CD, flash drive or laptop should be treated as though it were cash, with appropriate controls in place. Such media must be encrypted and stored in a locked facility with access granted only to Investigators and Supplemental Users.

- Restrict physical access to all servers, network hardware, storage arrays, firewalls and backup media only to those that are required for efficient operations.

Controls for Servers

- Keep servers from being accessible directly from the Internet, (i.e. must be behind a firewall or not connected to a larger network) and disable unnecessary services. It is better to begin with a server image that disables all non-essential services and restore those that are needed than to start with a full-featured image and disable unnecessary services.

- Enforce principle of Least Privilege to ensure that individuals and/or processes grant only the rights and permissions to perform their assigned tasks and functions, but no more.

- Secure WLS Restricted data from other users (restrict directory permissions to only the owner and group) and if exported via file sharing, ensure limited access to remote systems.

- If accessing systems remotely, use encrypted data access (such as Secure Shell (SSH) or Virtual Private Network (VPN)). It is preferred to use a tool such as Remote Desktop (RDP), X-windows or Virtual Network Computing (VNC) that does not permit copying of data and provides "View only" support.

- If data is used on multiple systems (such as a compute cluster), ensure that data access policies are retained throughout the processing of the data on all the other systems. If data is cached on local systems, directory protection must be kept, and data must be removed when processing is complete. Investigators and Supplemental Users must meet the spirit and intent of these protection requirements to ensure a secure environment 24 hours a day for the period of the agreement.

Destruction of Data

- WLS Restricted data must be destroyed when they are no longer needed or used. Delete all data for the project from storage, virtual and physical machines, databases, and random access archives (i.e., archival technology that allows for deletion of specified records within the context of media containing multiple records).

- Subject to section 19 of this Agreement, Investigators and Institutions may retain only encrypted copies of the minimum data necessary at their institution to comply with institutional scientific data retention policy and any data stored on temporary backup media as are required to maintain the integrity of the institution's data protection program. Ideally, the data will exist on backup media that is not used by other projects and can therefore be destroyed or erased without impacting other users/tenants. If retaining the data on separate backup media is not possible, as will be the case with many users, the media may be retained for the standard media retention period but may not be recovered for any purpose without a new Data Use Agreement. Retained data should be deleted at the appropriate time, according to institutional policies.

- Shred hard copies and CD ROMs or other non-reusable physical media.

- Delete electronic files securely. For personal computers, the minimum would involve deleting files and emptying the recycle bin or equivalent with equivalent procedures for servers. Optimally, use a secure method that performs a delete and overwrite of the physical media that was used to store the files.

- Ensure that backups are reused (data deleted) and any archive copies are also destroyed.