# WHI DATA USE AGREEMENT – CONSORTIUM or POOLING PROJECT USE

**DEFINITIONS:**

Consortium: a research project performed as a collaborative effort across multiple studies and/or cohorts with a formal governance structure independent of the WHI but not conflicting with WHI’s fundamental design and intended analyses.

Pooling Project: a research project in which WHI data are analyzed in conjunction with other studies/cohorts without an independent formal governance structure.

WHI data: refers to any portion, part, or subset of WHI study information, records, statistics, facts, figures, and numbers without limitation to, laboratory, examination, and questionnaire results collected by WHI or in a WHI ancillary study or Broad Agency Announcement (BAA) study.

Project Leader: the lead investigator of a Consortium or Pooling Project. Examples may include the chair of the Consortium’s governing committee or the PI of the Project grant. This person takes overall responsibility for assuring compliance with WHI data use policies, and also works with WHI Sponsoring PI to determine whether which additional consortium analyses require further review and approval.

Recipient: the investigator or other individual with the primary responsible for storing, managing, and providing access to the project data for the Consortium or Pooling project. This individual may or may not be the Project Leader and may or may not be at the same institution as the Project Leader. If not the Project Leader, this person will implement appropriate security and access mechanisms, in consultation with the Project Leader, to assure compliance with WHI data use policies.

Collaborator: an individual who will be using WHI data under the authorization of the Project Leader.

Analyst: an individual working under the Project Leader, Recipient, or Collaborator to analyze the project data.

Sponsoring PI: the WHI Investigator serving as the primary WHI Liaison with the Project Leader and Recipient. (Required if neither the Project Leader nor the Recipient are WHI investigators.) This individual will be responsible for communicating any WHI responsibilities and will work with the Project Leader to ensure all publications meets WHI authorship requirements.

**Preamble:** WHI investigators view the data developed by and in conjunction with the WHI program to be a unique and valuable national resource. We are intent on maximizing their use for valid scientific purposes within the constraints of our program. Specifically, we are protective of WHI participants’ confidentiality and the nature of their consent. We also wish to assure that the efforts of numerous people and sponsors to develop the resource are appropriately acknowledged. This agreement is intended to support these objectives for projects seeking to acquire, manage, and analyze individual-level WHI data in conjunction with other study data.

**TERMS AND CONDITIONS:**

On behalf of the \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Project, I, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, the Project Leader, and I, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, the Recipient have reviewed and understand the terms for use of WHI data. We agree to abide by these terms and accept responsibility for both overseeing the implementation of these policies within the Project and for protecting these data as required by WHI and all applicable laws. In addition, we will assure, to the best of our ability, that Project Collaborators and Analysts comply with all aspects of this data use agreement and will inform our WHI sponsor or other representative immediately upon learning of any violation of these terms. The key elements of the WHI data use policies are outlined here:

1. WHI data may be used only for analyses approved by the Project leadership and consistent with the aims of the Project as provided to WHI with this agreement.
2. WHI data may not be published as a stand-alone dataset through this mechanism. WHI data may also not be presented as a separate table or figure within a pooled/consortium analysis manuscript. (Note: data displays meant to show variability between cohorts are permitted). WHI specific analyses must be proposed through the usual WHI Publications and Presentations (P&P) processes.
3. WHI data may not be shared with commercial entities or anyone outside of the approved project without prior authorization from the WHI. The Project Leader will review requests for sharing based on project guidelines.
4. WHI data will not be used either alone or in conjunction with any other information in any effort whatsoever to identify participants.
5. All Consortium/Pooling Project manuscripts containing WHI data will be submitted to the WHI P&P committee for review and approval *prior to* submission to a journal.
6. WHI investigators will be included as authors on all papers in which WHI data are used, with representation generally expected to be proportional to the WHI data contribution and with consideration of consortia guidelines. The WHI liaison will provide the list of WHI affiliated authors to the P&P when the paper is submitted for review.
7. All applicable WHI associated funding will be acknowledged.
8. WHI P&P Committee will be informed when articles are accepted for publication.

**This agreement shall expire with the Project/grant expiration date (specify:\_\_\_\_\_\_\_\_\_\_\_\_\_\_) or 5 years from the data of this agreement, whichever is earlier. Continued or expanded use of WHI data, change in Project Lead or Recipient, or a refresh of the data will require a renewal of this agreement.**

# PROJECT INFORMATION:

**SCOPE OF PROPOSED PROJECT:** (Include brief description here and attach Specific Aims or CONSORTIUM description) **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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**NAME OF IRB providing review and approval: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

PROJECT LEADER NAME:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**By signing, I agree to the data use Terms and Conditions in this Data Use Agreement and have reviewed and agreed to abide by the WHI policies[[1]](#footnote-1), [[2]](#footnote-2) on the WHI website.**

PROJECT LEADER SIGNATURE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_DATE\_\_\_\_\_\_\_\_\_\_\_\_\_\_

# DATA MANAGEMENT AND RECIPIENT INFORMATION:

**DATA STORAGE:** Please describe where the data will be stored, how authorized users will access and analyze these data, and security systems in place to protect against unauthorized access or use. Attach relevant portion of grant proposal or consortium policy documentation. Security protocols should be consistent with the type of data to be shared and their associated risks. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**NAME OF IRB** providing review and approval, if separate from above**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

RECIPIENT NAME: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**By signing, I agree to the data use Terms and Conditions in this Data Use Agreement and have reviewed and agreed to abide by the WHI policies 1, 2 on the WHI website.**

RECIPIENT SIGNATURE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_DATE:\_\_\_\_\_\_\_\_\_\_\_\_\_

**SPONSORING PI INFORMATION (if applicable)** [[3]](#footnote-3)

**By signing, I acknowledge my role as Sponsoring Investigator to ensure compliance with WHI policies and my awareness and support of all aspects of this Data Use Agreement**

NAME OF SPONSORING PI: N/A\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

SPONSORING PI SIGNATURE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_DATE:\_\_\_\_\_\_\_\_\_\_\_**\_\_**

1. [AS policy](https://s3-us-west-2.amazonaws.com/www-whi-org/wp-content/uploads/AS-Policy.pdf)  [↑](#footnote-ref-1)
2. [P&P policy](https://s3-us-west-2.amazonaws.com/www-whi-org/wp-content/uploads/PP-policy.pdf)  [↑](#footnote-ref-2)
3. If Project Leader or Recipient is a WHI Investigator or Associate, a Sponsoring PI is not required. [↑](#footnote-ref-3)