

All of Us Research Hub & Data Access Requirements

To complete a Data Use Request (DUR), you must first sign and return this certification to the ORSP (orsp@osteo.wvsom.edu). Additionally, provide the enumerated elements identified in this document (most of these are required for the All of Us access). Return this form and requested documents as part of the ORSP-1 research project initiation request (or in an email identifying the All of Us resources as part of a new/amended specific aim of an already approved project).

Data Use Request (DUR) process, including WVSOM requirements

1. If you do not already have one, create a [Login.gov account](#).
2. Register as a researcher with All of Us (AoU).
3. Complete the AoU Responsible Conduct of Research Training and provide a copy of the Certificate of Completion to the ORSP.
4. Complete the CITI Human Subjects Biomedical Research course and notify the ORSP when it is completed.
5. Provide the ORSP with a copy of the signed Data User Code of Conduct to be submitted to AoU.
6. Sign and return this certification to the ORSP.

By signing this certification, you agree to the following (in addition to the All of Us User Code of Conduct you have attached):

- a. Data will only be used for the specified project as described in the DUR. Each project requires a separate, or updated, DUR to AoU. Data will be used exclusively for the Research Project proposed. Any other use of the Data is prohibited.
- b. Any access of the AoU data shall occur only with a WVSOM issued encrypted device. No access using the WVSOM affiliation may occur from a personal device.
 - i. The WVSOM Investigator agrees to review the [WVSOM Acceptable Use of Information Technology Resources policy](#) (GA-31).
- c. To know and follow all laws and regulations regarding research involving human data and data privacy that are applicable in the area where you are conducting research, including all applicable federal, state, and local laws, and [the Common Rule principles as defined by The Belmont Report](#).
- d. Any collaborators from a different institution, who will access the data, must have their own Data Use Agreement and Request forms in place through that collaborating institution.
- e. Investigators from WVSOM will adhere to [WVSOM's Human Research Protections Program](#) regarding the use of de-identified, Limited and Controlled Tier Data sets.
 - i. Note that for these types of data requests, the Investigator must have an IRB approval/determination letter to submit with the Data Use Request to AoU.
- f. If the Investigator separates from WVSOM, the Investigator must notify the AoU.
- g. WVSOM Investigators agree to not attempt to re-identify or contact any individuals who are the subjects of the Data, or their known relatives. Additionally, WVSOM investigators agree to not attempt to re-identify or contact Data contributors or healthcare providers.
- h. WVSOM Investigators shall not disclose, release, sell, rent, lease, loan, or otherwise grant access to the Data to any third party without prior written permission of AoU.
 - i. If received, such written approval must be provided to the ORSP prior to the disclosure of the Data to the third party.

- i. WVSOM Investigator agrees to use Data in compliance with all applicable federal, state, local, and tribal laws, regulations, and policies.
- j. The WVSOM Investigator agrees not to photograph, create screen shots, print, nor download Data viewed on the AoU.
- k. No data will be disseminated or published if it includes, or could be derived to include, a participant count of 1 to 20 (a count of 0 is permitted).
- l. Any unauthorized access, use or disclosure must be reported to both AoU *and* WVSOM IT. WVSOM IT must be notified first, within 4 hours of discovery of the incident, so that an appropriate remediation plan may be developed.
 - i. To report an unauthorized access, use, or disclosure incident to WVSOM IT, complete and submit an [INCIDENT REPORTING FORM](#). This report must be filed within 4 hours of discovery of the incident, in order to ensure that the AoU requirement, as below, is addressed by the time a report is filed with AoU (as below). Please choose the Incident Type as “HIPAA Breach” in the form.
 - ii. Once WVSOM IT and the ORSP have communicated with the Investigator, the WVSOM Investigator must report the unauthorized access, use, or disclosure to AoU. To do so, the WVSOM Investigator must notify All of Us Research Hub no later than 2 business days after discovery. Notification should include any known information regarding the incident and a general description of the activities or process in place to define and fully remediate the situation. Copy orsp@osteowvsom.edu on the email to AoU.
- m. WVSOM Investigators are encouraged to make the results of their research publicly available, ideally in an open access format and consistent with scientifically accepted publication or dissemination practices. In recognition of the effort that Data Contributor(s) made in collecting and providing the Data, User(s) who publish their results, or otherwise publicly present findings, agree(s) to acknowledge the AoU as the source of these Data and Data Contributors per guidelines in the [AoU Data Use Policies website](#).

By signing this document, I agree to follow the processes described above, and I attest to my understanding of my responsibility and obligations to WVSOM and for AoU under the WVSOM Data Use Agreement.

Printed Name

Signature

Date

eRA Commons User Name (or “None”)