

DATA USE & DISCLOSURE POLICY

The [Oregon Center for Aging & Technology](#) (ORCATECH) is a collaborative working group of investigators from a broad spectrum of disciplines and interests to develop a better way to take advantage of recent advances and translate that knowledge into the community setting. The purpose of this group is to develop and test continuous assessment technologies for assessing health behaviors, life activities, and physiological status in real world environments, and ultimately, provide the key information necessary for instituting appropriate health maintenance and illness prevention strategies.

The ORCATECH Living Laboratory (OLL) was established to encourage basic and applied bioengineering research that makes a significant contribution to improving human health. The OLL is focused on the development and use of continuous assessment technologies to detect changes associated with aging. The OLL exists to encourage collaborations and partnerships among allied quantitative and biomedical disciplines by bringing together engineering or computational science expertise with biological or clinical resources.

In order to achieve these goals, it is our intention that data and expertise generated from the OLL and ORCATECH be accessible for collaborative research. Collaboration occurs extensively with OHSU investigators and researchers at other institutions to analyze and publish findings of professional interest in aging and sensor systems technology research. Such collaboration facilitates efficient and productive use of the data, as well as rapid development and dissemination of knowledge.

This policy formally establishes the practice of sharing data from the ORCATECH Database with other investigators (within OHSU and from collaborating institutions and organizations). See the [ORCATECH Authorship Policy](#) for more information about authorship requirements.

1) ORCATECH Database

- a) May include data collected in the course of ORCATECH affiliated activities, including (but not limited to) the following:
 - i) ORCATECH Pilot Projects (NIH P30 AG024978)
 - ii) Biomedical Research Partnership: Intelligent Systems for Detecting Aging Changes (eIRB 2353; NIH 1R01AG024059, Intel Corporation)
 - iii) ORCATECH Living Laboratory (eIRB 2765; NIH P30 AG024978)
 - iv) ORCATECH Behavioral Assessment & Intervention Commons (eIRB 2765; Intel Corporation)
 - v) Alzheimer Disease Center Clinical Core – Oregon Alzheimer’s Disease Center Clinic (eIRB 725; NIH P30 AG008017)

- vi) The Oregon Brain Aging Study (OBAS eIRB#361; Office of Research & Development, Clinical Sciences Research & Development Service, Department of Veterans Affairs, NIH P30 AG008017, M01 RR000334)
- vii) Community Brain Donor Program (CBDP, eIRB 1639; Oregon Alzheimer's Disease Center, NIH P30 AG008017)
- viii) Preventing Cognitive Decline with Alternative Therapies (informally called the Dementia Prevention Study or DPS, eIRB 687; NIH P50 AT00066 Oregon Center for CAM in Neurological Disorders)
- ix) Klamath Exceptional Aging Project (KEAP, eIRB 588; Northwest Health Foundation, Merle West Center for Medical Research, NIH P30 AG008017)
- x) African American Dementia and Aging Project (AADAPt, eIRB 1480; Northwest Health Foundation, NIH P30 AG008017)

b) Includes the following types of data:

- i) physical and neurological exam findings
- ii) neurocognitive test scores
- iii) survey assessments
- iv) personal and family history
- v) positive/negative family history of dementia
- vi) personal demographics
- vii) genotypes
- viii) age at service evaluations
- ix) age at onset, age at death
- x) clinical diagnosis
- xi) neuropathology diagnosis and inventory information (when available)
- xii) health status
- xiii) medications
- xiv) laboratory tests
- xv) MRI volumetrics
- xvi) measures of activity, gathered by in-home sensor technologies
- xvii) contact information required to manage ongoing clinical care and study operations

2) Principles of Data Use and Disclosure

a) ORCATECH is committed to protecting patient and subject confidentiality in compliance with OHSU and HIPAA guidelines. Shared research records will be identified by a randomly assigned ID number having no relationship to any direct identifiers. Only the ORCATECH will maintain a code-breaking list, which will be held in confidence. Data will be shared according to the minimum necessary principle, where disclosures will include only the data necessary to accomplish the aims of the project.

- b) One mission of ORCATECH is to make its database available to collaborative investigators for the most effective use of the data in an open but secure environment. Limited data sets will be shared within the OHSU community, with researchers outside of OHSU, and with the National Alzheimer's Coordinating Center (NACC) NIH/NIA U01 AG016976. The only HIPAA defined identifier that will be shared is date of birth/age. [Note: limited data sets will include date of birth or age over 89.]
- c) ORCATECH will protect the integrity of original work contributed to the database. Specifically, investigators will be given first opportunity to analyze and publish with ORCATECH data from projects that they either have played a major role in designing and conducting or in cases where their specialized interpretation of the data was required.

3) Center Approved Investigators

Center approved investigators fall into one of three categories:

- a) Investigators named in the ORCATECH Center grant (NIA P30 AG024978), or
- b) Principal investigators or co-investigators of ORCATECH-affiliated studies, or
- c) Investigators designated by review of the ORCATECH Director and/or the ORCATECH Executive Committee.

4) Data and Recruitment Requests

a) Data Requests

i) The ORCATECH is authorized to disclose research data to investigators because:

- (1) subjects have either been consented with the understanding that results of their participation will be shared, or
- (2) the Oregon Alzheimer's Disease Center has obtained a Waiver of Authorization from the OHSU IRB (for data from its subject population).

ii) A Data Use Agreement will be completed for data shared with ORCATECH approved investigators outside of OHSU (see <http://www.ohsu.edu/cc/hipaa/forms.shtml>).

iii) Investigators initiate requests for data or subject recruitment by the submitting an ORCATECH Request Form to the Data Manager. ORCATECH Request Forms are obtained from the Data Manager or through the ORCATECH website.

iv) With the ORCATECH Request form, investigators will also provide the following supporting documentation:

- (1) A clear statement of the hypothesis or objectives for each project,
- (2) Current CV (if not already on file with the ORCATECH),
- (3) Protocol or description of the proposed analysis project,
- (4) Data requirements (data fields: e.g., age, height, weight, etc.),
- (5) A signed statement (on the request form) agreeing to comply with the ORCATECH Data Use and Disclosure Policy and Authorship Policy, (These policies are available on the ORCATECH website and will be provided to the applying investigator with the request form.)

- v) The Data Manager reviews the request and presents it to the ORCATECH Director and/or the ORCATECH Executive Committee for approval.
- vi) If approval is granted and if indicated, the Data Manager notifies a designated ORCATECH faculty member with related expertise to serve as the contact to the approved investigator. The ORCATECH contact may decide to meet with the investigator to discuss the project in more detail before the data is released.
- vii) Once the Data Manager receives written or verbal agreement from the designated ORCATECH contact, the requested data is provided.
- viii) All requests are logged by the Data Manager to track the number and nature of ORCATECH database requests.
- ix) Limited data sets may be provided to ORCATECH approved investigators to explore the feasibility of or to complete minimal risk projects such as:
 - (1) Abstracts, manuscripts or book chapters submitted for publication,
 - (2) Posters, lectures or other presentations for educational, professional or research conferences,
 - (3) Grant applications (i.e. pilot data to justify funding) or Grant progress reports,
 - (4) Theses, dissertations or other student projects, or
 - (5) Other ORCATECH operations.
- x) Requests for updates on previously approved requests can be handled in person, via e-mail or by phone.

b) Recruitment Request

- i) The OHSU Terms and Conditions of Service/ Consent for Treatment and Notice of Privacy Practices state that patients may be contacted regarding voluntary participation in clinical research. Volunteers in the ORCATECH's community based studies must be willing to receive invitations to participate in other related research studies (participation is voluntary); subjects will be made aware of this stipulation in study consent forms or a notification mailing.
- ii) In addition to the supporting materials listed above, the investigator must submit a protocol, consent form, and IRB approval.
- iii) The Data Manager reviews the request and presents it to the ORCATECH Director and/or the ORCATECH Executive Committee for approval. If approval is granted and if indicated, the Data Manager notifies a designated ORCATECH faculty member with related expertise to serve as the contact to the approved investigator. The ORCATECH contact may decide to meet with the investigator to discuss the project in more detail before the data is released.
- iv) Once the Data Manager receives written or verbal agreement from the ORCATECH Director or Executive Committee and the ORCATECH designated contact, subjects who meet study eligibility requirements will be identified.
- v) The ORCATECH Director sends a letter to the identified potential subjects or their caregivers explaining the study, alerting them that an approved investigator will soon contact them and offering reassurance that participation is entirely voluntary and refusal will in no way impact the care provided through the Oregon

Alzheimer's Disease Center. Alternatively, ORCATECH staff or designate may telephone participants or their authorized representative to discuss the research opportunity and obtain permission for the approved investigator to contact them. If patients or participants decline to be contacted regarding the research opportunity, their wishes will be respected.

vi) If permission is not refused, the Data Manager will give names and contact information of potential subjects to the approved investigator. Only the minimum necessary contact information will be provided.

vii) The investigator will be provided with a Subject Enrollment Status log form which must be completed, updated at least every 6 months for ongoing studies and submitted to the Data Manager for tracking purposes.

5) Access to ORCATECH Database for Center Staff and Approved Investigators

a) Full access to the data and structure of the database is restricted to the data manager and the database consultant. Access to all information in the database is controlled through individual passwords assigned by the data manager after project approval by the ORCATECH Director &/ or the ORCATECH Executive Committee. Write privileges are restricted to those persons authorized by the data manager for the purpose of data entry. Specialized access can be provided by individual passwords that allow only a portion of the data to be viewed and/or retrieved.

b) Approved investigators are authorized to have limited read-only browsing and print/export access to data in the ORCATECH database. As noted above, research records will be identified by a numeric ID number having no relationship to any direct identifiers (as defined by HIPAA). The only HIPAA defined identifier that will be accessible is date of birth/age. Confidential contact information may only be shared in special limited circumstances – see Recruitment Requests above.

c) To prevent duplication of research efforts and to assure accurate interpretation of the data, approved investigators are instructed that they **must** discuss any plans to use data retrieved from the 4D database (for papers, presentations, or grants) with the designated ORCATECH contact before proceeding.

6) Authorship Credit (also see ORCATECH Authorship Policy)

a) It is the responsibility of the ORCATECH contact for each data/subject request to ensure that the ORCATECH is acknowledged (e.g., “This research was supported in part by the Oregon Center for Aging & Technology NIA Grant P30 AG024978”; see list in section 1.a. for other applicable grant numbers) and that appropriate authorship credit is given in professional papers and presentations by investigators.

b) It is the responsibility of the ORCATECH Director and Executive Committee to determine whether any additional data generated (for each data/subject request) should be returned to the ORCATECH.

c) Investigators must comply with the ORCATECH Authorship Policy (available from the Data Manager or [the](#) ORCATECH website), which includes NIH Public Access Policies (i.e., submitting to PubMed Central).

d) For all publications, investigators must provide a copy of the final data used in published analyses saved in Excel or tab delimited format on a labeled zip disk, CD, or other suitable media to the ORCATECH Data Manager.

7) Oversight and Review

The ORCATECH will maintain a log of all disclosures, to be reported to IRB at each continuing review. The log will include date of disclosure, name of investigator, description of the data disclosed, and description of the project. At the time of continuing review, the ORCATECH will report any breaches of confidentiality or state that no instances have been brought to our attention.

- a) The following types of data will be allowed for disclosure exempt from IRB review because of the minimal risk involved for data and recruitment requests that are carefully reviewed and approved by the ORCATECH Director or Executive Committee.
 - i) Limited data sets with age over 89, but otherwise unidentified. The nature of ORCATECH research requires that ages be disclosed to collaborators in order to accomplish research goals.
 - ii) ApoE and other genotypes. All ORCATECH genetic samples and information were collected under protocol 7022 that specifically obtains consent for genotype and data disclosure to other investigators.
- b) If any identifying data other than age is requested, the ORCATECH will not disclose that data without authorized IRB review and approval, as outlined below. Collaborating investigators must provide assurances for the confidentiality and privacy of disclosed data.
 - i) Investigators with an IRB approved project must present the ORCATECH Executive Committee with a protocol, consent form and IRB approval letter from either the OHSU IRB or the IRB of another Federal Wide Assurance (FWA) institution.
 - ii) Projects not yet approved will be submitted to the OHSU IRB for expedited review.

Check www.orcatech.org for updates to this policy.