



School of Medicine

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**Layton Aging & Alzheimer's Disease Center and  
Oregon Center for Aging & Technology  
Research Repository Protocol**

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## A Introduction

The C. Rex and Ruth H. Layton Aging & Alzheimer's Disease Center (Layton Center) at Oregon Health & Science University (OHSU) is one of the Alzheimer's Disease Research Centers (ADCs) funded by the National Institutes of Health, National Institute on Aging (Oregon Alzheimer's Disease Center, P30 AG008017). ADCs were established to translate research advances into improved diagnosis and care for Alzheimer's disease patients while, at the same time, focusing on the program's long-term goal—finding a way to cure and possibly prevent AD. ADCs provide several important services:

- Diagnosis and medical management,
- Information about the disease, services, and resources,
- Opportunities to participate in drug trials and clinical research projects,
- An accessible source of data for collaborative research.

The Oregon Center for Aging & Technology (ORCATECH) is also a collaborative research center at OHSU, funded by the National Institutes of Health, National Institute on Aging (Oregon Roybal Center for Translational Research on Aging, P30 AG024978). As a sister-center to the Layton Center, ORCATECH is dedicated to developing technologies for continuous assessment in the home that will maintain independence and optimize health for our aging population. ORCATECH shares the Layton Center mission to provide data for collaborative aging research.

Together, the Layton Center and ORCATECH work closely to make the data and specimens that comprehensively characterize longitudinal cohorts of research volunteers available to the wider research community. In order to enact this aspect of our shared mission, we collaborate extensively with OHSU investigators and researchers at other institutions to analyze and publish findings of professional interest in aging and dementia research. Such collaboration facilitates efficient and productive use of the data, as well as rapid development and dissemination of knowledge. This repository protocol formally establishes the practice of sharing data and specimens from the Layton Center and ORCATECH with other investigators (within OHSU and from collaborating institutions). The Layton Center and ORCATECH collectively collect several different kinds of data and specimens, including but not limited to: clinical data, activity data, recruitment data, biomarker, genetic and pathology specimens and data. Requests from collaborative researchers most often include multiple kinds of data and/or specimens. Thus, this protocol details repository elements for each kind of data, as well as policies with respect to the repository as a whole, including reporting requirements, authorship requirements and consideration of cost.

Also note that the Layton Center is a collaborative site of the National Alzheimer's Coordinating Center (NACC), which was established by the National Institute on Aging (U01 AG016976) in 1999 to facilitate collaborative research among the NIA-funded Alzheimer's Disease Centers (ADCs) nationwide. NACC developed and maintains a large relational database of standardized clinical and neuropathological research data collected from each ADC, and this database provides a valuable resource for both exploratory and explanatory Alzheimer's disease research.

## B Repository Policies

The policies below apply to all repository data and specimens; additional or different circumstances are detailed in appropriate sections as necessary.

### B.1 Sources (see Repository Source document)

### B.2 Acquisition

- B.2.a IRB approval: Data and specimens (of all types, as described in this repository) may be submitted to the repository from studies with IRB approval that adhere to consent and authorization standards as below. Data included in the repository are primarily collected through studies approved by the OHSU IRB; if not an OHSU study, IRB approval must be certified along with the data submission.
- B.2.b Consent and authorization
- 1 Eligible submissions to the repository must have been obtained from subjects with their consent and understanding that data from their participation will be maintained and shared indefinitely, or a Waiver of Authorization from the OHSU IRB will be or has been obtained. Consent and authorization will be obtained from source protocols.
  - 2 Documentation of IRB-approved consent forms for the collection of the material being submitted to the repository will be available through OHSU's eIRB system or submitted along with data if not an OHSU study.

### B.3 Maintenance Information

- B.3.a Coding: The Layton Center and ORCATECH are committed to protecting patient and subject confidentiality in compliance with OHSU and HIPAA guidelines. Shared research records will be identified by an assigned ID number having no relationship to any direct identifiers. Only the Layton Center and 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. [Note that in the very occasional situation where investigators already have subject names (e.g. for recruitment purposes, subsequent data requests will NOT include database identification numbers to maintain security of the linking code. See Recruitment Data section.]

### B.4 Access

- B.4.a The following investigators will have access to repository materials:
- 1 Investigators named in the Layton Center grant (NIA P30 AG08017), ORCATECH grant (P30 AG024978) or
  - 2 Principal investigators or co-investigators of the Layton Center or ORCATECH source studies (See Repository Source document), or
  - 3 Approved Investigators, as designated by review of the Layton Center Director and/or the Executive Committee.
- B.4.b Access to the Layton Center Database for Center Staff and Approved Investigators

- 1 Full access to the data and structure of the database is restricted to the Clinical Data guardian and the database consultant. Access to all information in the database is controlled through individual passwords assigned by the Clinical Data guardian after project approval by the Layton Center Director &/ or the Executive Committee. Write privileges are restricted to those persons authorized by the Clinical Data guardian 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.
- 2 All staff and approved investigators with access to the database will be registered with this repository's IRB protocol. Compliance with all applicable OHSU Research Integrity Office training and research requirements will be maintained accordingly.
- 3 Approved investigators are authorized to have limited read-only browsing and print/export access to data in the Layton Center 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 age and date of assessment. In this way, investigators do not have database access to link the coded identifier to subject identity. Confidential contact information may only be shared in special limited circumstances – see Recruitment Data section.

#### B.4.c Guardian and Guardian Responsibilities

- 1 A guardian will be named for each data and specimen type, as described below
- 2 Ensuring that data are received and released according to OHSU policy and the IRB approved repository protocol.
- 3 Executing a usage agreement each time limited datasets as defined by HIPAA regulations are released to non-OHSU investigators for research purposes.
- 4 Ensuring the security and confidentiality of stored data.
- 5 Secure data distribution.
- 6 Tracking acquisitions and release of data.
- 7 Methods for identifying data for which consent has been withdrawn and will ensure no future use.
- 8 Identifying data which have limitations on future uses and ensuring that future uses are not contrary to those limits.
- 9 Certifying genetic opt out status with OHSU officials, if applicable.

### B.5 Release Process

- B.5.a One mission of the Layton Center and ORCATECH is to make its databases 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. De-identified data may be posted on publicly available websites.
- B.5.b 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 Layton Center/ORCATECH Director or Executive Committee:

- 1 Limited data sets that include age over 89 and some elements of dates (e.g., date of assessment; NOT birth date), but are otherwise unidentified. The nature of Layton Center and ORCATECH research requires that ages be disclosed to collaborators in order to accomplish research goals. The intent of the “age over 89” restriction is to reduce the risk of re-identifying a subject. Given that the majority of our subjects fall into this category, the risk of identification is extremely low. Note that over 40% of the subjects for whom we have data and/or specimens are over age 89 (as of July 2013). When possible, shared data sets will include only age at the time of assessment (including ages over 89), and do NOT include the year the assessment took place (de-identified, since year of birth cannot be derived).
  - 2 ApoE and other genotypes. All Layton Center specimens and genetic samples and information were collected under protocols which specifically required consent for genotype and data disclosure to other investigators, as well as specimen sharing. Note that all specimens were collected with express consent and authorization from volunteers that samples and information will be shared with other investigators for general research purposes. According to ORS 192.537 (Oregon Genetic Privacy Law), researchers “may use an individual’s DNA sample or genetic information that is derived from a biological specimen or clinical individually identifiable health information for anonymous research or coded research” when acquired under these circumstances.
- B.5.c Investigators initiate requests for data or subject recruitment by the submitting a Layton Center Request Form to the Clinical Data guardian. Layton Center Request Forms are obtained from the Clinical Data guardian or through the Layton Center website.
- B.5.d With the Layton Center 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 Layton Center),
  - 3 Protocol or description of the proposed analysis project,
  - 4 Data requirements (data fields: e.g., age, height, weight),
  - 5 A completed and signed Repository Sharing Agreement, indicating agreement of the recipient investigator to the terms and limitations of data/specimen use.
  - 6 If an investigator is requesting identifiable information (in addition to those described in B.5.b.1; e.g., date of birth for those over age 89), he or she will be directed to IRB for protocol approval or determination of exemption. Collaborating investigators must provide assurances for the confidentiality and privacy of disclosed data.
- 6.a Investigators with an IRB approved project must present the Layton Center or 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.
  - 6.b Separate IRB approval/determination will be required for each specific human subject research activity that uses otherwise identifiable data/specimens from the repository.
- B.5.e The Clinical Data guardian reviews the request and presents it to the Layton Center/ORCATECH Director and/or the Executive Committee for approval.
- B.5.f If approval is granted and if indicated, the Clinical Data guardian notifies a designated Layton Center or ORCATECH faculty member with related expertise to serve as the contact to the approved investigator. The Layton Center or ORCATECH contact may decide to meet with the investigator to discuss the project in more detail before the data is released.

- B.5.g A Data Use Agreement will be completed for limited datasets as defined by HIPAA regulations to be shared with Layton Center approved investigators outside of OHSU.
- B.5.h Once the Clinical Data guardian receives written or verbal agreement from the designated Layton Center or ORCATECH contact, the requested data is provided via email.
- B.5.i Limited data sets, as described in B.5.b.1, may be provided to Layton Center or 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 (e.g., pilot data to justify funding) or grant progress reports,
  - 4 Theses, dissertations or other student projects, or
  - 5 Other Layton Center or ORCATECH operations.

## **B.6 Certificate of Confidentiality**

Given that this repository and its source studies include sensitive information about mental health, cognitive status and in-home activity data, a Certificate of Confidentiality (CoC) has been obtained from the National Institutes of Health covering all active source protocols (See Repository Source document). This Repository was implemented to facilitate the standardized enforcement and accurate tracking of data and sample sharing, increasing confidence that all current and future source protocols will be consistently safeguarded and monitored. All living, active participants in the Repository source protocols who signed their consent forms prior to the attainment of the CoC, will receive a letter notifying them about the presence of the CoC and explaining its protections and limitations.

## **B.7 Reporting for releases**

- B.7.a The Layton Center and 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 Layton Center and ORCATECH will report any breaches of confidentiality or state that no instances have been brought to our attention.

## **B.8 Authorship and grant acknowledgement**

- B.8.a Authorship principles
- 1 The Layton Center and ORCATECH will protect the integrity of original work contributed to the repository. Specifically, investigators will be given first opportunity to analyze and publish with Layton Center and 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.
  - 2 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 Layton Center/ORCATECH contact before proceeding.
- B.8.b Assignment of credit

- 1 All individuals making a major contribution to a publication should be acknowledged by the inclusion of the individual's name as an author. The Layton Center/ORCATECH contact person designated to provide consultation for the Data Request will help identify faculty and/or staff who have contributed to the data requested. A major contribution may include: formulating the problem or hypothesis, structuring the experimental design, recruiting and testing of subjects, specimen collection, neurologic, neuropsychologic or neuropathologic diagnoses on subject samples, organizing and conducting data analyses, interpreting the results, or writing a major portion of the paper. A substantial contribution to one or more of these activities is generally considered sufficient for authorship.
- 2 An individual whose contribution consists solely of developing unique materials or techniques might also be listed as an author if those materials or techniques were developed specifically for the project and represent a major contribution to the overall project. In situations where several individuals make major contributions to a publication, the name of the individual who made the principal contribution should be listed as first author, with subsequent names listed in order of decreasing contribution. By convention, in certain disciplines, an individual who makes a major contribution to a publication may sometimes be listed as last author to identify the research group or unit in which the work was done even though that individual's overall contribution is not less than those of individuals listed earlier in the by-line. Other instances in which authorship order does not reflect relative contributions (e.g., alphabetical listing of author names) should be explained in a footnote.
- 3 Minor contributions do not necessarily warrant authorship, but should be acknowledged in the text or a footnote. These supportive contributions include: conducting literature searches, designing or building an apparatus, providing statistical advice, routine data collection, data tabulation or entry, designing a computer program, accessing data from the database, providing laboratory space or equipment, general supervision of a research group or acquisition of funding. Although any one of these activities alone would not ordinarily be considered sufficient for authorship, authorship might be justified if the completion of a combination of these (and possibly other) tasks by an individual constituted a major contribution to the overall project.
- 4 Layton Center/ORCATECH personnel are often consulted by outside investigators regarding aspects of study design, methods, data analyses, etc. We encourage investigators to utilize the expertise of Layton Center/ORCATECH personnel. However, if consultation extends beyond occasional advice, Layton Center/ORCATECH personnel may request authorship and/or acknowledgement on resulting publications.
- 5 To avoid potential authorship conflicts, research group members should discuss authorship and authorship ranking order before beginning any specific research project. Primary responsibility for initiating such discussions rests with the individual who expects to make the principal contribution to the published work.

#### B.8.c Authorship responsibilities

- 1 By accepting credit for a publication, authors also accept responsibility for the content of the publication. All authors share responsibility for ensuring a) the factual accuracy of the content of the publication, b) that proper acknowledgement is given (via specific citations) for published or unpublished materials that directly influenced the writing or research, c) the publication contains no plagiarism, d) that institutional and other requirements were met for protecting human or animal subjects used in completing the published work, and e) that possible conflicts of interest (e.g., industry relationships) are acknowledged in the text or in a footnote. The designated responsible author has primary responsibility for addressing these issues.
- 2 It is the responsibility of the Layton Center/ORCATECH contact for each data/subject request to ensure that the Layton Center, ORCATECH and other grants are appropriately acknowledged (e.g., "This research was supported in part by the Alzheimer's Disease Center NIA Grant P30 AG08017") and that appropriate authorship credit is given in professional papers and presentations by investigators. (See grant numbers listed with Repository Source document.)

- 3 It is the responsibility of the Layton Center/ORCATECH Director and Executive Committees to determine whether any additional data generated (for each data/subject request) should be returned to the Layton Center/ORCATECH. For example, if investigators generate unique data (e.g., lab result from specimen assay, composite score), investigators may be asked to also provide a copy of the final data saved in Excel or tab delimited format on a labeled zip disk, CD, or other suitable media to the appropriate guardian.
  - 4 Any paper submitted for publication that used Layton Center/ORCATECH subjects, data, or tissue should include an acknowledgement to the Layton Center/ORCATECH and a copy of the submitted manuscript should be sent to the Layton Center/ORCATECH.
  - 5 As of April 7, 2008, publications resulting from NIH funds must be submitted online to receive an NIH Manuscript Submission system reference number (NIHMS ID) or PubMed Central reference number (PMCID); see <http://publicaccess.nih.gov/>. The first author of a publication is responsible for submitting this publication, retrieving an ID and including this ID on further NIH applications, proposals, and/or progress reports. *Authors must inform Layton Center/ORCATECH of the assigned ID; these reference numbers are crucial for future proposals and/or progress reports.*
- B.8.d Process for assigning authorship credit and responsibility
- 1 Consent must be received from all individuals named as authors.
  - 2 Authors are responsible for determining the order of authorship and must ensure that major and minor contributions are appropriately acknowledged.
  - 3 All authors must be given a reasonable opportunity to examine the content of the manuscript and give their approval before it is submitted for publication. In addition, all authors must be notified about editorial decisions and, if revisions are required, must give their approval before the revised manuscript is submitted for publication. A copy of the manuscript and all editorial correspondence must be given to all authors.
  - 4 When authorship concerns arise, authors are strongly encouraged to seek the advice of colleagues who have not participated in the scholarly activity.

## **B.9 Cost**

- B.9.a Requesting researchers are encouraged to consult with the Layton Center and/or ORCATECH as they develop project proposals to consider costs associated with use of data and/or specimens.
- B.9.b Requesting researchers may be asked to cover staff effort and/or special efforts required to complete the request. The determination of cost and how much is the responsibility of the Layton Center/ORCATECH Director and Executive Committees.

## **B.10 Contact person**

Questions or comments regarding this policy should be directed to Tracy Zitzelberger, MPH at [zitzelbe@ohsu.edu](mailto:zitzelbe@ohsu.edu) or 503.494.7198.

## c Clinical Data

The Layton Center longitudinally collects a comprehensive protocol of clinical and neuropsychological data for most studies. Subjects are followed longitudinally and assessed annually in person and at six-months by telephone (or in person if severe hearing impairment); many years of data are available for most subjects.

### c.1 Contents

- C.1.a physical and neurological exam findings
- C.1.b neurocognitive test scores
- C.1.c survey assessments
- C.1.d personal and family history
- C.1.e positive/negative family history of dementia
- C.1.f personal demographics
- C.1.g selected genotypes
- C.1.h age at service evaluations
- C.1.i age at onset, age at death
- C.1.j clinical diagnosis
- C.1.k neuropathology diagnosis, data and inventory information (when available)
- C.1.l health status
- C.1.m medications
- C.1.n laboratory tests
- C.1.o MRI images
- C.1.p Data derived from MRI images, including volumetrics
- C.1.q Survey data related to aging research, including socialization, opinion, technology use, and other topics
- C.1.r Contact information required to manage ongoing clinical care and study operations

### c.2 Maintenance Information

- C.2.a Storage of data: Most clinical data are maintained in a 4th Dimension database at the Layton Center offices on the 13th floor of the Hatfield Research Building (OHSU Marquam Campus) by the Clinical Data Guardian. Some data are not entered into the main database, but into excel or Access database files (e.g., survey administered to subset of subjects); these files are maintained on password-protected OHSU computers. Hard copies of data are kept in locked offices or locked file cabinets or offices. Hard copy files of inactive or deceased subjects may be scanned into an electronic format; hard copies will be shredded and destroyed in a secure manner, and electronic files will be kept on a secure server.

- C.2.b Security: Access to all information in the database is controlled through individual passwords assigned by the Data Manager after approval by the Layton Center Executive Committee. Individual passwords may allow only a portion of the data to be viewed and/or retrieved by a given investigator after authorization. For example, browsers can look but can't change data and are unable to see confidential subject information like names, addresses and phone numbers. All transfer of information from the database is in accordance with HIPAA and OHSU IRB guidelines. Access to the structure of the database is restricted to the Data Manager and the Database Systems Manager. Write privileges are restricted to those persons authorized by the Data Manager for the purpose of data entry. Automatic incremental database backups to a separate external hard drive are performed each day. To ensure the physical safety of the data not only against system failure and hardware failure, but catastrophic events such as fire, the daily backups are also copied to a secure offsite storage location at the OHSU Advanced Computing Center (ACC) on OHSU's West Campus (12.8 miles away). As the drive fills, some of the oldest daily backups are selectively discarded to make room for new backups as follows: daily backup data files are retained for the most recent 2-3 months, weekly backup files are retained for several years prior, and monthly backup files are retained for the oldest data files. In addition the ACC maintains daily tape backups of the secure drive with a one-month retention including a weekly tape copy stored in an offsite vault. The database server resides on a desktop iMac. Client software resides in a mixed environment of Macintosh and Windows PC computers. All computers on campus are encrypted with Symantec Whole Disk Encryption in compliance with OHSU policies. The iMac and external backup hard drive are sitting on top of a large 5 drawer lateral file cabinet behind the office door and are separately secured with Kensington ComboSaver Combination Portable Notebook Locks.

### C.3 Guardian: *Robin Guariglia, RN*

## D Brain Imaging Data

### D.1 Contents

- D.1.a MRI films (hard copy)
- D.1.b MRI and PET data (electronic format)
- D.1.c Data generated from MRI and PET image analysis

### D.2 Maintenance Information

- D.2.a Storage of data: Data are securely transferred with only coded identifiers (not created from any identifying information) from PET and MRI machines via OHSU ethernet connection to research computers at the Layton Center and servers (housed in server room in the basement of the Biomedical Research Building with only authorized badge access). The database is managed by the Imaging Data guardian.
- D.2.b Security: Access to all information in the database is controlled through individual passwords assigned by the guardian. All transfer of information from the database is in accordance with HIPAA and OHSU IRB guidelines. Access to the structure of the database is restricted to the guardian, and senior level staff at the guardian's discretion. Automatic incremental database backups occur regularly to a separate external hard drive.

### D.3 Guardian: *Lisa Silbert, MD*

## E Activity Data

In addition to standard clinical follow up (with Layton Center standard protocols), ORCATECH uses a basic platform of sensor technologies in most participating homes, including motion sensors (at least one in every room and several along a common walkway), contact sensors (at entry door and refrigerator), and computer software that tracks participants computer use (see below for example measures). In homes where participants use computers (most do), weekly online health questionnaire data are available (see below for example measures); these data may help explain changes in activity patterns. In a subset of homes, additional technologies are also used, for example bed mats (to capture sleep data), MedTracker (to track time of pill taking, usually multivitamin).

Note that dates associated with activity data are distinct from assessment dates. For example, subjects routinely complete web-based health forms on a weekly basis from their homes, and walking speeds calculated for a certain time period are derived from passive in-home sensors. These dates do not represent assessment dates with study staff.

### E.1 Contents

Note that activity data is comprised of raw data that must be algorithmically translated into usable measures. For example, raw sensor firing data must be analyzed into a resultant total activity measure. These algorithms are in development and constantly improving.

- E.1.a Data and measures derived from in-home assessment technologies (e.g., walking speed, total activity, patterns of activity over time)
- E.1.b Data and measures derived from computer use (e.g., total computer use, average time in application, inter-keystroke interval).
- E.1.c Data from weekly on-line health questionnaires (e.g., falls, depression, medication changes); note that this information is collected monthly by telephone for subjects who do not use a computer.
- E.1.d Data and measures derived from bed mats or load cells on the bed (e.g., total time in bed, sleep restlessness)
- E.1.e Data and measures derived from use of MedTracker device (e.g., percent compliance, time of pill taking)
- E.1.f Data and measures derived from additional in-home technologies (e.g., GPS cell phones, biometric scale)
- E.1.g Data and measures derived from additional activity-tracking technologies (e.g., in-car driving sensors)

### E.2 Maintenance Information

- E.2.a Storage of data: Data are securely transferred with only coded identifiers (not created from any identifying information) from participant homes via broadband connection to ORCATECH servers. The ORCATECH servers are housed at OHSU's Data Center West. The data is backed up via tape machine which is housed at OHSU's Market Square Building data center. Rotated backup tapes from this machine are stored in a secure location within OHSU's Center for Health and Healing. The database is managed by the ORCATECH Activity Data Guardian.

- E.2.b Security: Access to all information in the database is controlled through individual passwords assigned by the guardian after approval by the ORCATECH Executive Committee. Individual passwords may allow only a portion of the data to be viewed and/or retrieved by a given investigator or staff member after authorization. For example, individuals can only access an appropriate subset of participant information pertaining to their project of interest. All transfer of information from the database is in accordance with HIPAA and OHSU IRB guidelines. Access to the structure of the database is restricted to the guardian, and senior level staff at the guardian's discretion. Write privileges are restricted to those persons authorized by the guardian for the purpose of data entry and management. Automatic incremental database backups occur regularly to a separate external hard drive.

### E.3 Guardian: *Thomas Riley*

## F Audio Data

The Layton Center and ORCATECH collaborate with colleagues in the OHSU Center for Spoken Language and Understanding to investigate methodologies to distinguish subjects with memory impairment from healthy controls using markers of speech and language. In addition to standard clinical follow up (with Layton Center standard protocols), audio recordings may be made of neuropsychological testing visits, and some subjects may be asked to record everyday speech for a period of time (e.g., using a special body-worn device).

### F.1 Contents

- F.1.a Audio recordings of annual neuropsychological testing
- F.1.b Audio data from body-worn recording device
- F.1.c Derived data metrics (e.g., syntactic complexity, word counts)

### F.2 Maintenance Information

- F.2.a Coding: The Layton Center and ORCATECH are committed to protecting patient and subject confidentiality in compliance with OHSU and HIPAA guidelines. Audio data files are labeled with the Layton Center subject identification number and subject initials.
- F.2.b Storage of data: Storage of specimens: Audio data are maintained in a secure database at the OHSU Advanced Computing Center on the West Campus by the Audio Data guardian.
- F.2.c Security: Access to all information in the database is controlled through individual passwords assigned by the guardian after approval by the Layton Center Executive Committee.
- F.2.d Note that while "voice prints" are considered personal health information, recordings in this repository are simply voice recordings and NOT subject to PHI designation.

### F.3 Guardian: *Steven Bedrick, PhD*

## G Video Data

The Layton Center and ORCATECH investigate a variety of interventions performed via telemedicine/audio video communication with research participants, ranging from clinical care to social engagement research. Video recordings stored under this section typically include audio as well, though this may vary by project. Video data may include recordings of interventions as well as neuropsychological testing and other assessments related to a given research project. Much of the video data will be automatically captured by software, as in the course of a telemedicine visit. Video data may also be captured in the course of filming research projects or subjects, e.g. focus groups and may include an audio component.

### G.1 Contents

- G.1.a Video recordings of neuropsychological testing and assessment
- G.1.b Video recordings of dementia care administered via telemedicine
- G.1.c Video recordings of caregiver assessments and support interventions
- G.1.d Video recordings of conversational engagement interventions
- G.1.e Derived data metrics (e.g., facial recognition, eye tracking, syntactic complexity, word counts)

### G.2 Maintenance Information

- G.2.a Coding: The Layton Center and ORCATECH are committed to protecting patient and subject confidentiality in compliance with OHSU and HIPAA guidelines. Telemedicine files are labeled with the date and time of the recording and the name of the recorder used. Non-telemedicine video data files may be labeled with the Layton Center subject identification number.
- G.2.b Storage of data: Telemedicine video data are stored according to telemedicine department policy on OHSU's TelePresence Content Server. Other video data are maintained in a secure database at the OHSU Advanced Computing Center on the West Campus by the Audio Data guardian.
- G.2.c Security: Access to all information in the secure database is controlled through the repository guardian. Access to the TelePresence Content Server requires OHSU credentials and targeted access rights granted by the OHSU telemedicine department. Access to repository data will be limited to the repository guardian and any study staff approved for a given protocol. Researchers desiring telemedicine video data must request specific data via the repository guardian.

### G.3 Guardian: *Robin Guariglia, RN*

### G.4 Release Information

- A.4.a Video information may be identifiable in that participants may be recognized, and identifiable information may be included in the audio and/or visual part of the video data, e.g. forms containing clinical data may be visible or subject names may be used. It may be possible to redact video data before they are shared, depending on the circumstances. Please see Cost section for details. Disclosures of identifiable information may be subject to RIB review. See Release Process for details.

## H Recruitment Data

### H.1 Contents

- H.1.a Subject name
- H.1.b Subject contact information (e.g., address, phone number, email address)
- H.1.c Subject clinical information to allow for appropriate study matching/recruitment (e.g. dementia diagnosis; this information will vary by subject and data source and will only be included in recruitment information for subjects who consent to this separately).

### H.2 Sources

- H.2.a Subjects participating in Layton Center and ORCATECH studies are asked to be willing to receive invitations to participate in other related research opportunities. Those who refuse are noted and excluded from recruitment disclosures. (See Repository Source document.)
- H.2.b ORCATECH and the Layton Center host volunteer registries of community members who want to be contacted about future research studies about aging, technology, and/or dementia. Participants in these registries may or may not have previously taken part in other projects. They will sign a separate consent and authorization form.

### H.3 Acquisition

- H.3.a IRB approval: Recruitment data may be submitted to the repository from studies with IRB approval that adhere to consent and authorization standards as below. Data included in the repository are primarily collected through studies approved by the OHSU IRB; if not an OHSU study, IRB approval must be certified along with the data submission.
- H.3.b Consent and authorization
  - 1 The OHSU Terms and Conditions of Service/ Consent for Treatment and Notice of Privacy Practices state that patients and study volunteers may be contacted regarding voluntary participation in clinical research. New Layton Center Clinic Patients/ caregivers are also mailed a survey prior to their first evaluation that requests permission to be contacted by Layton Center staff (or designate) to discuss available research projects. If permission is not refused, names and contact information may be provided to an approved study investigator. Volunteers in the Layton Center and ORCATECH community based studies will be given the opportunity to refuse to receive invitations to participate in other related research studies on study consent forms
  - 2 Participants in the ORCATECH/Layton Center Volunteer Registries will provide consent and authorization to provide their contact information and permission to contact them in the future about research recruitment opportunities.

### H.4 Maintenance Information

- H.4.a Storage of data: Recruitment data are maintained in the Layton Center 4th Dimension database by the Clinical Data Guardian; also in the ORCATECH database maintained by Activity Data Guardian.
- H.4.b Security: see Repository Policies section, Release Process.

### H.5 Guardian: *Robin Guariglia, RN*

### H.6 Release Information

- H.6.a Guidance to collaborating investigators: Collaborating investigators will be advised that their study consent form must include description that the data from the participants' involvement in the Layton Center/ORCATECH study will also be used in their study.
- H.6.b In addition to the procedures and required supporting materials listed Repository Policies, Release Process the investigator must also submit a protocol, consent form, and IRB approval to the Clinical Data Guardian.
- H.6.c The Clinical Data guardian reviews the request and presents it to the Layton Center/ORCATECH Director and/or Executive Committee for approval. If approval is granted and if indicated, the Clinical Data guardian notifies a designated faculty member with related expertise to serve as the contact to the approved investigator. The Layton Center/ORCATECH contact may decide to meet with the investigator to discuss the project in more detail before the data is released.
- H.6.d Once the Clinical Data guardian receives written or verbal agreement from the Layton Center/ORCATECH Director or Executive Committee and the designated contact, subjects who meet study eligibility requirements will be identified.
- H.6.e The Layton Center/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 Layton Center or OHSU. Alternatively, study 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.
- H.6.f If permission is not refused, the Clinical Data guardian will give names and contact information of potential subjects to the approved investigator, working with Activity Data Guardian as appropriate if ORCATECH subjects are involved. Only the minimum necessary contact information will be provided.
- H.6.g The investigator will be provided with a Subject Enrollment Status log form which must be completed and updated at least every 6 months for ongoing studies and submitted to the Clinical Data guardian for tracking purposes.
- H.6.h Very occasionally, investigators who have recruited subjects only know them by name and subsequently request additional clinical information about them. To protect the code-breaking link between the database identification numbers and names, investigators who already have subject names will NOT be given additional clinical data with the database identification number.

## I Biomarker and Genetic Specimens

### I.1 Contents

- I.1.a DNA
- I.1.b Blood, including plasma and/or serum
- I.1.c cerebrospinal fluid (CSF)
- I.1.d saliva (not prospectively collected)
- I.1.e urine (not prospectively collected)

### I.2 Sources

I.2.a Collected by this repository

### I.3 Maintenance Information

- I.3.a Storage of specimens: Specimens are stored in alarmed -80°C freezers on the 6th floor of University Hospital South (OHSU Marquam Campus), the building adjacent to the Layton Center offices. Data associated with specimens is included in the Layton Center 4th Dimension database.
- I.3.b Security: Access to the freezers. To ensure proper consistent storage, alarms will immediately notify appropriate personnel if a freezer malfunction or power outage occurs. The inventory of samples is carefully maintained, and these data are conveyed to the Layton Center Clinical Data guardian so that the database can be kept up to date as well. Direct access to specimens is restricted to OHSU personnel granted access to the research building.

**I.4 Guardian:** *Joseph Quinn, MD*

### I.5 Release Information

- I.5.a In addition to the procedures and required supporting materials listed in Repository Policies, Release Process, the requesting investigator must also submit IRB approval to the guardian.
- I.5.b Releases will comply with the Genetic Information Nondiscrimination Act (GINA) as well as the Oregon Genetic Privacy Law (ORS 192.531 through ORS 192.549).
- I.5.c Because of the large number of specimens available, no one has been denied a request. If specimens become limited in the future, we will prioritize specimen use along the following lines of decreasing priority: research and pilot projects within OHSU and University of Washington ADCs (UW is the Layton Center's primary collaborative partner); projects within OHSU and UW focused on AD, related dementing illnesses and brain aging; projects outside of OHSU focused on these same topics; and projects focused on other neurodegenerative diseases.
- I.5.d If approval is granted and if indicated, the guardian notifies a designated Layton Center faculty member with related expertise to serve as the contact to the approved investigator. The Layton Center contact may decide to meet with the investigator to discuss the project in more detail before the data is released.
- I.5.e Usage Agreements will be obtained from non-OHSU recipient investigators as necessary.
- I.5.f Material transfer agreements are used when necessary for the transfer of biological materials to non-OHSU recipient investigators.
- I.5.g Once the guardian receives written or verbal agreement from the designated Layton Center contact and all necessary usage agreements are in place, the requested specimens are securely shipped via certified overnight delivery with appropriate handling and packaging according to the nature of the specimens.
- I.5.h All requests are logged by the guardian to track the number and nature of requests.
- I.5.i Requests for clinical data associated with specimens will be released as described in Repository Policies, Release Process
- I.5.j All specimens are supplied to researchers without any personal identifying information, as described in Repository Policies, Release Process.
- I.5.k A statement of biohazard and absolute need for universal precautions accompanies all specimens.

## J Pathology Specimens

### J.1 Content

- J.1.a Brain tissue
- J.1.b Central nervous tissue (e.g., spinal cord, nerve tissue, CSF)

### J.2 Acquisition

- J.2.a IRB approval: Pathology specimens obtained through autopsy do not fall under the definition of human subjects research because the subjects are decedents (reference eIRB 1623, Oregon Brain Bank, non-human subjects research determination 12/1/2006).
- J.2.b Consent: Eligible submissions to the repository must have been obtained from decedent subjects with the consent of the decedents' next of kin with the understanding that specimens will be maintained and shared indefinitely. Consent will be obtained by telephone according to the policy of OHSU Office of Decedent Affairs.
- J.2.c Autopsy: After next of kin consent is obtained, Dr. Woltjer and his staff will work with the family's chosen funeral home to coordinate transportation of the body to and from OHSU for removal of the brain and/or other tissue of interest at the first opportunity after death. OHSU will cover the cost associated with tissue donation, including transportation (the funeral home will bill OHSU).

### J.3 Maintenance Information

- J.3.a Storage of specimens
  - 1 Frozen specimens are stored in alarmed -80°C freezers in the Neuropathology Unit, basement level Jones Hall for Basic Medical Sciences (OHSU Marquam Campus).
  - 2 Fixed specimens are stored in appropriate storage space in the same Neuropathology Unit.
- J.3.b Security: To ensure proper consistent storage, alarms will immediately notify appropriate personnel if a freezer malfunction or power outage occurs. The inventory of samples is carefully maintained, and these data are conveyed to the Layton Center Clinical Data guardian so that the database can be kept up to date as well. Direct access to specimens is restricted to OHSU personnel granted access to the research building.

### J.4 Guardian: *Randall Woltjer, MD*

### J.5 Release Information

- J.5.a Because of the large number of specimens available, no one has been denied a request. If specimens become limited in the future, we will prioritize specimen use along the following lines of decreasing priority: research and pilot projects within OHSU and University of Washington ADCs (UW is the Layton Center's primary collaborative partner); projects within OHSU and UW focused on AD, related dementing illnesses, and brain aging; projects outside of OHSU focused on these same topics; and projects focused on other neurodegenerative diseases.
- J.5.b Requests for pathology specimens will go directly to the guardian (Randall Woltjer) and will be decided at his discretion in consultation with the Layton Center Director and Executive Committee. Dr. Woltjer will work directly with the requesting investigator to consult on the project and use of Layton Center pathology specimens.
- J.5.c Material transfer agreements are used when necessary for the transfer of biological materials to non-OHSU recipient investigators.

- J.5.d Once the guardian approves the request and all necessary usage agreements are in place, the requested specimens are securely shipped via certified overnight delivery with appropriate handling and packaging according to the nature of the specimens.
- J.5.e All requests are logged by the guardian to track the number and nature of requests.
- J.5.f Research involving pathological specimens from deceased individuals is not strictly considered human subjects research. However, given that many research requests for brain tissue include clinical information associated with the specimens. Requests for clinical data associated with specimens will be released as described in Repository Policies, Release Process.
- J.5.g All specimens are supplied to researchers without any personal identifying information, only the Layton Center coded identifier.
- J.5.h A statement of biohazard and absolute need for universal precautions accompanies all specimens.

## **κ Data from Biomarker, Genetic and Pathologic Specimens**

This repository houses not only specimens, but data generated from those specimens.

### **K.1 Contents**

- K.1.a SNP genotype
- K.1.b Data generated from biomarker samples
- K.1.c Data generated from pathology samples

### **K.2 Maintenance Information**

- K.2.a Storage of specimens: Genetic data are maintained in a Progeny database at the Layton Center offices on the 13th floor of the Hatfield Research Building (OHSU Marquam Campus).
- K.2.b Security: Access to all information in the database is controlled through individual passwords assigned by the guardian after approval by the Layton Center Executive Committee.

### **K.3 Guardian: *Joseph Quinn, MD***

## **L Research Activities**

### **L.1 Summary**

The Layton Center and ORCATECH investigators conduct secondary analyses using repository data to better understand aging and dementias. Such work makes efficient and productive use of the data, as well as leading to rapid development and dissemination of knowledge.

### **L.2 Aims**

This research seeks:

- L.2.a To identify risk factors of diseases associated with aging.
- L.2.b To identify protective factors for successful healthy aging.
- L.2.c To disseminate findings of professional interest in aging and dementia leading to improved elder care and improved diagnosis and care of Alzheimer's disease patients.

- L.2.d* To support the professional development of investigators through supervised access to Layton Center and ORCATECH Research Repository research resources for minimal risk projects.

### **L.3 Methods**

- L.3.a* Layton Center and ORCATECH Research Repository procedures for release of repository materials will be followed.
- L.3.b* Both cross-sectional and longitudinal analyses are performed with the data and biomarkers collected via our longitudinal aging cohort studies (see Repository Source document). Statistical methods include but are not limited to: ANOVA, correlation, categorical data analysis, univariate and multivariate linear and logistic regression, principal components (factor) analysis, longitudinal mixed effects and generalized estimating equations models.