

The ORCATECH Living Lab Program (OLL)
A community resource for research on enabling proactive health

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Overview of the Living Laboratory

The ORCATECH Living Laboratory (OLL) is a population of community-dwelling seniors who have agreed to participate on an ongoing basis in research on technology-based health monitoring, intervention, and support of independent aging. The Living Lab is used to explore technologies to support independent living, to assess new behavioral markers, and to evaluate approaches for assessing neurological and other relevant health changes, all in the participant's home. This resource is intended to facilitate:

- Rapid evaluation of emerging technologies in a naturalistic field setting, with the goal of reducing development time and time-to-market:
 - Lowers cost of conducting field trials, since recruiting and characterization of the subject population has already been done.
 - Administrative issues related to IRB and intellectual property are facilitated “up front”
 - Improves evaluation of potential and unanticipated issues, since the home environments are well-characterized.
- Provide pilot data for larger grant applications
- Comparison between technologies with similar goals, in head-to-head comparisons in the same home
- Pilot studies of health outcomes that may be informed by continuous behavioral data
- Conduct of focus groups and survey research relating to technology and aging
- Integration of data from different technologies, by providing a core set of data that is consistent and well-characterized across all subjects.

The Living Lab seniors live in diverse home environments within the community, ranging from large single-family dwellings to studio apartments in retirement communities. These seniors undergo an extensive series of neuropsychological and clinical tests, including the assessments that make up the Uniform Data Set used by the NIH-funded Alzheimer's Disease Centers. In addition, the characteristics of their home environment (type of home, home construction materials, number of rooms, etc.), and of their socialization habits (regular outings and visitors) are documented. Every subject also completes a short weekly online questionnaire in which they report illnesses, falls, visitors or time spent away from home, and any changes to their physical environment or emotional state.

Services Available

IRB assistance

All of the Living Lab participants have provided informed consent to participate in the Living Lab under the OHSU Institutional Review Board (IRB). As new technologies and pilot studies are proposed, new protocol descriptions and consent forms must be drafted and approved. The ORCATECH staff can assist with and expedite this process by processing new studies under the ORCATECH Living Lab umbrella. Services include assistance in drafting lay language protocols and consent forms, in ensuring involved investigators and staff are appropriately trained and entered into the IRB system, and in submitting and managing IRB protocols and annual reviews.

Technology evaluation

Prior to deployment into the Living Lab, all new technologies must undergo usability testing in the ORCATECH Point of Care Laboratory. This testing is done by experienced research technicians, who will install and test the technology, evaluate its potential impact on participants, and determine what integration is needed to remotely monitor the status of the technology when it is deployed in the field. Because the participants in the Living Lab are not all technologically sophisticated, and because they are asked to participate in a wide variety of protocols and testing, we are naturally careful to assess the impact of each new technology on the subjects prior to its deployment.

Integration of data into the ORCATECH Management Console (OMC)

This console (“the OMC”) allows the research team to remotely monitor the health and compliance of subjects, as well as the health and status of technologies, on an ongoing basis. (See the overview of OMC at <http://www.orcatech.org/livinglab/ORCATECHmanagementConsole.ppt>). In some cases, particularly if data is to be collected over a period of weeks or months, it may make sense to integrate the management of deployed sensors and questionnaires into the OMC. If integration with OMC is done, OLL Partners will be granted console status to view their data and relevant subject and technology reports during the duration of their study. Data can always be downloaded on request.

Technology deployment and pilot study management

In order to avoid confusion among the participants of the Living Lab, and preserve standardization, all new technologies and pilot studies will be administered by ORCATECH. In practical terms, this means that ORCATECH personnel will obtain informed consent to participate from the subjects, deploy the technologies, and monitor the data collection. In some cases, it may be appropriate for the OLL Partner to accompany the ORCATECH research assistant on subject visits to assist with education and administration of tests. However, ORCATECH staff will remain the primary point of contact for any issues arising during the study. If issues require resolution by the OLL Partner, then ORCATECH staff will facilitate this.

Any electronic technology to be deployed in the living lab must have FCC approval. ORCATECH personnel can assist with obtaining this approval. Typically, FCC approval for a device with no intentional emissions (or a device that contains emitters with FCC approval, such as a Bluetooth module) takes about 2 weeks to obtain and costs about \$1500.

How to Participate in the Living Lab

The application process

Researchers and companies interested in using the Living Lab are encouraged to contact the ORCATECH Administrative Director by email prior to making an application, to discuss the proposed project. Online applications are available at <http://www.orcatech.org/livinglab/ORCATECHLivingLabUseApplication.pdf>. Applications are reviewed biweekly, and prospective OLL partners will be contacted after the review to discuss their intended use of the Living Lab. Depending on the proposed use, additional information may

be requested. The specific process to be followed will also depend on the proposed use, as described below.

Field testing of new technologies

For field tests of new technologies, ORCATECH staff will meet with the OLL partner to discuss the planned study, the requirements of the technology, and the type of data to be collected. Together they will draft a plan for usability testing of the technology in the OHSU Point of Care lab. ORCATECH staff will conduct the testing, after receiving training from the OLL partner on the use of the technology (if needed). If data collection is to be integrated into the OMC, then the ORCATECH console programmer will also meet with the partner to define the requirements for integration of the new technology into the management suite.

OLL partners should submit a description of the planned field tests, which ORCATECH staff will use to create a consent form and Lay Language protocol for IRB submission. If the OLL partner already has an approved OHSU IRB protocol, then this will be reviewed by ORCATECH staff to ensure that no modifications are needed to allow the field testing to be carried out in the Living Lab.

If the usability testing finds that the technology is particularly cumbersome, or if the proposed protocol is unusually burdensome for the subjects, ORCATECH staff will work with the OLL partner to identify modifications to reduce the impact on the subjects and to improve the potential for good compliance among the subjects. Once the technology has been approved for use in the Living Lab, any necessary modifications to the management console will be completed and reviewed with the OLL partner for their approval.

At that point, ORCATECH staff will hold an informational meeting with the Living Lab participants and the OLL partner, in which the OLL partner will explain the purpose of the field testing, demonstrate the use of the technology, and describe the protocol. ORCATECH staff will collect informed consent from interested Living Lab participants and schedule appointments to install the technology. The OLL partner may accompany the ORCATECH installer on these visits, but the ORCATECH staff will remain the primary point of contact for the field study.

Data from the study will be made available to the OLL partner on a daily basis, assuming the technology itself supports that. Data which is transferred directly to the OLL partner (rather than uploaded through the OMC) must be uploaded to ORCATECH on a weekly basis. A web site will be available to facilitate the upload process.

At the end of the field testing period, ORCATECH staff will uninstall the technology and arrange to have it returned to the OLL partner. A survey of the attitudes and experience of the Living Lab participants with the technology during the field testing will be conducted by ORCATECH staff and a report will be sent to the OLL partner within 30 days.

Pilot studies of outcomes/measures

The process for initiated pilot studies is essentially the same as that for field testing of new technologies, except that in addition to preparing the technology, particular subject characteristics may be of particular importance, and additional clinical, neuropsychological or behavioral testing may be needed.

The ORCATECH staff will work with the OLL partner to identify the best group of subjects to participate in the pilot study. They will also help the partner to select appropriate assessments

and work with the IRB to get those additional assessments approved as part of the IRB submission.

Some pilot studies will not require additional technologies, but will simply involve new assessments and/or secondary analyses of existing sensor and clinical data. In this case, ORCATECH personnel will work with the partner to fast-track the IRB submission to get the project underway as quickly as possible.

Focus groups and survey research

The Living Laboratory includes both the subjects themselves, and “collaterals” who know the subject well (often a spouse or adult child). These individuals are generally willing to participate in focus groups or surveys relating to technology and aging research and products. It should be noted that by virtue of their willingness to participate in the Living Laboratory, our subjects are clearly interested in and supportive of the concept of technologies for independent living. Therefore, ORCATECH staff will also assist OLL partners in recruiting additional focus group or survey research participants who may be less experienced with technology, or less inclined to view technology in a positive light.

When an OLL partner makes a request to engage the Living Lab participants in focus groups, an ORCATECH staff member will meet with the partner to identify the number and demographics/characteristics of the desired participants, and the protocol to be used. The ORCATECH staff member will then create the necessary IRB materials to get approval for the study. Once approval is obtained, the ORCATECH staff member will identify interested participants, and meet with the OLL partner to review and finalize the list of potential participants. The ORCATECH staff member will then schedule the focus groups as needed. A similar process is used for developing a survey panel and conducting this kind of research.

ORCATECH staff can provide as much assistance as the OLL partner requires to complete the focus groups, including, if desired, arranging facilities, conducting the sessions, collecting and transcribing the data, and analyzing and reporting out the results.

Consulting Services

ORCATECH staff are available to consult on a wide range of topics relating to the use of technology for independent living and aging research, including clinical evaluation, usability and acceptance of technology by elders, issues in field deployments of wired and wireless technologies, subject recruitment, study design and obtaining funding for larger projects. OLL partners wishing to work with an ORCATECH investigator or staff person on development of their project, or to consult on specific issues, should contact the ORCATECH Administrative Director.

Set-up of Remote Living Lab

Although the ORCATECH Living Lab is a valuable resource, some investigators and companies may wish to set up a similar facility in their own city or area. ORCATECH faculty and staff can assist with this in a variety of ways, ranging from advising on how to proceed to provision of equipment specifications and software to manage deployments, to actual deployment (subject recruitment, equipment purchase, and installation). Interested partners should contact Dr. Jeffrey Kaye directly to discuss their proposed project.

Requirements for participation

All technology evaluations and pilot studies done within the Living Lab will create research data of some kind. All OLL Partners must agree to the Data Sharing and Data Use policy (described below).

Administration

Application Forms

Online applications are available at <http://www.orcatech.org/livinglab/ORCATECHLivingLabUseApplication.pdf>. Applications are reviewed biweekly, and prospective OLL partners will be contacted after the review to discuss their intended use of the Living Lab. Depending on the proposed use, additional information may be requested.

Fees

While use of the Living Lab has the potential to greatly reduce the cost of conducting field testing of technology and behavioral studies, each additional study that uses the resource necessarily incurs a cost. In order to offset this expense, ORCATECH charges fees for the use of the resource, based on the status of the OLL partner. OLL partners are classified as supporting partners, non-profit and government-funded investigators, or industry-funded investigators. For more fee information please see *Living Laboratory Usage Fees* document.

Supporting partners are OLL industry partners who support the Living Lab through grants. These partners are not charged fees for the use of the resource. Students are graduate students at an accredited university who are using the Living Lab in the conduct of their dissertation research, provided that research is not funded by a for-profit business. Non-profit and academic investigators are clinical or basic scientists or engineers who are using the Living Lab in the conduct of government-funded or foundation-funded research. In both of these cases, the partial costs are borne by ORCATECH. Industry investigators are partners who are conducting research funded primarily or exclusively by a for-profit business. Industry partners are charged the actual cost of the service.

Data sharing/data use policy

ORCATECH encourages dissemination and sharing of knowledge. We also respect the importance of intellectual property and its protection in a competitive world. Accordingly, conditions for data sharing are determined in part by the purpose of the research and the nature of the funding for each project. This detail will be discussed with the OLL partner once funding sources and the nature of the project have been established.

The Living Laboratory Homes and Subjects

Subject recruitment

As of June 2008, the Living Lab currently includes 34 seniors (aged 76.4 ± 7.9 years) living in the greater Portland area (27 homes). Subjects were screened for dementia using the Mini-

Table 1. Demographics and clinical assessment of the Living Lab subjects.

ID	Age	Gender	MMSE	CDR	ID	Age	Gender	MMSE	CDR
342	79	M	•	•	10013	69	F	30	0
365	70	F	•	•	10014	79	M	29	0.5
7605	77	M	17	0.5	10015	77	F	28	0
7627	76	F	•	•	10016	80+	M	29	0
10000	90+	M	29	0	10017	90+	M	30	0
10001	74	F	29	0	10018	70	F	30	0
10002	80+	F	29	0	10019	68	M	29	0
10003	78	F	28	0	10020	70	M	28	0
10004	90+	F	30	0	10021	61	F	29	0
10005	66	F	30	0	10022	80+	M	•	•
10006	75	F	27	0	10023	80+	F	•	•
10007	78	M	27	0.5	10024	77	F	29	0
10008	69	F	30	0	10025	71	F	30	0
10009	72	F	26	0	10026	72	M	19	•
10010	80+	F	27	0	10027	•	F	•	•
10011	80+	F	30	0	10028	67	M	30	•
10012	75	F	29	0	10030	73	F	•	•

Mental State Examination (MMSE) (exclusionary score <24) and the Clinical Dementia Rating scale (exclusionary score >0). Table 1 shows the demographics of the subjects and their baseline test scores. Up to date detailed demographics and other clinical data will be provided if needed for selection of subjects.

Technology deployment

Homes in the Living Lab have the following technologies deployed on a permanent basis. New technologies are introduced temporarily as pilot studies are run.

- Motion sensors (X10 MS16a) to estimate activity in the home and to measure speed of walking;
- Door sensors (X10 DS10A) to estimate when subjects leave home and when visitors arrive;
- RFID location tracking devices (Ekahau RFID tags, which report signal strength to wireless access points distributed in the environment) and a custom algorithm that disambiguates who is moving through the space;
- A medication tracking device, to track adherence of participants to their own non-prescription pill regimen;
- A home computer, from which daily use measures are taken (time spent in email, web surfing, word processing) and motor measures are taken (inter-keystroke intervals, mousing to target)

- A kiosk interface, which includes a handset on the home computer and through which a short weekly automated cognitive test may be administered.
- Phone sensors for detecting on-hook and off-hook, as well as caller ID information
- Bed mats and/or load cells for assessing restlessness and activity in bed.

In

Table 2. Characteristics of the monitored homes.

ID	Monitoring Start Date	Home Construction	# Residents	# Rooms
342	1/29/2008	wood frame	2	9
365	2/8/2008	wood frame	1	9
7605/7627	3/12/2008	wood frame	2	10
10000	3/3/07	wood frame	1	16
10001	2/23/07	steel frame/drywall	1	6
10002	3/9/07	wood frame	1	7
10003	3/2/07	wood frame	1	9
10004	3/27/07	steel frame/drywall	1	4
10005	3/7/07	wood frame	1	9
10006/10007	3/6/07	wood frame	2	13
10008	3/8/07	wood frame	1	7
10009	7/25/07	wood frame	1	6
10010	9/19/07	wood frame	1	11
10011	7/20/07	Concrete	1	3
10012	7/20/07	wood frame	1	14
10013	7/19/07	Wood frame	1	10
10014/10015	8/13/07	wood frame	2	8
10016	1/30/2008	steel frame/drywall	1	5
10017	3/8/2008	steel frame/drywall	1	4
10018/10019	1/25/2008	wood frame	2	10
10020/10021	1/26/2008	wood frame	2	12
10022	3/15/2008	Manufactured Home	1	9
10024	1/28/2008	steel frame/drywall	1	4
10025	1/25/2008	steel frame/drywall	1	4
10026/10027	3/18/2008	wood frame	2	13
10028	3/29/2008	wood frame	1	14
10030	3/19/2008	wood frame	1	6

addition, participants complete a weekly questionnaire about changes in their health and home status, including changes in medications, falls, injuries, hospitalizations, illnesses, visitors to the home, overnight absences from the home, and movement of furniture (space changes).