

**If you are submitting a grant application with specific OCTRI resources, you must request a cost estimate to include in the proposal budget. Without a cost estimate on file we cannot guarantee the resources you plan on using will be available or feasible for your project.**

**Please visit <http://bit.ly/2dHjMRf> to submit a request for a cost estimate and letter of support.**

#### **Oregon Clinical and Translational Research Institute (OCTRI) General Boilerplate:**

The Oregon Clinical and Translational Research Institute (OCTRI) is a well-established Clinical and Translational Science Award recipient, initially funded in 2006 through the NCATS CTSA program. Our vision is to be a leader in translating scientific innovations into health gains for individuals and communities in Oregon, and beyond. As the regional hub for clinical and translational science in the Oregon and southern Washington, OCTRI provides research strategy, expertise, support, services, tools and training for investigators, administrators, research staff and the next generation of the clinical and translational research workforce. Our resources include infrastructure for conducting patient-based research, investigator funding for new research ideas, translational and clinical informatics expertise, regulatory support and guidance, and strong career development support for clinical and translational research training. In addition, as part of the CTSA consortium, OCTRI provides significant infrastructure for supporting multi-site clinical trials through the national Trial Innovation Network.

#### **Oregon Clinical and Translational Research Institute (OCTRI) Facilities, Equipment and Resources:**

##### **Recruitment Resources:**

OCTRI supports the research community with the tools for successful study recruitment and retention. Recruitment consultations include advice on best practices and a tailored recruitment strategy. Helpful resources include, the Research Data Warehouse (RDW). This virtual warehouse contains all of OHSU's electronic health record data, cancer registry data and pathology data. This virtual research data warehouse is a rich resource for researchers seeking to identify and recruit participants to their research trial based on specific criteria. Informatics analysts work with an investigator one on one to develop complex and efficient queries to identify potentially eligible participants. Alternatively, investigators can use a self-service model called Cohort Discovery (an i2b2 platform). In Cohort Discovery investigators use a web-based drag and drop model to design their own query and, with appropriate IRB approvals in place, request a limited dataset (which includes contact information) from our analysts. Another recruitment resource supported by our informatics staff includes REDCap surveys. REDCap is a web-based data management system that includes the ability to create survey forms and post links to the survey either on posters, websites or in other venues. People interested in the study fill out a short eligibility survey and provide electronic consent to the investigator collecting their contact information within the REDCap database. This allows researchers to quickly identify people who are both interested and potentially eligible to participate. This resource is also available to use in conjunction with the national research repository, ResearchMatch (local administrative support available through OCTRI). ResearchMatch is a registry of interested potential participants can create a profile outlining their demographics and specific health information. Researchers can query the ResearchMatch repository to find potentially eligible subjects and send them an IRB approved message inviting them to learn more about the study. As a part of this workflow a REDCap survey link may be utilized to streamline the recruitment process. The survey can be used to screen and in some cases obtain electronic consent for participants interested in the study.

Similar to ResearchMatch, the OCTRI Clinical and Translational Research Center (CTRC) maintains a local registry of people who are willing to be contacted to participate in future research. OHSU investigators can obtain/gain access to this registry (with appropriate regulatory approvals) and quickly find a list of potential subjects who have agreed to be contacted to take part in their research. This registry also includes pre-screened anonymous biological samples from healthy subjects (serum, plasma, urine, saliva and stool) that are immediately available as control samples.

For those cases where recruitment success hinges on having trained staff available to make phone calls, staff events, prepare and distribute posters or post studies to a social media platform, the CTRC also maintains a staff of trained study coordinators available to assist with recruitment needs.

For projects experiencing difficulty with recruitment or for those who would like an expert consultation regarding their recruitment plan, OCTRI also provides a venue for investigators to meet with representatives from a variety of clinical research programs, including a recruitment specialist, within the CTSA to determine what the best methods for recruitment onto their study are.

**REDCap Specific:** OCTRI's installation of REDCap is highly secure and robust web-based research data collection and management system.

Features of REDCap that protect participants' privacy and data security include:

- **Physical Security:** OCTRI's REDCap software is housed on servers located in ITG's Advanced Computing Center providing locked physical security.
- **Electronic Security:** The REDCap servers are housed behind both the OHSU firewall and a second ACC firewall. All web-based data transmissions are encrypted with industry-standard SSL methods.
- **Controlled User Access:** REDCap employs a robust multi-level security system that enables researchers to easily implement "minimum necessary" data access for their research staff, including specification of data fields that are identifiers. This feature includes "single click" ability to provide completely deidentified (removing all identified data fields and shifting dates) data for analysis or other purposes. User activities are logged to enable auditing of all data access. Access is integrated with OHSU's network such that users who are also OHSU employees are authenticated against their OHSU network credentials.
- **Data Integrity:** REDCap is jointly managed in accordance with OHSU Information Security Directives by ACC staff and members of OCTRI's Biomedical Informatics Program, ensuring fidelity of database configuration and back-ups. User activities are logged to enable auditing of all data changes.

**Research Data Warehouse and Cohort Discovery Specific:** OCTRI's Clinical Research Informatics program maintains a repository called the Research Data Warehouse (RDW) containing OHSU's electronic health record (EHR) data (Epic), cancer registry data, and pathology data. Through the RDW, researchers have access to the health records of over 600,000 patients having in excess of 10 million encounters. Researchers may access the RDW for preparatory to research purposes through Cohort Discovery, a self-service, web-based tool for obtaining counts of patients meeting investigator-specified inclusion and exclusion criteria. For more complex queries during conduct of the project, investigators may work with highly trained and experienced data analysts to navigate the complex clinical data. The RDW can be used for a variety of research purposes including study feasibility, hypothesis generation, recruitment and retrospective chart review.

**Regulatory Knowledge.** This unit provides guidance to investigators for regulatory and compliance requirements. Consultations may include advice on best practices for submitting IRB applications at both OHSU

#### **Facilities:**

The OCTRI Clinical and Translational Research Center (CTRC) is a dedicated research facility for clinical studies at OHSU, and is equipped and flexibly staffed to support a broad range of protocols. CTRC facilities include an eight bed unit in the Hatfield Research Center, immediately adjacent to the main OHSU hospital. There is an outpatient unit with an infusion area, exam rooms, procedure rooms and phlebotomy space. All of the inpatient rooms are equipped with continuous EEG monitoring, three of which are equipped with advanced sleep monitoring capability, including light and temperature control and the ability to obtain blood samples remotely through pass-through windows. The CTRC is staffed with RNs for inpatient and extended study visits, or intensive outpatient studies, as well as with RAs to facilitate study visits in our outpatient clinic. CTRC nursing equipment includes electrocardiographs, syringe infusion pumps, Alaris multichannel infusion pumps, Propaq monitors, metabolic scales, otoscopes, ophthalmoscopes, portable suction and code carts.

The CTRC also houses a core laboratory adjacent to the clinical unit, which provides laboratory support to studies by performing a wide variety of assays and procedures. The laboratory is equipped to process, store and ship samples. Available lab equipment includes: Siemens IMMULITE 1000 chemiluminescence-based analyzer, Synergy HTX multimode ELISA plate reader, gamma counter, walk-in freezer and refrigerator, low temperature -80 freezers (10), Beckman DU 530 spectrophotometer, fluorimeter, Hewlett Packard HPLC systems with autosamplers, HPLC fluorescence detector, HPLC Diode array detector, liquid nitrogen storage facilities (6 dewars), CO<sub>2</sub> tissue culture cabinets (2), biosafety hood, fume hoods (2) and centrifuges (7). Additionally, there is low temperature (-80C and liquid nitrogen), long term biological sample storage available. Molecular biology related equipment in the lab includes Applied Biosystems ABI Prism 3130XL genetic Analyzer and Sequencer, ABI Prism Genescan and DNA sequencing analysis software, MJ Research Tetrad 4 block PCR machine, Applied Biosystems 9700 and 9800 PCR thermocyclers, Gel-Doc Imaging system, DNASTar sequence alignment software and electrophoresis system(s).

The CTRC bionutrition unit is located near the CTRC clinical facilities, and includes a research kitchen for the design, testing, and provision of research meals. These facilities house equipment for measurement of body composition by DEXA, BodPod, and bioimpedance analysis, and energy expenditure by indirect calorimetry.

The CTRC study coordinator unit provides intensive support for study conduct on the CTRC, across the OHSU campus and in the community. The staff can be hired to enter data, recruit participants, manage regulatory records, maintain study documents and facilitate study visits. The CTRC Research Volunteer Registry is a repository that contains names, contact and demographic information, and medical information on healthy volunteers who have pre-consented to be contacted for research studies. This repository also contains pre-collected biospecimens (serum, plasma, urine, saliva and stool) that are available to study teams for a control comparison or assay testing.