

Faculty Guide to Start-Ups Sited at OHSU

So you're going to be a Founder.....

Congratulations! The Oregon Health and Science University is proud of the intellectual achievements of its faculty and offers this Guide as an aid to those who are forming their own “start-up” companies that are located in space on the OHSU campus. We hope this is a helpful resource as you sort out roles and responsibilities during this period of your professional growth.

A common cause of confusion during a start-up's early phase is the difference between the start-up's activities and OHSU. OHSU has a keen interest in ensuring your start-up's success, and often holds equity in the company. However, the start-up is a private, independent legal entity that is separate from OHSU. It is important to carry out start-up activities in a way that does not confuse start-up activities or employees with OHSU and vice versa. OHSU and start-up resources are not interchangeable. The start-up is a private, independent company. Guidance follows on how to set out clarity in common activities from the outset.

Steps and issues on siting a start-up at a non-OHSU location, such as the Portland State Business Accelerator or OTRADI, are outside the scope of this Guide, but some of the topics in this Guide may generally inform those start-up efforts as well.

This guide was developed by Janet Billups, policy advisor to the vice president for research, at the request of Dan Dorsa, Ph.D., and the OHSU Research Council with input from the scientific community and research administration. If you have questions not addressed by the guide, please contact research@ohsu.edu.

What draws you to this?

Some faculty members are attracted to the idea of supplementing their OHSU research funding with less traditional funding sources, such as Small Business Technology Transfer (STTR) or Small Business Innovation Research (SBIR) grants. Be cautious about forming a start-up if the primary reason is to bring in supplemental income. Creation of a start-up is laborious and requires considerable administrative and business attention that can distract you from your research. In addition, SBIRs and STTRs have different expectations than traditional NIH funding, as do grants from various agencies in the Department of Defense (DoD).

On the other hand, forming a start-up can be exciting and empowering to people drawn to the intersection of commerce and science. Some of the better reasons for the creation and advancement of a start-up include:

- A desire to bring an existing technology to the market
- A genuine interest in participating in business development
- Entrepreneurial curiosity

See the section on STTRs, SBIRs, industry and DoD contracts for more information.

Where do I start?

Often a faculty member is unaware of the various units within OHSU they may need to contact before locating a start-up at OHSU. The first step is your department Chair. You will want to have a clear and candid conversation about the reasons for forming a start-up and how OHSU's academic missions will be balanced with the start-up's focus.

Three key offices are your next stop:

- Technology Transfer and Business Development (TTBD) to discuss the terms of an intellectual property license (IT) and other business related matters (BD). The BD group in particular is best positioned to answer substantive questions about forming a start-up. See the TTBD page.
- Campus Planning to reach agreement on the lease of OHSU space and related resources, which must be in place before the start-up can begin its work on campus.
- Conflict of Interest in Research, Conflict of Interest, Outside Activities (COIR/COI/OA)

For many, these will be the only OHSU offices to contact. Other OHSU offices to contact will depend on the scope of the start-up's activities at OHSU and include:

- Human Resources if any OHSU personnel will provide any service to the start-up
- Research Grants and Contracts (RGC) and Sponsored Projects Administration (SPA)
- Research Core Resources
- Human Research Core Resources
- Institutional Animal Care and Use Committee (IACUC)
- Department or Division of Comparative Medicine (DCM)
- Institutional Review Board (IRB)
- Institutional Biosafety Committee (IBC)
- Environmental Health and Radiation Safety (for hazardous substances and waste management)
- Occupational Health

Information pages for each of these units follows.

Please be sure to make all of your contacts well before:

- Developing any grant proposal for your start-up that may use OHSU space, facilities, resources, services or personnel;
- Making any commitments to individuals, companies or funding agencies for the start-up that may affect or involve OHSU resources, facilities or personnel; or
- Making any assumptions in the planning processes about use of OHSU facilities or services and the fees that may accompany that use.

The purpose of taking pro-active steps to work with OHSU units from the beginning is to best support you, and your new company, in efficiently siting the company at OHSU. Early contacts will help avoid the confusion and delays that can occur when a start-up's plans are not coordinated with OHSU units.

**Small Business Technology Transfer (STTR)
Small Business Innovation Research (SBIR)
Department of Defense
Industry contracts**

STTRs and SBIRs are two of the primary funding sources that founders consider when drawn to the idea of a start-up company. Helpful links that describe the two are <http://www.sbir.gov/about/about-sbir> and <http://www.sbir.gov/about/about-sttr>.

Both grant forms have advantages and disadvantages as well as both parallels and differences with NIH grant applications. One significant difference between traditional NIH grants and STTR/SBIR grants is that the latter carry an expectation that the funds will be used to bring existing technology to market. This funding is not intended to support the long-term basic science exploration of knowledge that characterizes NIH funding. STTRs and SBIRs thus should not be viewed primarily as a means to supplement or substitute funding for a faculty member's academic research.

What is OHSU's role with respect to STTRs and SBIRs? STTRs do require a university partner for the grant application, but the applicant and the grant awardee is exclusively the start-up, which has sole authority and responsibility for the grant development and management. OHSU offices, such as RGC, SPA and TTBD, may provide input, but only as the grant relates to OHSU's designation as a university partner. They, as well as departmental administrative staff, may not take on grant development, management or administrative tasks on behalf of the start-up. Start-ups do sometimes hire OHSU employees to work for the start-up on their own time; see the page on "Human Resources" for guidance.

What about other granting agencies or industry contracts? The U.S. Department of Defense has many "silos" of money which can be applicable to start-up technology, such as the U.S. Army Medical Research and Materiel Command (USAMRMC), Office of Naval Research (ONR), Defense Advanced Research Projects Agency (DARPA). This Guide generally applies to DoD funding as well as industry contracts with start-ups.

Is OHSU approval required before submitting a grant application for my start-up? Some Departments now require SBIR and STTR grant applications, as well as DoD or industry grants or contracts, to be submitted to the Chair for review prior to submission in order to ensure that correct assumptions are made regarding access to OHSU facilities, equipment, resources or employees. This also protects the start-up from submitting grant applications with entries that might have to be later changed, to the disadvantage of the start-up. Check with your Chair to learn of any departmental expectations before investing too much time in a grant application or industry contract negotiation.

What is the relationship between these grant funds and OHSU? As with other aspects of the start-up's relationship with OHSU, it is important to remember that any award is to the start-up, not to OHSU. Revenue, expenses, management and the science of these grants and contracts must be managed at arms-length from OHSU grants and are not interchangeable or to be commingled with OHSU activities. If OHSU employees are planning to work on grant writing or development, then be sure to first get approval for the person to work for the start-up (see "Human Resources" page).

Who do I contact with questions?

- Your Chair for expectations in developing or carrying out start-up STTR, SBIR or DoD grant applications or industry contracts.
- The CoIR office to discuss potential conflicts between your role as a faculty member and a founder.
- TTBD, RGC or SPA for questions relating to OHSU's role as a university partner in an STTR.

Technology Transfer and Business Development

Will the start-up use intellectual property that is owned by OHSU, such as an invention owned by OHSU through a faculty member's assignment agreement to OHSU? OHSU employees who are interested in forming a start-up typically first contact the Technology Transfer & Business Development (TTBD) Office. The TT and BD groups have different functions relative to start-ups, and those functions are closely coordinated. TTBD also has an on-line Faculty Guide that includes, at page 30, guidance relative to start-ups. See http://www.ohsu.edu/xd/research/techtransfer/upload/Guide-to-TTBD_FINAL-WEB-VERSION-for-4-3-13-presentation-2.pdf.

Technology Transfer (TT). This TTBD group works with faculty and other OHSU employees to evaluate intellectual property developed at OHSU, pursue patent applications on intellectual property, and negotiate license agreements covering intellectual property. All start-ups that would like rights to or the freedom to practice under intellectual property owned by OHSU must have license agreements with OHSU. See the TTBD Faculty Guide (link above) for guidance on the licensing process. NOTE: You will need to have a company representative other than the OHSU PI/faculty founder negotiate the license agreement with Technology Transfer.

Who do I contact with questions? Andrew Watson, Director of Technology Transfer, watsonan@ohsu.edu; 503-494-8309 or the Technology Development Manager assigned to your technology/intellectual property.

Business development (BD). This TTBD group works with potential founders to evaluate whether a start-up should be formed, to provide professional business resources to potential faculty founders, and to offer guidance in the formation stages of a new company. When you contact BD with your start-up idea BD will form a small team consisting of a person from BD and person(s) from TT as appropriate, such as an already-assigned Technology Development Manager (TDM). This team will work with you in the planning and initial phases of your start-up through several means:

- The Springboard Program, which is designed to catalyze the development of new ventures based on OHSU technologies. It covers the cost of legal and accounting experts and facilitates business and strategic plan development. <http://www.ohsu.edu/xd/research/techtransfer/technology-development/springboard-program-summary.cfm>
- The Startup Advisory Group (SAG) (see page 30 of the TTBD Faculty Guide referenced above), which is a no-cost, independent business-focused advisory board comprised of life science industry senior executives, business and financial professionals, and consulting scientists/physicians. The SAG may assess the commercial potential of a new start-up or existing tech ventures coming out of the OHSU community and provide assistance, advice and mentorship to start-up company related activities. The SAG may also provide introductions to the Oregon Entrepreneur Network, venture capital, and angel investors.
- Facilitating the start-up's setup at OHSU with other OHSU units; your BD contact will email each of the relevant internal OHSU units on the "Where Do I Start" page to alert the unit of possible plans to site your prospective start-up at OHSU, with a copy to you so that you can move forward with substantive arrangements with the unit.

Who do I contact with questions? Abhijit Banerjee, Ph.D., MBA, Director of Business Development for TTBD; banerjea@ohsu.edu, 503-346-0362.

Additionally, for Knight Cancer start-ups contact Joe Carroll, Ph.D., Associate Director for Business Development (Knight), carrollj@ohsu.edu, 503-494-8254.

Lease of space and access to administrative infrastructure

Will the start-up use space, equipment or other resources at OHSU? Start-ups whose staff members carry out any work at OHSU must lease their space from OHSU. OHSU has space at Marquam II where a number of OHSU start-ups conduct their work (primarily on the 2nd floor). In addition, a few start-ups have leased a portion of the bench in their laboratories. OHSU welcomes faculty-founded start-ups to OHSU space as a springboard to success, but expects companies to move to private quarters as they mature.

May I use OHSU space, such as a portion of my bench? Yes, once the start-up has signed a lease agreement with OHSU. A request form to initiate this process can be found at the following link:
<http://www.ohsu.edu/xd/about/services/cpdre/space-planning/index.cfm>.

Is there a rental fee? Yes. The base rental rate is set by CFS. County property taxes, OHSU ID/Access Badge and Key fees, telecommunications fees, and alterations to the space are in addition to the base rental rate. Common research space (i.e. glass wash and cold rooms) is leased in a proportion share to the amount of wet lab bench space occupied. Your campus planning contact has information on the rental rate.

May I use my OHSU email or U.S. Postal address? OHSU's email and postal addresses may not be used for start-up communications. Please obtain an email and postal address before company operations commence.

May I use the Library? OHSU's subscriptions and licenses limit access to those Library resources to OHSU employees. Start-up employees who are not employees of OHSU have the same Library access as the general public, but that is more limited than OHSU employee access. Executive Vice Provost David Robinson manages all non-OHSU user access to the Library and can answer your questions.

What about parking? Start-up employees may have access to available campus parking if that access is set out in the lease. OHSU Transportation & Parking rates and rules apply if parking is granted in the lease.

What about access to and use of the computer network? Only OHSU employees are allowed access to the OHSU systems. Employees of a start-up may not access or use the OHSU systems unless the individuals are also OHSU employees. Please connect with your ITG contact before making any assumptions about access, or even before you make preliminary siting plans. Some start-up sites at OHSU are easier for ITG to manage, such as the Marquam II Building, while a start-up lease of a portion of a bench is more complex to manage.

What about telecommunications? This access should be set out in the lease; please contact ITG for set-up.

What about other OHSU resources and personnel? Are they included in the lease? No. Please consult the particular pages of this Guide for information about service units such as Research Cores, DCM, IACUC, IBC and IRB as well as the page on "Human Resources" for OHSU personnel who might perform work for the start-up.

Who do I contact with questions?

- Space lease: Brian Newman, Director, Campus Planning, Development & Real Estate, 503-346-0005; newmanb@ohsu.edu;
- ITG: Kerry Walker, Manager, ITG Infrastructure Design and Operations, 503-418-3246; walkerke@ohsu.edu.

Human Resources

Will the start-up have its own employees? Does it also plan to hire OHSU employees? This can be an area of confusion for start-ups, particularly those that are located at OHSU. OHSU employees and students are not fungible with start-ups in terms of their time or effort. It may be tempting, and efficient, to have a staff person who is working on an OHSU project take four steps to the right to work at the start-up's leased portion of the other end of the bench. However, remember that the start-up is not OHSU, and the start-up's activities and relationships must be clearly distinguished from OHSU. This is especially true for dual OHSU/start-up employees. Their time and effort must be carefully accounted for.

May I hire OHSU employees to work for my start-up? OHSU employees who might logically be asked to serve the start-up range from administrative assistants to laboratory staff to faculty. Those employees may be recruited to serve the start-up under specific circumstances. The founder's Chair and the employee's Chair (if different) must give permission for OHSU employee's start-up employment. A written description needs to be submitted to the Chair(s) describing the distinction between the two activities, the way in which the person's OHSU work may be affected, and the parameters for allowing the arrangement. External work for a start-up will need to be carefully structured to ensure that OHSU missions are respected and preserved. Some additional considerations:

- The employee cannot generally provide services while on OHSU time (but see the next entry).
- If the parameters allow the employee to provide services to the start-up during the regular business day, then the employee's OHSU FTE may need to be adjusted to reflect the reduced OHSU commitment. **IMPORTANT NOTE:** This may create grant effort reporting complexities for staff who work for the start-up; before submitting a grant application, founders should contact RGC for guidance to mitigate risks to both start-up and OHSU grants management obligations.
- OHSU employees cannot use their OHSU email or U.S. postal address for start-up business.
- The start-up needs to remind its employees that their service is independent of OHSU, and that OHSU has no role or responsibility with respect to compensation, worker's compensation, workplace concerns, employment differences or the like.
- All OHSU employees who provide services to the start-up need to submit a Conflict of interest disclosure in eCoI. This applies not just to the PI, but also to other faculty, laboratory, program staff or administrative staff who work for the start-up. Contact the CoI Office if you have any questions about the requirements for disclosure.

May I bring start-up employees who are not OHSU employees to my start-up space to provide services? Yes, provided the delineation between the start-up and OHSU is made clear to the start-up employees. Also, start-up employees are obligated to follow all OHSU policies relating to people on campus, including the Code of Conduct, smoking policy, security, badges and parking.

May I hire students to work for my start-up? Upon hearing about exciting start-up research, students have approached founders to ask about working for the start-up, either as a paid employee or an unpaid intern. It is important to remember that the OHSU community's primary commitment to students is the advancement and support of their academic experience. Founders who are mentors also face a potential conflict when their students are working for the mentor's company as well as in the mentor's lab. Founders who want to consider bringing students to the start-up will need to balance the student's overriding focus on academics with the start-up's work, with greatest deference being shown to the student's academic pursuits. The Conflict of Interest form asks about student involvement. Before involving a student in your start-up confer first with the CoI office and the Associate Dean for Students (or Graduate Students) of the relevant school to learn whether student involvement is permissible.

Who do I contact with questions?

Your Chair and the Chair of any OHSU employee you are interesting in hiring, if different.

Human Resources:

- Jennifer Crosby-Meurisse, HR Director, Research, Basic Sciences and Academics, crosbyme@ohsu.edu 503-494-7456
- Linda Strahm, HR Director, School of Medicine, strahml@ohsu.edu 503-494-6763

Grants management implications:

- Nancy Duncan, Interim Director, Sponsored Projects Administration, duncanna@ohsu.edu 503-494-3715
- Deborah Golden-Eppelein, Director, Research Grants and Contracts, goldenep@ohsu.edu 503-494-4853

Authorization for the start-up to hire OHSU employees: Your Chair and the employee's Chair (if different).

Conflicts of Interest for the PI and OHSU employees to be hired by the start-up:

- Kara Drolet, Ph.D., CoIR Committee Chair; Associate Director, ORIO; manningk@ohsu.edu 503-494-7887. www.ohsu.edu/xd/about/services/integrity/coi/

Student involvement:

- The Associate Dean for Students (or Graduate Students) or other equivalent of the applicable school
- Kara Drolet, Ph.D., CoIR Committee Chair; Associate Director, ORIO; manningk@ohsu.edu 503-494-7887. www.ohsu.edu/xd/about/services/integrity/coi/

Conflict of Interest in Research Conflict of Interest Outside Activities

Does a faculty member have any financial interest in the start-up? Will the faculty member spend any time (even outside of business hours) at a start-up that uses the faculty member’s academic expertise? If you are reading this Guide, then the answer to this question is likely “yes”, or at least “possibly”. Federal law requires OHSU to create policies and processes for managing conflicts of interest between the faculty member’s OHSU role, financial interests in the start-up, and the start-up’s activities.

I am thinking of founding a company. Who should I contact about potential conflicts, and when? Initially, it is up to your Chair (or Dean, if you are a Chair) to set any limits for time spent by faculty on outside activities. The next step is to go to the CoI office for information about policies related to Conflicts of Interest in Research (CoIR), Conflict of Interest (CoI) and Outside Activities (OA). Questions may include whether a PI may hold a company fiduciary position in light of the PI’s role at OHSU, and how to best manage conflicts, including day-to-day conflicts involving employee work in the start-up and OHSU space. Please inquire with your Chair and the CoIR office before setting up your start-up in order to learn of any guidelines or limitations.

My start-up has been created, and I am developing a grant proposal for an SBIR or STTR. Should I contact the CoI office, and if so – when? Yes, and it is in your best interest to contact the office for guidance and submit your CoI disclosure in eCoI prior to submitting a grant application. The last thing you want to happen is to be awarded a grant, then learn that you have potential conflicts or outside activities that have to be managed in a way that is inconsistent with the grant application. Remember also to contact SPA and RGC prior to developing the grant proposal in order to mitigate any grants compliance risks for either your OHSU grants or the start-up’s grants.

If I do have a potential conflict, then who decides whether I can proceed, or how it is to be managed? In addition to the oversight of a Chair, OHSU has appointed a Conflict of Interest in Research Committee with faculty representing the schools, research centers and institutes. They evaluate potential conflicts, such as those surrounding use of the founder’s OHSU intellectual property licensed to the start-up in their OHSU research, and develop a management plan for the potential conflict.

I can imagine having many questions, with perhaps one of the first being “May I subcontract my start-up’s grant work to OHSU, with me serving as PI on both grants?” You are right – you will likely have many questions that this brief Guide will not attempt to answer. Your best resource for answers is the CoI office. However, this particular question is significant enough to address in this Guide. The CoI committee decides upon the management plan. A typical management plan may require the OHSU PI role and other key functions (such as data analysis) of the subaward to be carried out by non-conflicted OHSU personnel. The CoI office can provide you with guidance.

What if I don’t subcontract any work to OHSU, but have the start-up do it all directly? Should I still contact the CoI office? Certainly. Even if you are not subcontracting to OHSU or using OHSU intellectual property the Outside Activities policies may be involved. It is recommended that you get advice and counsel up front before a grant application has been submitted or, ideally, before a start-up is formed.

Who do I contact with questions? Kara Drolet, Ph.D., CoIR Committee Chair; Associate Director, ORIO; manningk@ohsu.edu 503-494-7887. www.ohsu.edu/xd/about/services/integrity/coi/

Where do I find the CoI disclosure? The CoI disclosure is completed within the eCoI system, which is part of Big Brain: <https://bigbrain.ohsu.edu/coi/>.

Sponsored Projects Administration (SPA) and Research Grants and Contracts (RGC)

Pre-Award and Post-Award. When a start-up founder has sponsored research at OHSU, then the founder faces potential grants management risks, particularly with government grants. Also, a founder or other OHSU employee who is funded in part by the OHSU grant can run into effort reporting and grant financing risks if part of the person's FTE is reduced to focus on the start-up's work.

Both SPA and RGC are eager to hear from you about proposed start-up research in order to help you and OHSU avoid grants management compliance pitfalls. As with the other key areas of this Guide, the best advice is to contact RGC and SPA early in your planning process before you make decisions about start-up research staffing that may turn out to be a problem for you.

Who do I contact with questions?

- Nancy Duncan, Interim Director, Sponsored Projects Administration, duncanna@ohsu.edu 503-494-3715.
- Deborah Golden-Eppelein, Director, Research Grants and Contracts. goldenep@ohsu.edu 503-494-4853.

Money Matters

OHSU accounts and start-up accounts. It is critical that start-ups not use or commingle OHSU accounts with start-up activities or planned or managed in a way that functionally views the two as a collective endeavor. The start-up needs to separately plan for, manage and pay for all its costs, personnel needs, services and supplies through its own external accounts without reference to OHSU accounts, which are available only for OHSU activities. Contact RGC or SPA with any questions.

What will it cost me to lease space and use OHSU resources? Who at OHSU sets the fees? The following offices have this information – please see their page of this Guide for more information:

- Equity share and other terms of intellectual property development and use: Technology Transfer; watsonan@ohsu.edu;
- Rental rate for space, including specific terms such as liability insurance: Campus Planning; see <http://www.ohsu.edu/xd/about/services/cpdre/space-planning/index.cfm>
- Animal related costs –
 - Central and Waterfront Campus: DCM, saunderk@ohsu.edu
 - ONPRC: Associate Director of the ONPRC, robertsc@ohsu.edu, 503-690-5259
- Research Cores – chitty@ohsu.edu, 503-494-5887
- Human Research Cores – octri@ohsu.edu
- IRB -- <http://www.ohsu.edu/research/rda/isirbfees.shtml>
- IBC -- Kara Drolet, Ph.D., [Associate Director, ORIO; manningk@ohsu.edu; 503-494-6727]
 - IBC website: <http://www.ohsu.edu/xd/research/about/integrity/ibc/index.cfm>
- IACUC:
 - Central and Waterfront Campus: Bill Dale, Ph.D., Research Integrity Officer, daleb@ohsu.edu, 503-494-7887
 - West Campus: Charles Roberts, Ph.D., Associate Director of ONPRC, robertsc@ohsu.edu, 503-690-5259

OHSU CORES Service Centers

OHSU has an innovative core resources program that provides technology partner services for research. See <http://www.ohsu.edu/cores> for information on cores:

- Advanced Computing Center - Consulting, research storage, application hosting, support for research computing systems.
- Advanced Imaging Research Center - Novel MRI, data analysis, user education.
- Advanced Light Microscopy - Access to and education on the use of advanced instrumentation for fluorescence microscopy in cells, tissues, and animals.
- Bioanalytical/Pharmacokinetics - Support and consultation for the analysis of small molecules using state-of-the-art LC-MS/MS, GC/MS, or HPLC instrumentation.
- Biomolecular Structure Laboratory - Crystallization, x-ray diffraction and computational analysis of macromolecules and complexes.
- DNA Services - Automated fluorescent "long read" capillary DNA sequence analysis, solid-phase oligonucleotide synthesis, and help with bioinformatics.
- Flow Cytometry - Cell sorting and analytical flow cytometry, data analysis, consultation, and user education and training.
- Gene Profiling - Microarrays, real-time PCR, and targeted sequencing: RNA profiling and DNA variation analysis (Affymetrix/ Illumina microarrays, RT-PCR, Ion PGM sequencing); RNA/DNA isolation and quality assessment.
- Histopathology - Collection, distribution of samples of normal and neoplastic human tissues for research specimen imbedding, sectioning, staining, and immunohistochemistry; Sequenom MassARRAY system.
- Massively Parallel Sequencing - Sample preparation and genomic scale sequencing services on the Illumina HiSeq 2000.
- Proteomics - Mass spectrometric services to allow protein identification, detection of post-translational modifications, and profiling of changes in relative protein abundance.
- Transgenic Mouse Models – Development of genetically engineered mouse models, cryopreservation, and other services.
- Virology – Production of viral vectors, virus stocks and antigens. Viral diagnostics for virus quantification and serology. User consultation and education.

Who do I contact with questions? What are the fees? Andrew Chitty, Shared Resources Program Manager, chitty@ohsu.edu, 503-494-5887 can answer questions about core resources and fees in addition to the contacts noted above for specific cores.

Human Subject Research Cores

Biostatistics & Design Program (BDP). The BDP is a resource for biostatistics collaboration and support for all types of biomedical research. The BDP can provide pre-award support (study design, protocol development, sample size and statistical analysis planning), as well as post-award support (data management, data analysis, manuscript preparation, etc). <http://www.ohsu.edu/xd/research/centers-institutes/octri/about/organizational-structure/programs/biostatistics-and-design.cfm>

Clinical and Translational Research Center (CTRC). The CTRC is a central resource for inpatient and outpatient clinical research, with facilities, expert research staff and study conduct/coordination. The CTRC can conduct research studies in its facilities, at other facilities on the OHSU campus, and off-site. The CTRC bionutrition unit can design and conduct nutrition studies, and has equipment for the measurement of body composition and energy expenditure. <http://www.ohsu.edu/xd/research/centers-institutes/octri/about/organizational-structure/programs/ctrc.cfm>

Clinical and Translational Research Center Core Lab. This lab offers research specimen collection and preparation options, biochemical assays and genetic analyses. <http://www.ohsu.edu/xd/research/centers-institutes/octri/about/organizational-structure/programs/core-lab.cfm>

Investigator Support and Integration Services (ISIS). ISIS provides expertise in preaward and regulatory services, including study budgeting, IRB preparation and submission, IND/IDE applications, and Data & Safety Monitoring Plan (DSMP)/Data & Safety Monitoring Board development and support. ISIS Navigators are available for triage and advice concerning OCTRI resources for clinical and translational research. The OHSU Clinical Trials Office is a unit in ISIS that provides study start-up services and negotiation of contracts for OHSU industry-sponsored clinical trials. <http://www.ohsu.edu/xd/research/centers-institutes/octri/about/organizational-structure/programs/investigator-support.cfm>

Research Pharmacy. The Research Pharmacy supports the conduct of human studies by maintaining control and accountability of research medication use for OHSU research subjects (e.g. storage, randomization, and dispensing). <http://www.ohsu.edu/xd/research/centers-institutes/pharmacy/>.

Clinical Trials Office (CTO). CTO, a unit within ISIS, provides study start-up services, including budget negotiation and IRB submissions, and negotiation of contracts for OHSU industry-sponsored trials. <http://www.ohsu.edu/xd/research/administration/clinical-trials-office/>

Clinical Research Informatics (CRI). CRI provides computing infrastructure and expertise in the collection and management of clinical and translational research data. CRI accesses Epic data through the Research Data Warehouse (RDW), and works with PIs and Clinical Informatics to develop research data collection strategies in Epic. CRI software engineers, analysts, and database architects provide pre- and post-award consultation, custom database software development, and REDCap data collection and management. <http://www.ohsu.edu/xd/research/centers-institutes/octri/about/organizational-structure/programs/biomedical-infomatics.cfm>

Translational Bioinformatics. Translational Bioinformatics is a core that works in a collaborative model to develop new bioinformatics biostatistical methods in genetics, proteomics and systems biology. It also provides consultation and bioinformatics expertise necessary for the conduct and analysis of “omics” experiments. <http://www.ohsu.edu/xd/research/centers-institutes/octri/about/organizational-structure/programs/biomedical-infomatics.cfm>

Is there a fee for use of these core services? Yes. The fee will depend on a number of factors, including the funding source. Get in touch with the appropriate contact noted below to discuss fees.

Who do I contact with questions? Biostatistics and Design Program: bdp@ohsu.edu; 503-418-9241.

Research Pharmacy: Phone: 503 494-6865, Fax: 503 494-1096; All others: octri@ohsu.edu 503-418-9790.

Institutional Animal Care and Use Committee (IACUC)

Is an IACUC review required for start-up projects sited at OHSU? All animal work done on OHSU premises is subject to OHSU IACUC approval in order to assure appropriate oversight of animal-related activities. The OHSU IACUC thus serves as the IACUC for start-ups located at OHSU.

Will I be charged for IACUC services, and who sets the fee? Yes. For Central and Waterfront Campus protocols, please contact the Research Integrity officer (contact information below). Fee information for west campus protocols is available from the Associate Director of the ONPRC.

What authority does the IACUC have over animal research conducted in my leased space on campus? The OHSU IACUC has the same responsibility and authority over start-ups sited at OHSU as it does over OHSU animal research.

What steps do I need to take for the OHSU IACUC to review my protocol and exercise oversight? The eIACUC form has a box for outside entities such as start-ups; you must mark this box when you submit your protocol. That box leads to the terms and conditions for a start-up to use the OHSU IACUC.

What if I have sub-contracted some work from my start-up to OHSU? Does the OHSU IACUC review that protocol? Yes, because it is then an OHSU project. RCG and SPA need to set up the usual subcontract or grant sub award documentation. The usual protocol approval process for the subcontracted work should be followed through eIACUC.

May I use a non-OHSU IACUC? Any animal research on OHSU premises must also be approved and monitored by the OHSU IACUC.

Must I obtain my own federal-wide Assurance for animal work that I conduct at OHSU? For that matter, what is a federal-wide Assurance? The Assurance is a contract with the federal government that sets out a start-up's obligations with respect to PHS-funded animal research oversight. The Assurance is managed by the NIH Office of Laboratory Animal Welfare. A start-up's grant application *might* require an Assurance number, depending on the circumstances. You can contact the relevant OHSU Research Integrity Officer to obtain basic information and ask questions; the OLAW Division of Assurances can advise whether your start-up must obtain an Assurance. Contact the Division at (301-496-7163) or e-mail (olawdoa@mail.nih.gov). See also http://grants.nih.gov/grants/olaw/obtain_assurance.htm

Who do I contact with questions?

- Central and Waterfront Campus: Bill Dale, Ph.D., Research Integrity Officer, daleb@ohsu.edu, 503-494-7887
- West Campus Fee questions: Charles Roberts, Ph.D., Associate Director of ONPRC, robertsc@ohsu.edu, 503-690-5259. Other West Campus questions: George Haluska, Ph.D., Research Integrity Officer, haluskag@ohsu.edu, 503-690-5289.

Division of Comparative Medicine for ONPRC
Department of Comparative Medicine Central and Waterfront Campuses

Are animals and animal care services being requested for start-up projects? The Division of Comparative Medicine (DCM) for the ONPRC and the Department of Comparative Medicine (DCM) for the Central and Waterfront Campuses provide professional and technical services for laboratory animal care, veterinary medical care, animal research project support, and genetically engineered model development and preservation for the OHSU research community. All animal work done on OHSU premises are subject to the oversight of the DCMs which adhere to the federal Animal Welfare Act and other applicable laws, all federal regulations on animal care and use, and the “Guide for the Care and Use of Laboratory Animals”.

May I submit a request for animal housing and care for a grant that is being carried out exclusively by my start-up? Yes, subject to personnel and animal resource availability as determined on a case-by-case basis. The start-up’s needs must be approved prior to making any assumptions about access in order to assure that animals and proper equipment, space, personnel and expertise are available.

What are the fees? Fees will be charged that recover the full cost rather than the lower, subsidized costs that are generally charged to OHSU users. Fees may include charges for daily care, caging rental, equipment rental, technical services, and/or space rental. Contact the appropriate campus office noted below for information.

What process do I follow to secure animal use and DCM services? Please make contact with the office noted below to obtain approval for the use of animals well before making any plans or assumptions about animal availability. Be sure to advise the office that the request is coming from a start-up, not from you in your role as an OHSU PI. Keep in mind that no animals can be ordered or used until an approved IACUC protocol is in place.

- **Central and Waterfront Campuses:** Contact the CWC DCM to inquire about the availability of space, caging and animal purchases and to discuss fees. All animal purchases for the central and waterfront campuses must be made through the CWC DCM Animal Purchaser.
- **ONPRC.** Contact the Associate Director of the ONPRC to initiate a request and to obtain fee information. Approval must be obtained from the ONPRC Research Advisory Committee and the Animal Utilization Committee, and an Animal Planning Form must be filed with the ONPRC DCM to initiate a facilitation meeting.

What if I have sub-contracted some research from my start-up to OHSU? Can DCM provide animal care and use services? Yes, because the project is then an OHSU project. Charges will be in accordance with current practices.

Who do I contact with questions?

- Central and Waterfront Campus: Kim Saunders, DVM, Director and Professor, Department of Comparative Medicine, saunderk@ohsu.edu, 503-494-8425.
- ONPRC: For fees and approval requirements: Charles Roberts, Ph.D., Associate Director of ONPRC, robertsc@ohsu.edu, 503-690-5259. For facilitation meetings and animal care following approval: Kerry Taylor, DVM, Chief, Division of Comparative Medicine, taylorker@ohsu.edu, 503-690-5220.

Institutional Review Board (IRB)

Is OHSU IRB review required for start-up projects sited at OHSU? Yes. If the research involves human participants (generally defined as interacting with living individuals or their private identifiable information), OHSU IRB review is required. If you have any questions about whether IRB review is required, please contact the OHSU IRB Chair (contact information below).

What if I have sub-contracted some work from my start-up to OHSU? Does the OHSU IRB review that protocol? Yes. This would be considered OHSU research and the OHSU IRB is required to review the project.

Will I be charged for IRB services? The start-up may be charged the industry fee for IRB review, depending on the funding source. See fee details at: <http://www.ohsu.edu/research/rda/isirbfees.shtml>.

Who do I contact with questions? Kathryn Schuff, MD, OHSU IRB Chair, schuffk@ohsu.edu, 503-494-1685.

Institutional Biosafety Committee

Is an Institutional Biosafety Committee (IBC) review required for start-up projects sited at OHSU?

The OHSU IBC is primarily organized to provide IBC review functions for OHSU grants. However, protocols that are submitted by start-ups in space leased at OHSU may also require OHSU IBC review if the research involves recombinant DNA, infectious agents, or certain biological toxins or synthetic nucleic acid research. See the IBC website for a description of the types of research requiring IBC review:

<http://www.ohsu.edu/xd/research/about/integrity/ibc/index.cfm>

May I submit a protocol to the IBC for a grant that is being carried out exclusively by my start-up? Yes, but the start-up must contact the IBC office to initiate submission of an IBC protocol prior to submitting a protocol for instruction on the terms and requirements for start-up submissions.

Will I be charged for IBC services? Yes, start-up companies housed on OHSU premises will be charged for IBC review and ongoing monitoring. The fee will be set by the OHSU Research Integrity/ Institutional Biosafety Committee (IBC) office. Please reference the contact information provided below prior to developing your plans or protocol submission in order to discuss and determine the applicable fee.

What authority does the IBC have over research conducted in my leased space on campus? The OHSU IBC has the same responsibility and authority over research conducted in start-up space as it does over OHSU research.

What if I have sub-contracted some work from my start-up to OHSU? Does the OHSU IBC review that protocol? Yes, and in fact OHSU IBC review is required because it is an OHSU project. The usual protocol approval process should be followed. No additional arrangement is necessary for the portion of the work conducted at OHSU through the subcontract although RCG and SPA still need to set up the usual subcontract or grant sub award documentation.

Am I required to use the OHSU IBC, or may I use a non-OHSU IBC? Any research on OHSU premises that requires IBC review must be reviewed and approved by the OHSU IBC.

Who do I contact with questions?

- Kara Drolet, Ph.D., [Associate Director, ORIO; manningk@ohsu.edu; 503-494-6727] IBC website: <http://www.ohsu.edu/xd/research/about/integrity/ibc/index.cfm>

Hazardous Substances and Waste Management

The Office of Environment Health and Radiation Services (EHRS) provides guidance and services to the OHSU community on the safe use and disposal of chemicals, biologicals, blood and other potentially infectious material, (including body fluids), radiation safety and chemical, biological and radioactive waste. A start-up is responsible for managing its substances and wastes. EHRS does not provide services to the start-ups, with the exception of those services related to proper handling of biological hazards overseen by the Institutional Biosafety Committee (IBC) and other services that may be required for enrollment in the Occupational Health program. Please check those pages of this guide for information on IBC and Occupational Health oversight.

The following additional guidance is provided to start-ups that are sited at OHSU:

Compliance with Safety Regulations. Any start-up operation that includes hazardous substances (chemical, biological, radiological, compressed gases, etc.) must be compliant with all applicable regulatory agencies, such as Oregon Occupational Safety and Health Agency (OR-OSHA) the City of Portland (particularly the Fire Code), Oregon Department of Transportation (OR-DOT) Oregon Department of Environmental Quality (DEQ) and the U.S. Centers for Disease Control (CDC), and must ensure the safety and health of all OHSU employees, visitors, patients and other individuals interacting with the start-up. Appropriate design plans for processes performed (which may include air flow, ventilation, sound mitigation, odor control, etc.) shall be taken into consideration by the start-up and planned for prior to its occupation of OHSU space.

Waste handling. OHSU does not provide hazardous waste disposal services for start-ups who lease OHSU space. It is the responsibility of the start-up to contract with the appropriate outside vendor(s) to provide needed services. Coordination with Facilities and Real Estate (F&RE) is essential to ensure property access control, parking, dock scheduling, etc. for the vendor while on campus.

Emergencies. Start-ups are responsible for spills, clean-up and all emergencies, but OHSU may also step in to address emergency situations with the cost billed to the start-up. Start-ups need to follow OHSU's emergency response procedures for chemical or other hazardous spills, including related medical emergencies for personnel. See <https://o2.ohsu.edu/emergency-management> for OHSU emergency response procedures.

Who do I contact with questions?

- EHRS: John Burnham, Ph.D., Director of Environmental Health and Radiation Safety, burnhamj@ohsu.edu. West campus EHRS telephone: 503-690-5390. Central and waterfront Campus telephone 503-494-7795.
- IBC/Research Safety: Kara Drolet, Ph.D., Associate Director, ORIO; manningk@ohsu.edu; 503-494-6727.
- Occupational Health: Central and Waterfront Campus: Shirley Manning, CMA, Employee Health, mannings@ohsu.edu, 503-494-6628.

Occupational Health

OHSU expects all individuals – even non-OHSU employees -- who work with animals, or animal or human blood or tissue of any type, or enter areas that have animals (including animals in laboratories or animal housing) to be enrolled in the OHSU Occupational Health program. This policy is in addition to the expectations of the *Guide for the Care and Use of Laboratory Animals*, which directs that all individuals who are exposed to blood and tissue of macaques need to have access to emergency information in the event of scratches that may expose the person to the Macacine herpes virus. Please be sure that any start-up employee contacts Occupational Health for guidance on enrollment.

In the event of chemical or other hazardous spills, including related medical emergencies for personnel, the start-up needs to follow OHSU's emergency response procedures. See <https://o2.ohsu.edu/emergency-management>. See also the page of this Guide on “Hazardous Substances and Waste Management”.

Who do I contact with questions on Occupational Health?

- Central and Waterfront Campus: Shirley Manning, CMA, Employee Health, mannings@ohsu.edu, 503-494-6628
- West Campus: Sara Eide, RN, Occupational Health, eides@ohsu.edu, 503-629-4031