

Today's Presenters

- Peter Barr-Gillespie, Ph.D., Executive Vice President and Chief Research Officer, OHSU Research & Innovation and Dana Director, Ph.D., VP Research Administration
- Cynthia Morris, Ph.D., M.P.H., Director, Oregon Clinical and Translational Research Institute
- Paul Newton, J.D., Director, Human Research Protection Program; IRB Chair
- Sonnet Jonker, Ph.D., FAPS, Professor of Medicine, Division of Cardiovascular Medicine



Research Development & Administration



Overview

 Introduction to Research Administration and partners

• Q & A



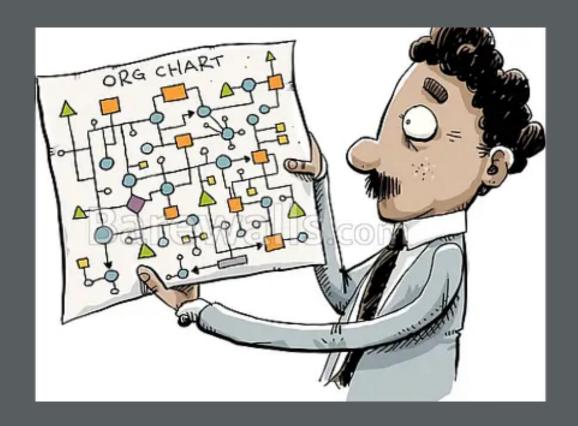
Dana Director, PhD, VP Research Administration Peter Barr-Gillespie, PhD, Chief Research Officer & Executive VP

> "RDA" is the hub for management of OHSU research projects.





Who or what is "RDA" and where does it live at OHSU?





unofficial

President **unofficial** OCIC

Equity & Inclusion

Provost

SOM Dean

Chief Research Officer

CEO Healthcare

OHSU Foundation

HR

CFO

CAO

General Counsel

Deans: SON

SOD SOPH

COP

Rural Health **Programs** Plan

Academic Affairs

Faculty Affairs

Student Affairs

Student Life

Student Health & Wellness

Educational Improvement & **Evaluation**

Library

Registrar

International **Affairs**

Basic Science Depts

Clinical Depts

OHSU Practice

Medical **Education &** Graduate Studies **Programs** (Graduate Program in Biomedical Sciences -

Knight Cancer Institute

PBMS)

Knight Cardiovascular Institute

> Divisions/ Programs/ Centers

Research Institutes: ONPRC; VGTI;

OIOHS; Vollum;

CECGT; OCRM

AIRC; OCTRI

Research Development

Research Administration (OPAM, CRSO, BSG)

Research Integrity

Export Controls

OHSU Innovates

Postdoctoral Affairs

Comparative Medicine/AVs

Diversity In Research

University Shared Resources

RAPP

Health System and Hospitals: **OHSU Hospital** Doernbecher **Kohler Pavilion**

> Ambulatory Clinics

Affiliates (Adventist, HMC, MCMC, etc.)

Food & Nutrition Services, inc. **Farmers Market**

Patient Safety & Quality Management

Occupational Health

Infection Prevention & Control

So much more!

All philanthropy associated with Doernbecher

501(c)(3) arm of OHSU

OHSU and

Donations

Gifts

Private Foundations

President's List

Talent **Acquisition &** Management

Total Rewards

Employee & Labor Relations

Healthcare HR

HRBPs

Employee Wellness

HRIS

Advice & **Council Center**

Diversity, Equity, Inclusion, & Belonging

Information **Technology Group**

Central Financial Services:

Accounts Payable Accounts Receivable Payroll

Risk Management

Purchasing

Campus Services

Facilities

Parking & **Transportation**

Environmental Health & Safety

Public Safety

Campus Planning Design & Construction

Real Estate

Logistics

President's Chief of Staff

Government Relations (Federal, State, Local)

> Community Relations

Public Affairs

Strategic Commumications

Brand Strategy

Legal Counsel, Strategy, and Services

OHSU Policies

Audit & Advisorv Services

Corporate & Clinical Integrity

> Code of Conduct

Public Records Request Management



OHSU Research & Innovation Overview

Chief Research Officer

Research Development

Research Administration (OPAM, CRSO, BSG)

Research Integrity

Export Controls

OHSU Innovates

Postdoctoral Affairs

Comparative Medicine/AVs

Diversity In Research

University Shared Resources

RAPP

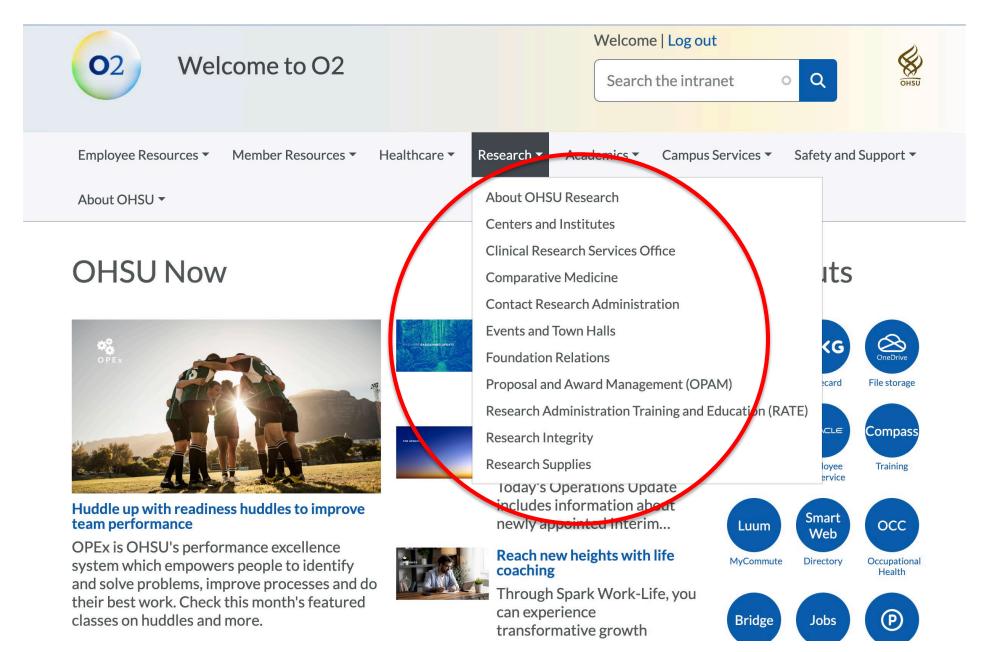
Recent changes:

- Export Controls moved from Provost's Office to Research Integrity
- New *Industry Research* Agreements team:

Consolidating contracting and agreements teams from CTO and TT to form new cohesive group



Central Research Administration on o2:



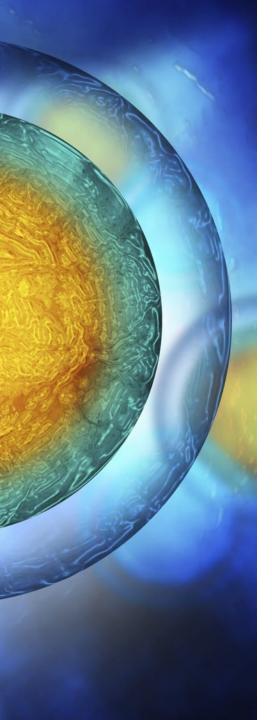




Office of Proposal & Award Management (OPAM):

- The central OHSU office that oversees all sponsored projects
- All grants and contracts are channeled through OPAM for compliance and fiscal oversight - Institutional delegated signature authority
- Pre- and Post- award systems (InfoEd and OGA)
- Training and education





Clinical Research Services (CRSO):

- Clinical Research Billing Office
- Clinical Trials Management Systems (eCRIS and OnCore)
- ClinicalTrials.gov
- Training and education





Research Integrity (ORIO):

- Institutional Review Board(s) IRB
- Institutional Animal Care & Use Committee(s)
 - IACUC
- Institutional Biosafety Committee IBC
- Conflict of Interest in Research ColR
- All integrity systems (eIRB, eIACUC, eIBC, eCOI
- Training and education





University Shared Resources (USR):

- Your campus technology partners providing stateof-the-art scientific resources
- Advanced Computing, Imaging, light microscopy
- Bioanalytics, biostatistics, bioinformatics
- Flow cytometry
- Proteomics
- More



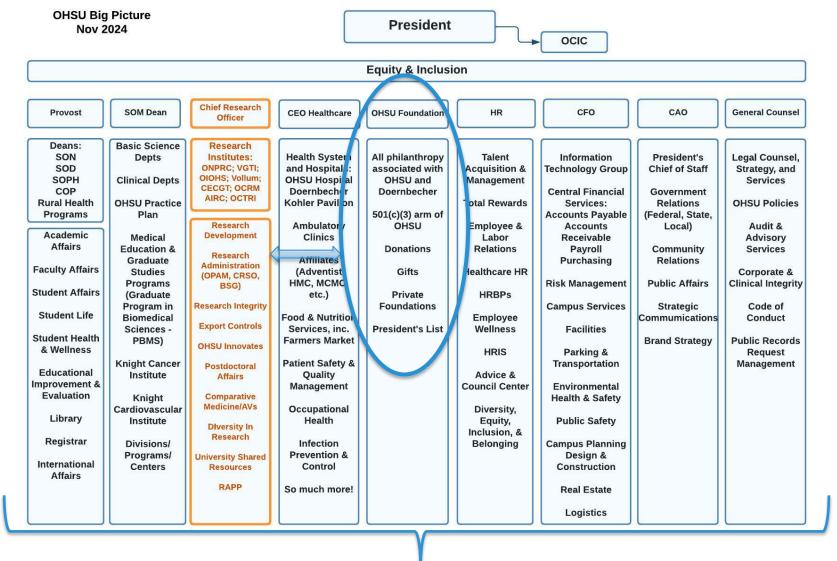


OHSU Innovates

- Technology Transfer services
 - Licensing
 - Patenting
 - Intellectual property
- Collaborations & Entrepreneurship
 - Developing partnerships
 - Helping PIs develop start-ups
 - Entrepreneurial education programs

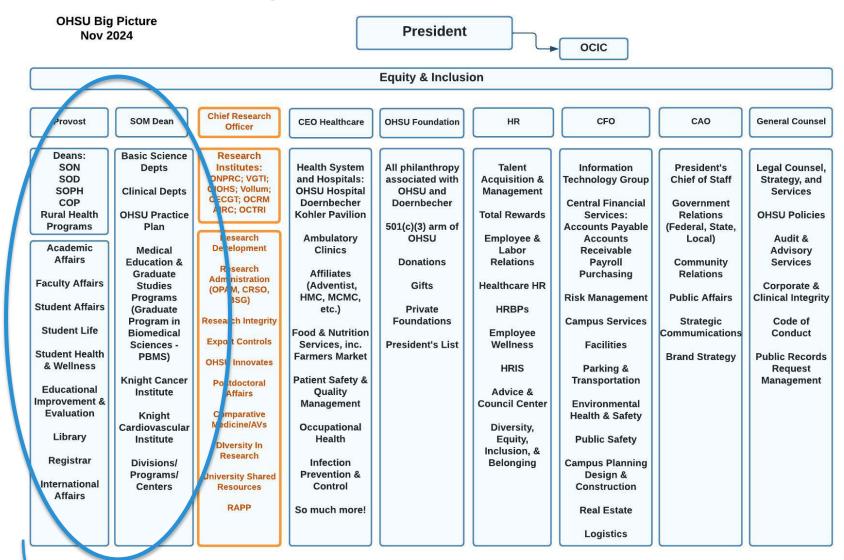


We're all in this together... OHSU Foundation



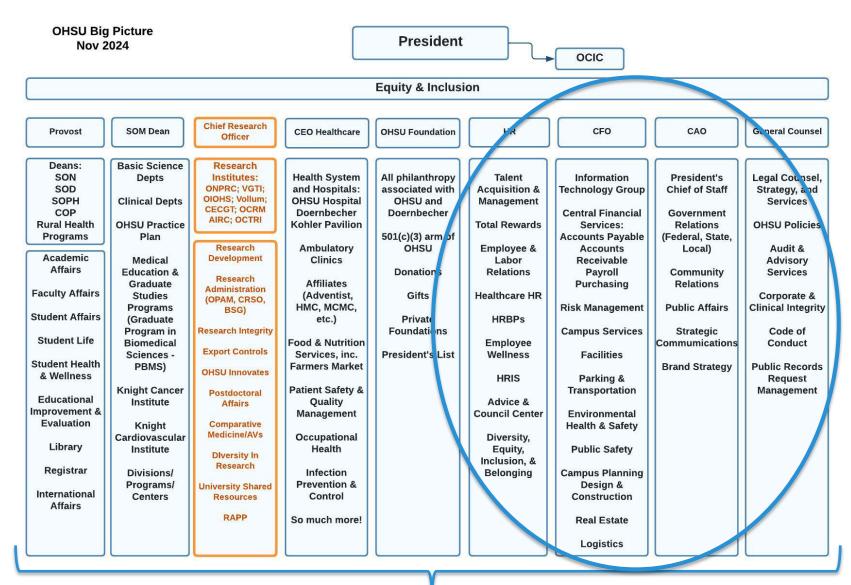


We're all in this together... partners across OHSU



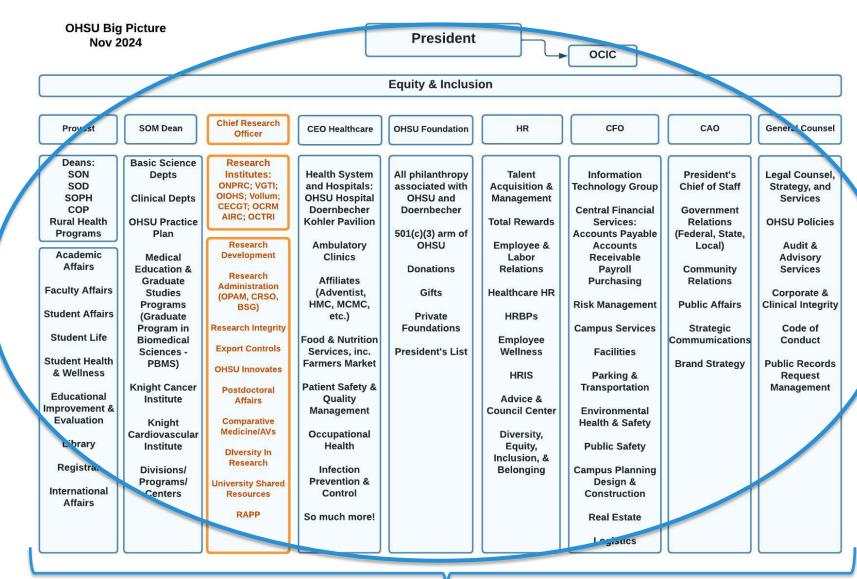


We're all in this together...central services

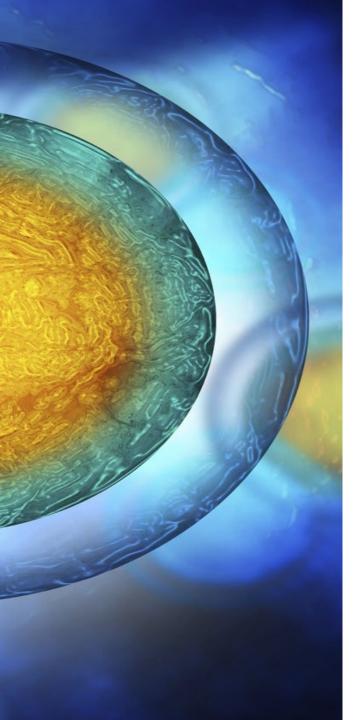




We're all in this together...







Staying connected

- Research Town Halls
- Weekly admin huddles
- Monthly large format RAIN meetings
- Clinical Research Coffee Chats
- Advisory groups (staff and faculty)
- Research Administration Training & Education (RATE) program
- Take it on the road...
 - Faculty or department meetings
 - Participate in dept. research workshops





Questions & Discussion

Oregon Clinical & Translational Research Institute

OCTRI

"Oak Tree"



60+ hubs!

OCTRI = CTSA Clinical & Translational ® Science Awards

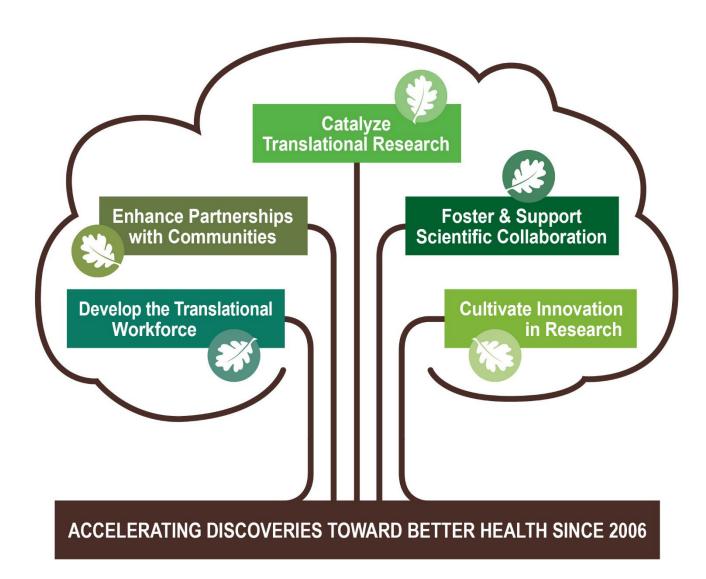
What are CTSAs?

National network of medical research institutions — called hubs — working together to improve the translational research process to get more treatments to more patients more quickly.

Where are the hubs?



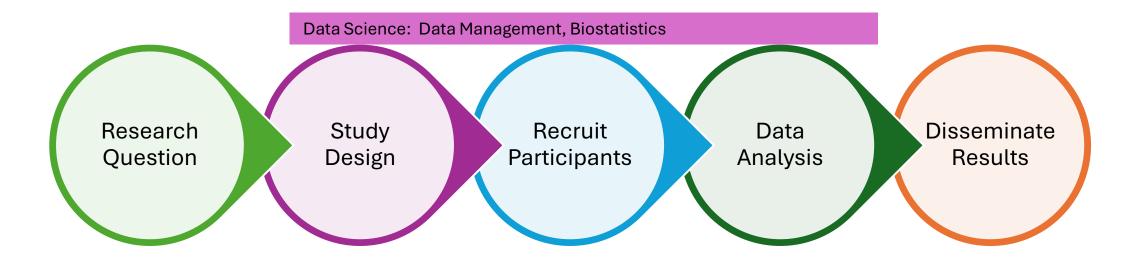
What is OCTRI?



How OCTRI builds research

Community Engagement

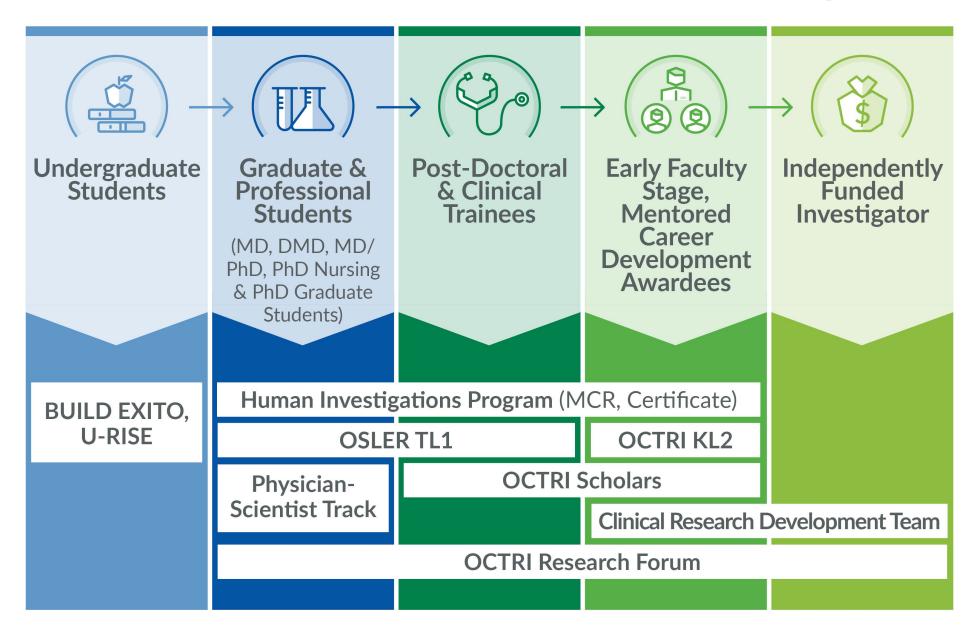
Community Engagement



Workforce Development Clinical Research Development Team: Recruitment, regulatory, CTRC

Entrepreneurship. Pilot award, program evaluation,xx

Translational Workforce Development





Training Researchers: Human Investigations Program

- The core of career development since 2001
- >1400 individual students have enrolled, ~55 per year
- 25% faculty, 45% fellows or senior residents, 26% graduate or medical students, 4% community
- Online synchronous hybrid curriculum, some in-person sessions
- Initial introduction to translational science
- Offer Master of Clinical Research, Certificate, and individual courses



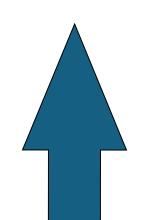
Training Researchers: Human Investigations Program

Key Course Initiatives

- Grant writing
- Data science
- Clinical research design
- Academic leadership
- Communication for team science
- Advanced biostatistics

- Dissemination & Implementation Science
- Scientific writing and data presentation
- Clinical trials
- Community engagement

Clinical Research Education at OHSU



Master of Clinical Research

- Certificate program, typically 2-3 years
- Education to master competencies of clinical research plus additional training in specific interests
- Mentored capstone

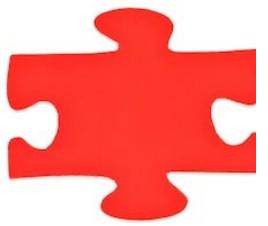
Certificate in Human Investigations

- Required didactic coursework (2 years)
- Focused education to acquire competencies of clinical research
- Mentored capstone

Non-degree

 Attend course(s) a la carte to acquire specific skill or knowledge





Building Research: From Knowledge to Practice

- Support to develop grants
- Practical skill building workshops, seminars
- Clinical Research Development Team (CRDT) can help develop a feasible, fundable proposal
- Outcomes: Of all CDA awards since 2007, 78% have moved to an NIH RPG or equivalent, 65% have NIH R01 or equivalent

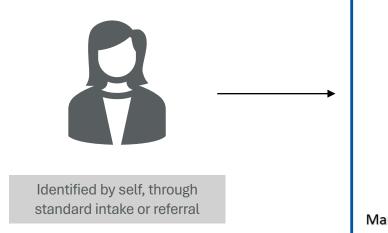
There are things that we know we don't know...There are things we don't know we don't know. Donald Rumsfeld

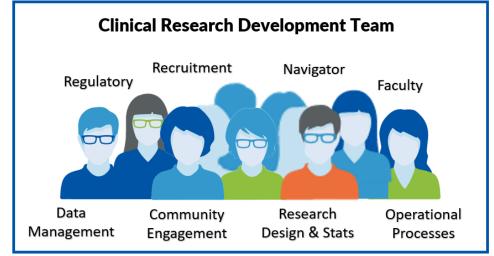
Clinical Research Development Team

1. Investigator with grant idea or protocol to implement

3. Written output to guide investigator to next steps

2. Meet with CRDT for coordinated advice and guidance





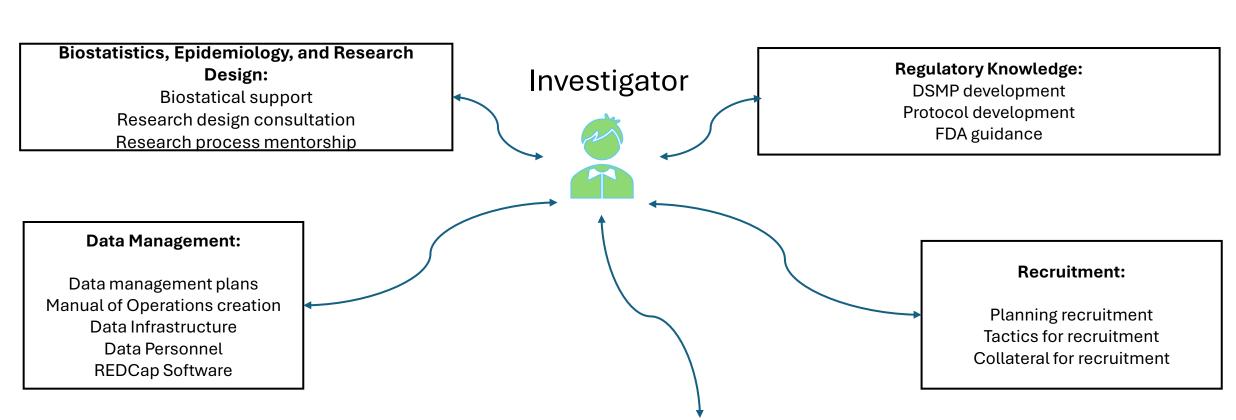
Optimized Research

- Inclusive
- Reach
- Efficient



Note: CRDT is the biggest version of this type of quality input we provide, but there are other variations

Optimization through OCTRI



Clinical and Translational Research Center:

Participant interactions
Research Implementation
Clinical Infrastructure
Personnel

And others not highlighted here....

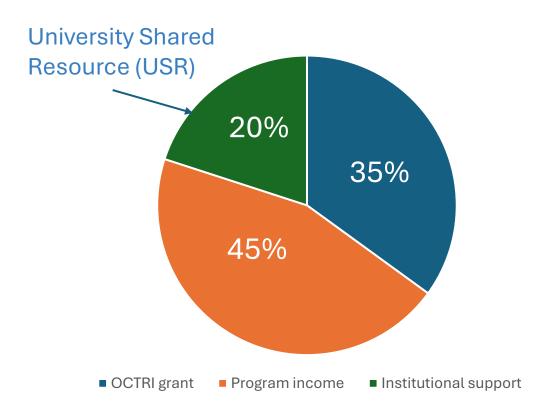
Statewide reach of OCTRI programs, partners, and community coalitions



OCTRI Clinical and Translational Research Center (CTRC)

- Physical facilities: inpatient unit, infusion area, outpatient clinic, laboratory, metabolic kitchen, body composition and energy expenditure facilities
- Over 40 experienced research staff
- Supports patient-oriented research protocols from all disciplines
 - Intensive phenotyping
 - Experimental therapeutics
 - PK sampling
 - Sleep and circadian rhythm studies
 - Bionutrition and metabolic studies

\$2.6M annual operating budget:



OHSU Innovates

Intellectual Property
Protection and Transactions

Collaboration Management





Technology Funding

New Ventures

Entrepreneurial Education







Research Data Service Overview

- One stop solution
 Research governance,
 Clinical Data
 knowledge and data mana
 gement and delivery
- Develop Data Sets and Data Marts to meet custom research needs
- OHA Death Data
- Affiliate Data



4 Analysts



8 Engineers



100 new studies annually



40 Research Repositories



5 National Studies



OMOP CDM



I2B2 Self Service



PCORNET CDM



*TriNetX for self-service data delivery

How to get started



Contact an OCTRI Navigator to connect with research resources 503-418-9790 octri@ohsu.edu

OHSU IRB

IRB members review human subjects research proposals to ensure that research conducted at OHSU is safe and ethical for participants:

- Staff of about 20 Chair, Vice Chairs, Managers, Specialist and Analysts
- Four Committees
- Ethical, legal, scientific, regulatory, institutional requirements are addressed

Board discussions are focused on making sure the procedures and study design meet ethical and regulatory criteria, which generally includes:

- Sound and reasonable research design
- Minimized and reasonable risks to subjects
- Equitable selection of subjects
- Appropriately obtaining or waiving informed consent (and documentation)
- Confirming there is a plan for monitoring data and safety
- Verifying that participant's privacy and confidentiality are protected
- Additional safeguards are in place for vulnerable populations or participants
- OHSU institutional policies are followed
- Novel ethical questions are addressed and resolved

For more information, please contact <u>irb@ohsu.edu</u>.

Animal Research at OHSU

Sonnet Jonker, IACUC Chair November 11, 2024

Regulatory oversight

USDA

- Animal Welfare Act (1966)
- Title 9 of the Code of Federal Regulations (Final Rule, 1989)
 - Unannounced inspections by the USDA/APHIS/AC at least annually

NIH Office of Laboratory Animal Welfare

- Health Research Extension Act of 1985
- US Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training (1985)
- Public Health Service (PHS) Policy (1986)
 - Incidents reported

Standards for animal use

- The Guide for the Care and Use of Laboratory Animals (1956), (8th Edition, 2011)
- Guide for the Care and Use of Agricultural Animals in Research and Teaching (1988), (4th Edition, 2020)
- American Veterinary Medical Association Guidelines for the Euthanasia of Animals (1963), (9th Edition, 2020)
- Accreditation through AAALAC, International a third party, nonprofit organization conducting peer reviews of animal care programs

Institutional Animal Care and Use Committee (IACUC)

- Reviews animal study proposals
- Inspects facilities where animal are housed and used
- Investigates concerns of animal welfare and animal treatment
- Fvaluates the OHSU program for animal care and use
- Reports to the Institutional Official
- Reports to the USDA (AWA) and PHS (OLAW)

IACUC versus DCM

- Office of Research Integrity
 - ■IACUC Office
 - ■Runs the day-to-day logistics of animal use oversight.
 - **■**IACUC Committee
 - Meets monthly and has regulatory authority.
- Department of Comparative Medicine
 - Veterinarians, veterinary technicians and staff that take care of your animals every day.

IACUC Office



Kaetlin Merriman IACUC Director



Sabiha Al-Dhalimy Integrity analyst "iacuc@ohsu.edu"



Joan Phillips
Research integrity Specialist
OPAM and inspection
outreach

Research Integrity Specialists (protocol pre-review)

Emily Philipp-Petrick



Dreeanna Morris











Elizabeth Sweeney

IACUC Committee

Members

- Jared Fischer, Vice Chair, Knight Cancer
- Sonnet Jonker, Chair, Cardiology
- Jennifer Kopanke, Comparative Medicine
- Alina Maloyan, Cardiology
- Kaetlin Merriman, Vice Chair, Office of Research Integrity
- Suzanne Mitchell, Behavioral Neuroscience
- Tim Nice, Molecular Microbiology and Immunology
- Kimberly Ray, Office of Research Integrity
- Kim Saunders, Comparative Medicine
- Karen Schnoll, Community Member
- Joseph Sciurba, Comparative Medicine
- Haining Zhong, Vollum

Alternates

- Debra Brickey, Environmental Health and Safety
- Ryan Cornelius, Nephrology & Hypertension
- Todd Graham, Dotter/Interventional Radiology
- Joan Phillips, Office of Research Integrity
- Dustin Webster-Wharton, Community Member
- Shelley Winn, Molecular and Medical Genetics

02

Welcome to O2

Welcome | Log c

Search the int

Employee Resources ▼

Member Resources ▼

Healthcare ▼

Research *

Academics ▼

Campus Services ▼

Saf

OHSU Now





Events and Town Halls

Comparative Medicine

About OHSU Research

Centers and Institutes

Clinical Research Services Office

Contact Research Administration

Foundation Relations

Proposal and Award Management (OPAM)

Research Administration Training and Education (RATE)

Research Integrity

Research Supplies

COMPAGE EVICT



Research Integrity

Welcome | Log c

Search the int

Employee Resources ▼

Member Resources ▼

Healthcare ▼

Research -

Academics ▼

Campus Services ▼

Saf

Home / Research Integrity

Institutional Animal Care and Use Committee

Institutional Review Board

Institutional Biosafety
Committee

CITI Program

Conflict of Interact

Research Integrity

What information are you looking for?

Find out what resources are available to you, and learn about approvals required based upon the type of research you do. Other resources are

Home / Research Integrity / Institutional Animal Care and Use Committee

Institutional Animal Care and Use Committee >

Getting Started: Institutional Animal Care and Use Committee Protocols

elACUC Guidance
Documents

Institutional Animal Care and Use Committee Review Process Frequently Asked Questions

Institutional Animal Care and Use Committee Policy
Comment

Institutional Review Board

Institutional Animal Care and Use Committee

The OHSU Institutional Animal Care and Use Committee reviews, approves and oversees biomedical research involving animal subjects. Our overarching goals include ensuring that laboratory animals at OHSU receive the highest quality care and protecting the health and safety of people who work with and around animals. We believe that excellence in research and teaching requires excellence in our animal care and use program.

If you have questions about veterinary or animal husbandry care, find your contact by location

Marquam Hill and South Waterfront Campuses: contact the

Research Integrity systems











Helpful links

 Department of Comparative Medicine - For Marquam Hill

Department of Compositive Medicine

and Cauth Matarfrant

- Lots of trainings necessary
- Policies available from O2 site
- Standard procedures available from within elACUC
- Everyone gets mad at eIACUC
- After you manage to submit your protocol you may be asked to make many large or small changes by up to 4 different sets of people
 - Pre-review
 - **EHS**
 - Veterinarians
 - IACUC committee

- Describe everything the animal will experience from start to finish
- Use complete grammatical sentences and define abbreviations
- A flow chart can be helpful
- For the sake of your science:
 - Stay up to date on refinements in the field
 - Know when a particular experimental detail is necessary, and be prepared to explain the scientific reason
- Describe all possible adverse outcomes from interventions, genotypes, etc to avoid reportable "unanticipated outcomes"