



# New Faculty Foundation: Building for Success

## Diving deeper into your faculty role

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November 11, 2024

# 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





# RDA 101F

## Introduction to Research Development & Administration for Faculty

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OHSU Research & Innovation  
Research Development & Administration



# Overview

- Introduction to Research Administration and partners
- Q & A

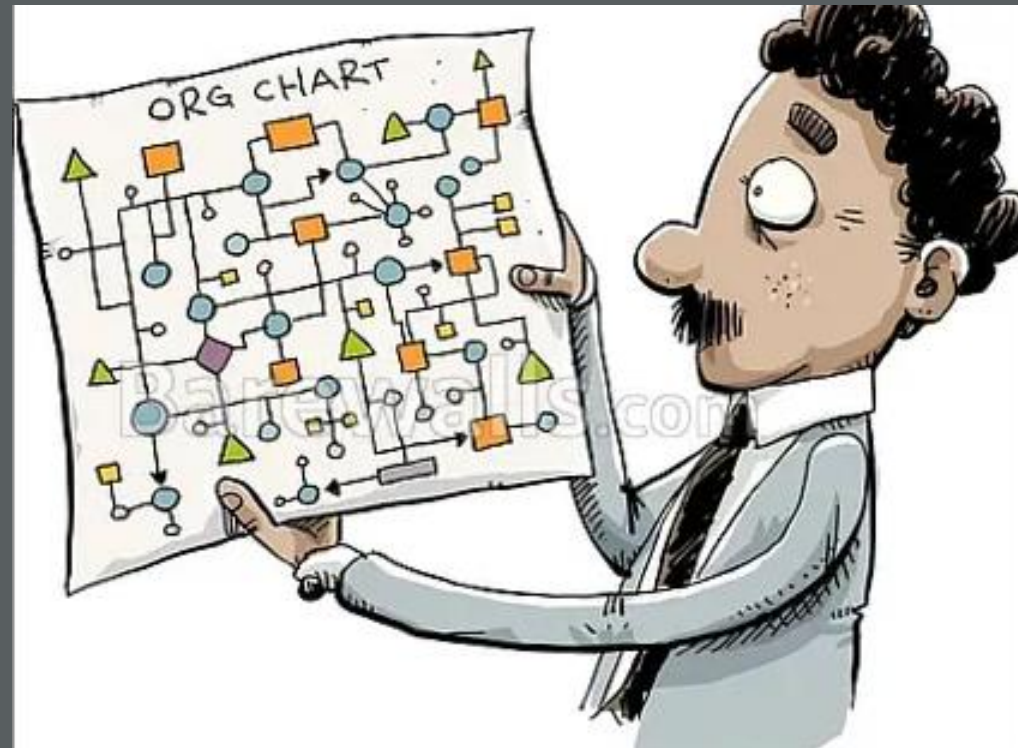


Dana Director, PhD, VP Research Administration  
Peter Barr-Gillespie, PhD, Chief Research Officer &  
Executive VP

“RDA” is the hub for  
management of OHSU  
research projects.



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



**\*\*unofficial\*\***

**President**

**OCIC**

**\*\*unofficial\*\***

**Equity & Inclusion**

Provost	SOM Dean	Chief Research Officer	CEO Healthcare	OHSU Foundation	HR	CFO	CAO	General Counsel
<b>Deans:</b> SON SOD SOPH COP Rural Health Programs	<b>Basic Science Depts</b>  <b>Clinical Depts</b>  OHSU Practice Plan	<b>Research Institutes:</b> ONPRC; VGTI; OIOHS; Vollum; CECGT; OCRM AIRC; OCTRI	<b>Health System and Hospitals:</b> OHSU Hospital Doernbecher Kohler Pavilion	All philanthropy associated with OHSU and Doernbecher  501(c)(3) arm of OHSU  Donations  Gifts  Private Foundations  President's List	<b>Talent Acquisition &amp; Management</b>  Total Rewards  Employee & Labor Relations  Healthcare HR  HRBPs  Employee Wellness  HRIS  Advice & Council Center  Diversity, Equity, Inclusion, & Belonging	<b>Information Technology Group</b>  Central Financial Services: Accounts Payable Accounts Receivable Payroll Purchasing  Risk Management  Campus Services  Facilities  Parking & Transportation  Environmental Health & Safety  Public Safety  Campus Planning Design & Construction  Real Estate  Logistics	<b>President's Chief of Staff</b>  Government Relations (Federal, State, Local)  Community Relations  Public Affairs  Strategic Communications  Brand Strategy	<b>Legal Counsel, Strategy, and Services</b>  OHSU Policies  Audit & Advisory Services  Corporate & Clinical Integrity  Code of Conduct  Public Records Request Management
Academic Affairs  Faculty Affairs  Student Affairs  Student Life  Student Health & Wellness  Educational Improvement & Evaluation  Library  Registrar  International Affairs	<b>Medical Education &amp; Graduate Studies Programs (Graduate Program in Biomedical Sciences - PBMS)</b>  Knight Cancer Institute  Knight Cardiovascular Institute  Divisions/Programs/Centers	<b>Research Development</b>  <b>Research Administration (OPAM, CRSO, BSG)</b>  <b>Research Integrity</b>  <b>Export Controls</b>  <b>OHSU Innovates</b>  <b>Postdoctoral Affairs</b>  <b>Comparative Medicine/AVs</b>  <b>Diversity In Research</b>  <b>University Shared Resources</b>  <b>RAPP</b>	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!					

# 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:



Welcome to O2


Welcome | [Log out](#)



[Employee Resources](#) [Member Resources](#) [Healthcare](#) **[Research](#)** [Academics](#) [Campus Services](#) [Safety and Support](#)

[About OHSU](#)

## OHSU Now



**Huddle up with readiness huddles to improve team performance**



OPEX is OHSU's performance excellence system which empowers people to identify and solve problems, improve processes and do their best work. Check this month's featured classes on huddles and more.

- About OHSU Research
- Centers and Institutes
- Clinical Research Services Office
- Comparative Medicine
- Contact Research Administration
- Events and Town Halls
- Foundation Relations
- Proposal and Award Management (OPAM)
- Research Administration Training and Education (RATE)
- Research Integrity
- Research Supplies



Today's Operations Update includes information about newly appointed Interim...

**Reach new heights with life coaching**




Through Spark Work-Life, you can experience transformative growth






ecard File storage




Employee service Training



MyCommute Directory Occupational Health







# 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 - CoIR
- All integrity systems (eIRB, eIACUC, eIBC, eCOI)
- Training and education



# University Shared Resources (USR):

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

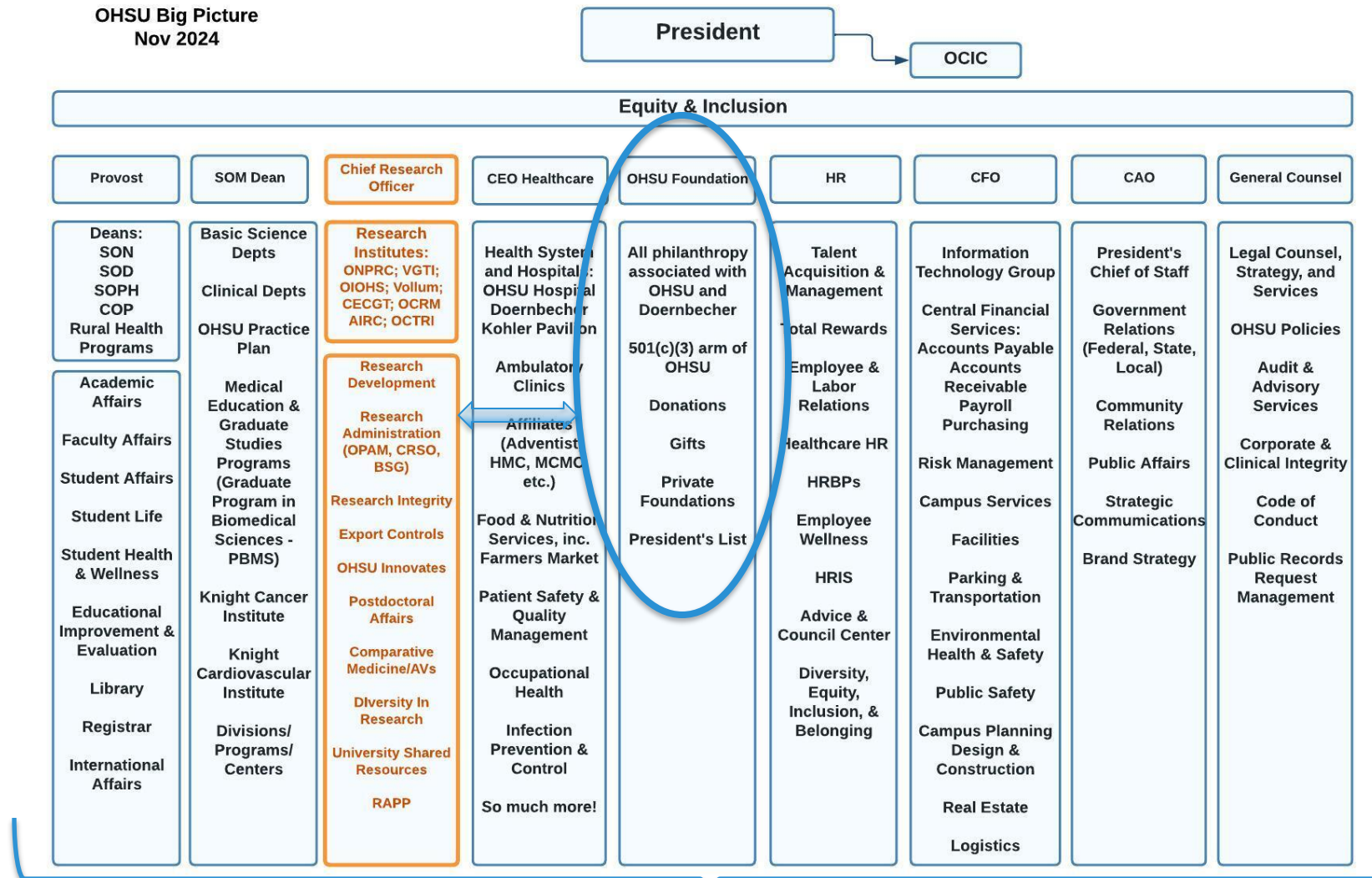


# OHSU Innovates

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



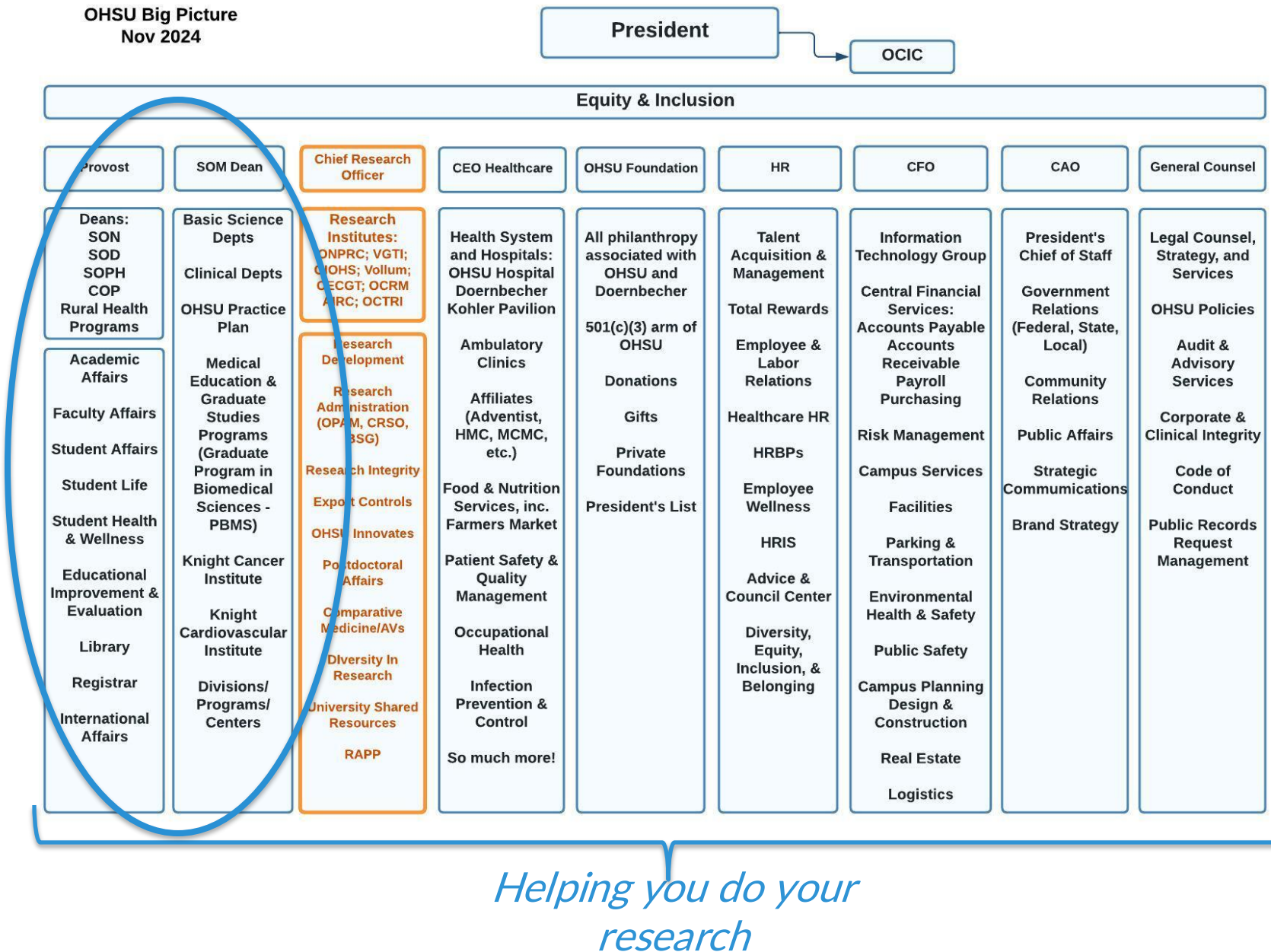
# We're all in this together... OHSU Foundation



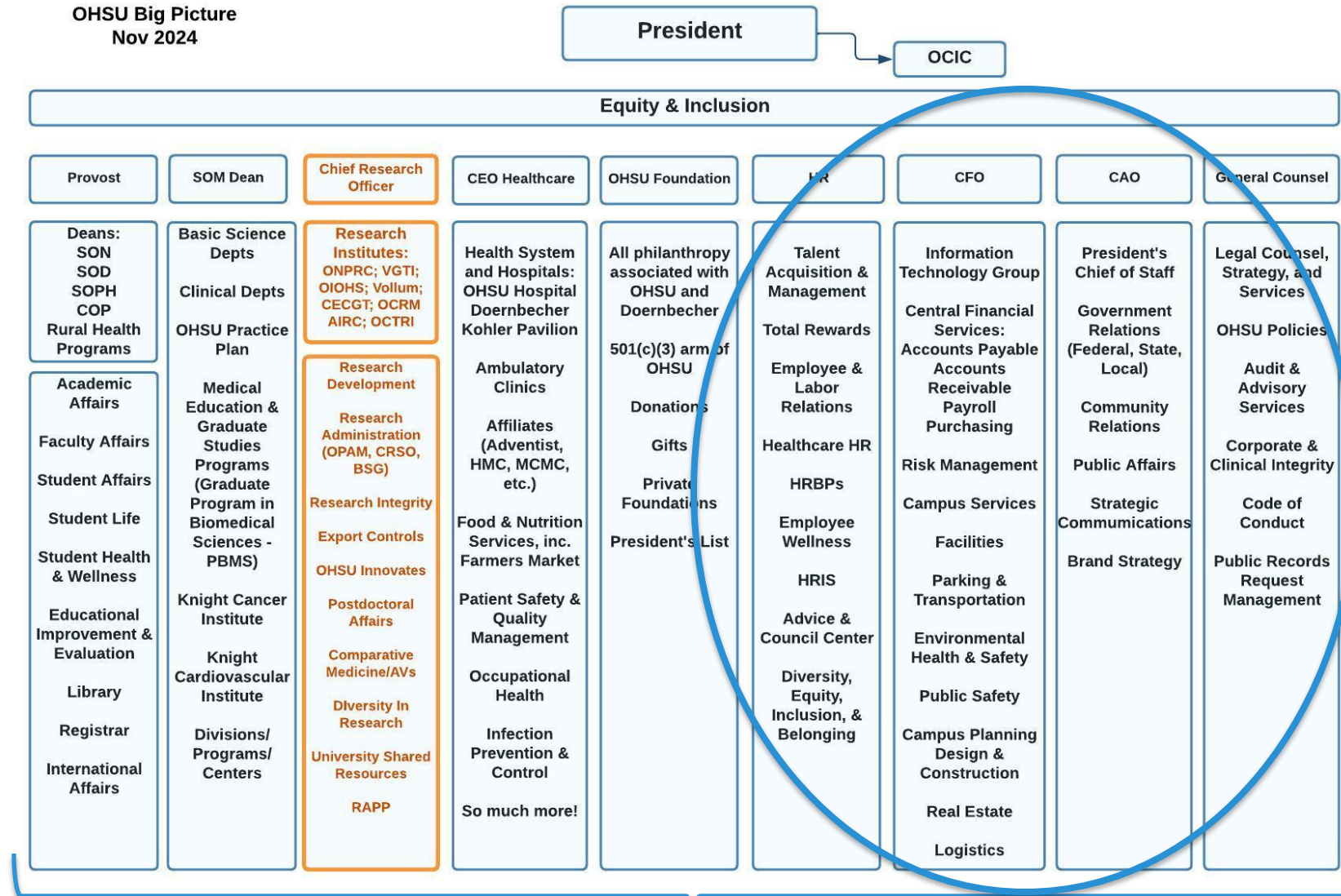
*Helping you do your  
research*



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



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

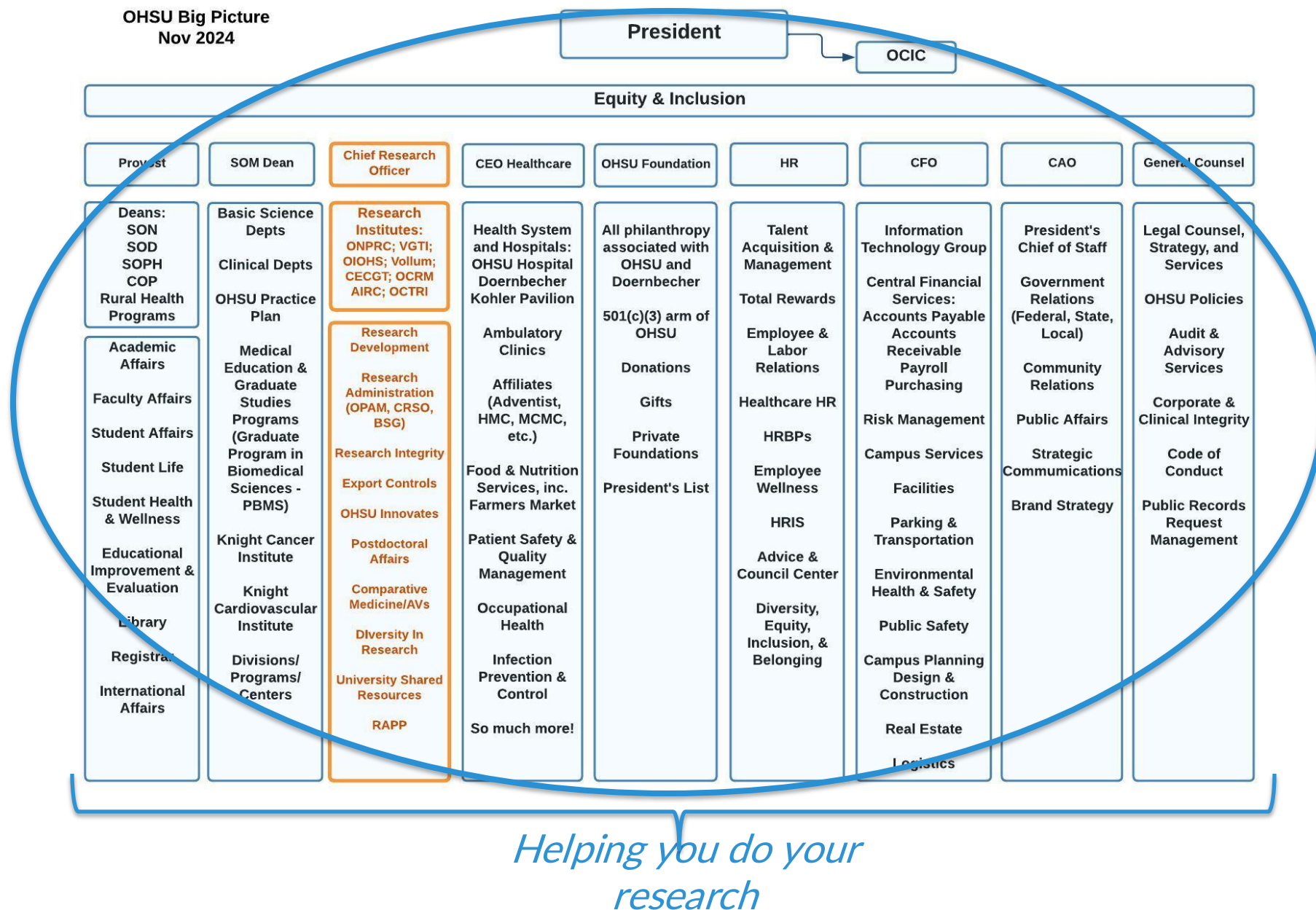


*Helping you do your  
research*





# 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

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## OCTRI

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## “Oak Tree”



**60+ hubs!**

# OCTRI = CTSA Clinical & Translational Science Awards<sup>®</sup>

## What are CTSAs?

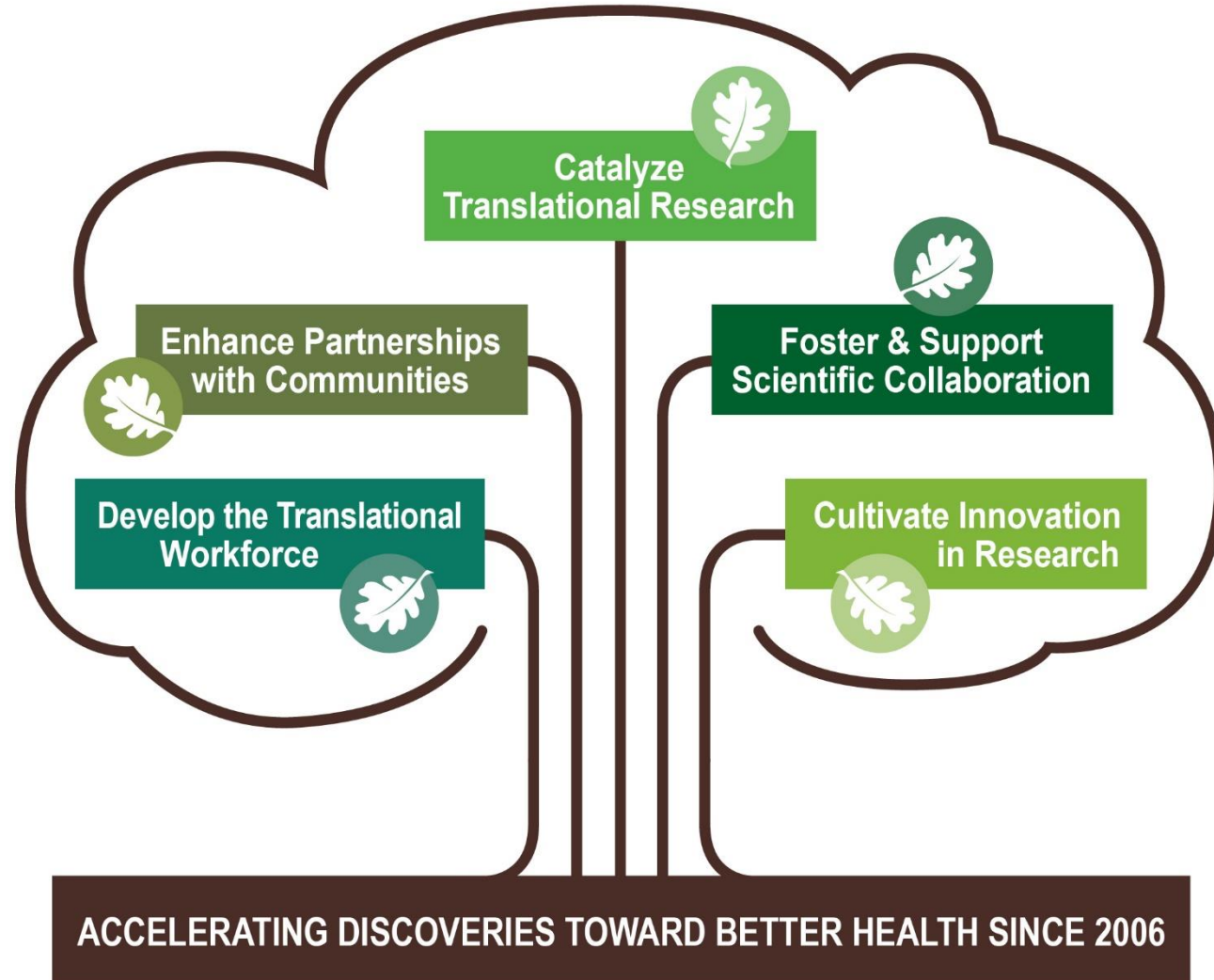
National network of medical research institutions — called hubs — working together to improve the translational research process to *get more treatments to more patients more quickly.*

## Where are the hubs?

### CTSA Hubs

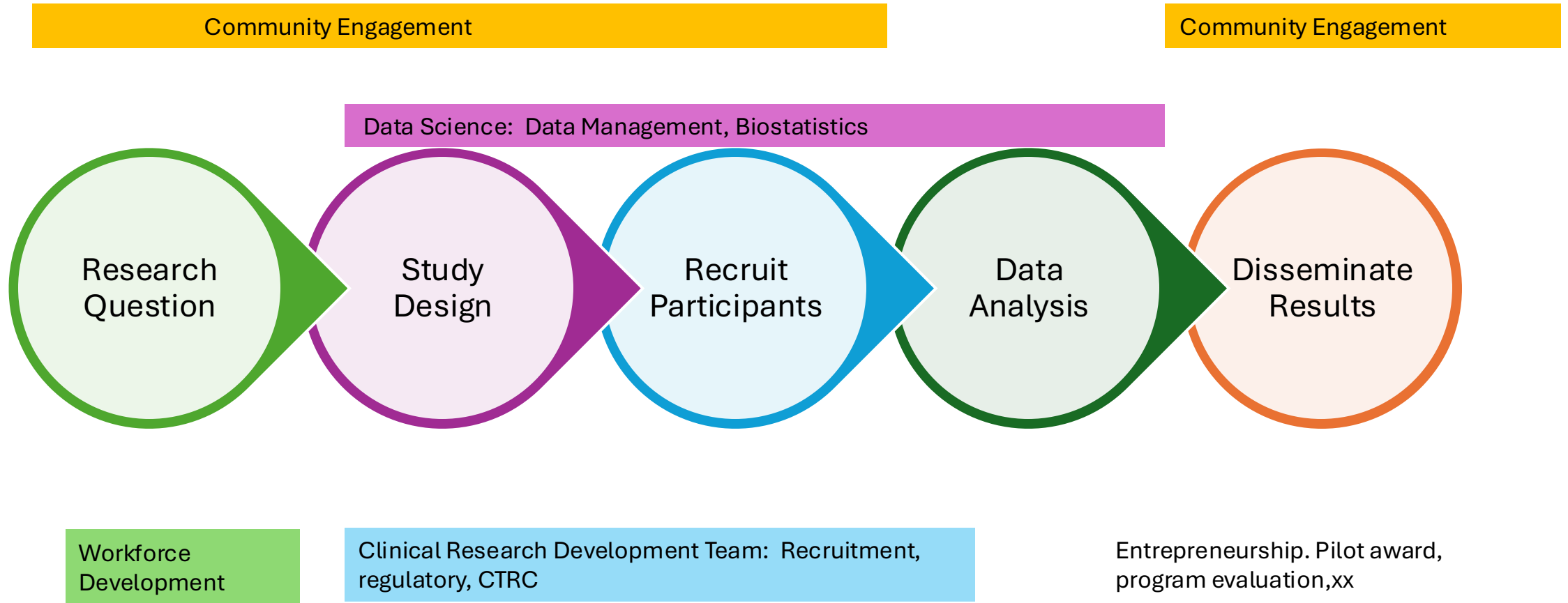


# What is OCTRI?

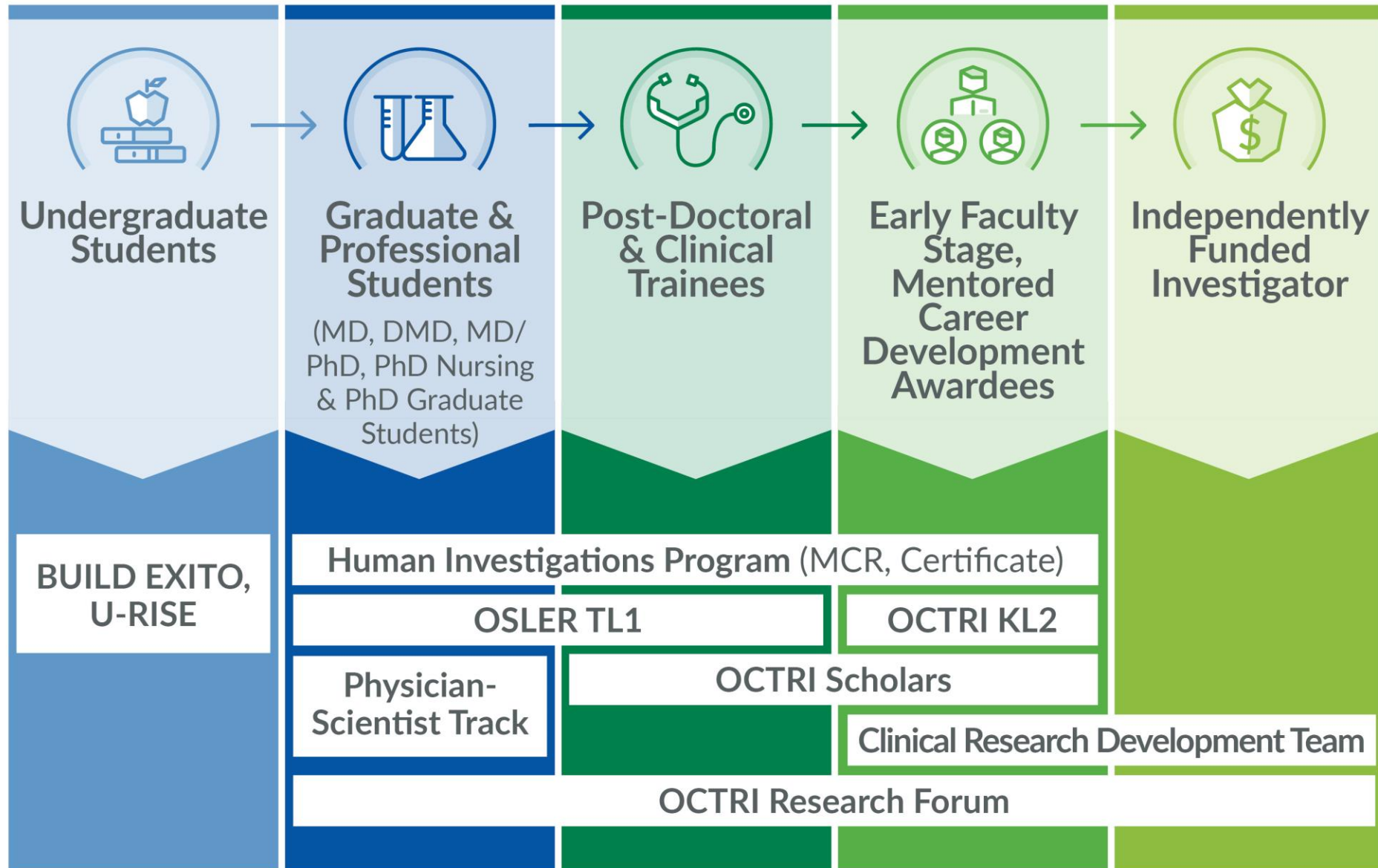




# How OCTRI builds research



# Translational Workforce Development



An illustration on the left side of the slide shows two hands placing puzzle pieces. One hand is at the top, placing a yellow piece into a gap between a green piece on the left and another yellow piece on the right. Another hand is at the bottom left, holding the green piece. The puzzle pieces are large and have a simple, stylized design.

# 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



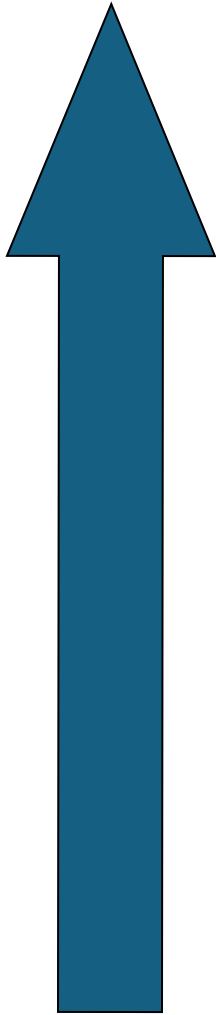


# Training Researchers: Human Investigations Program

## 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

2. Meet with CRDT for coordinated advice and guidance

3. Written output to guide investigator to next steps



Identified by self, through standard intake or referral



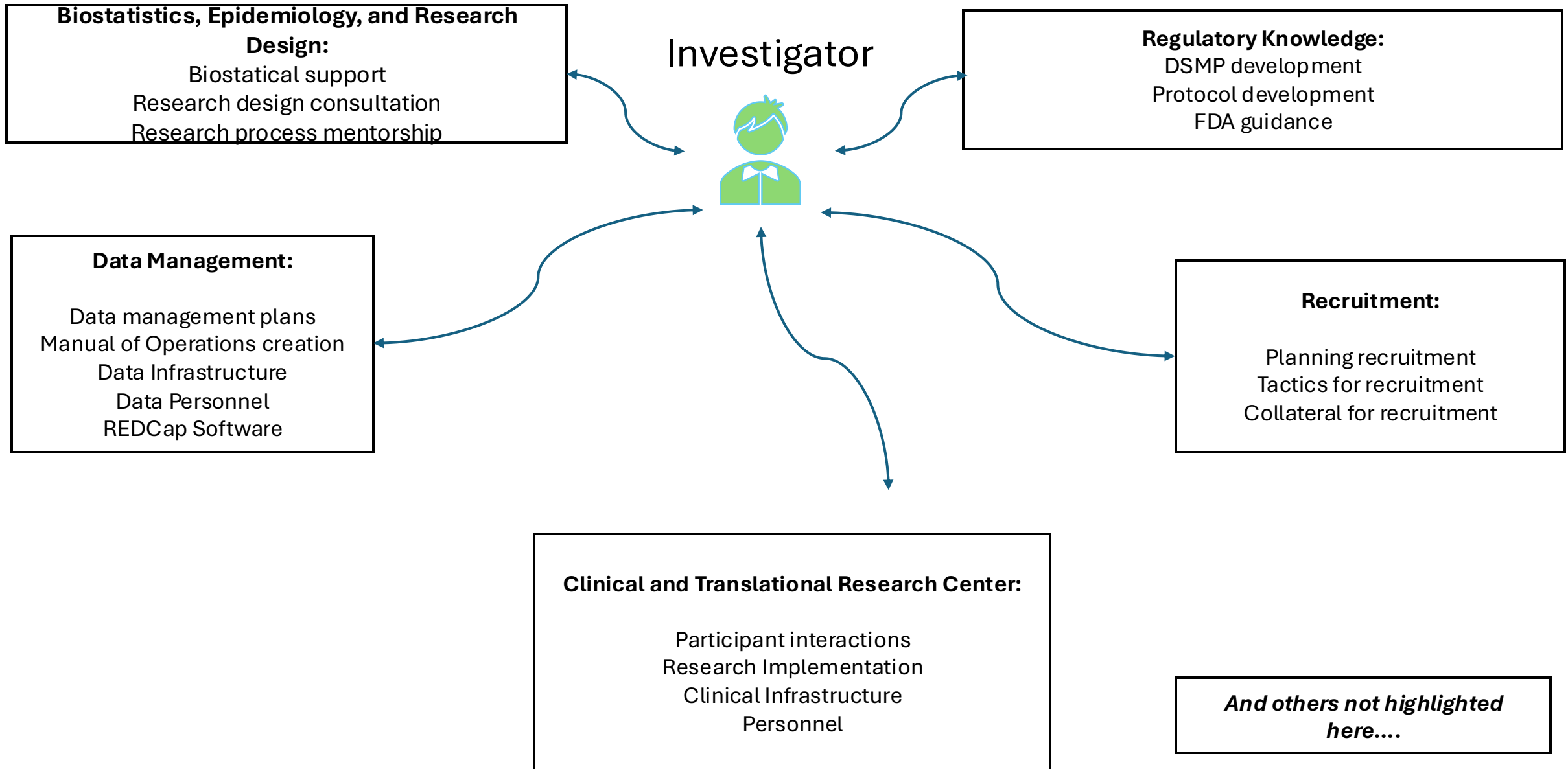
Optimized Research

- Inclusive
- Reach
- Efficient

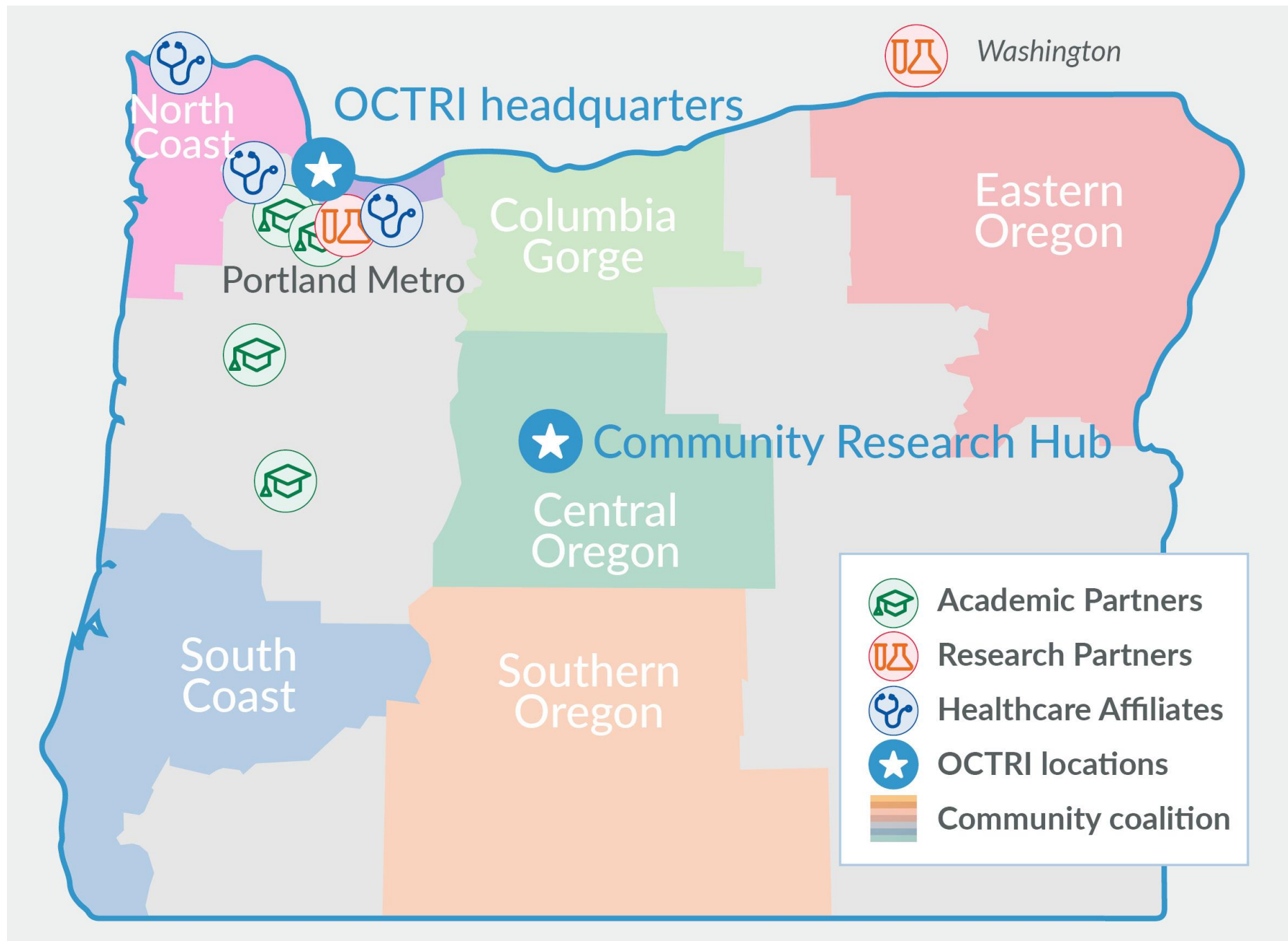


Note: CRDT is the biggest version of this type of quality input we provide, but there are other variations

# Optimization through OCTRI



Statewide reach of OCTRI programs, partners, and community coalitions



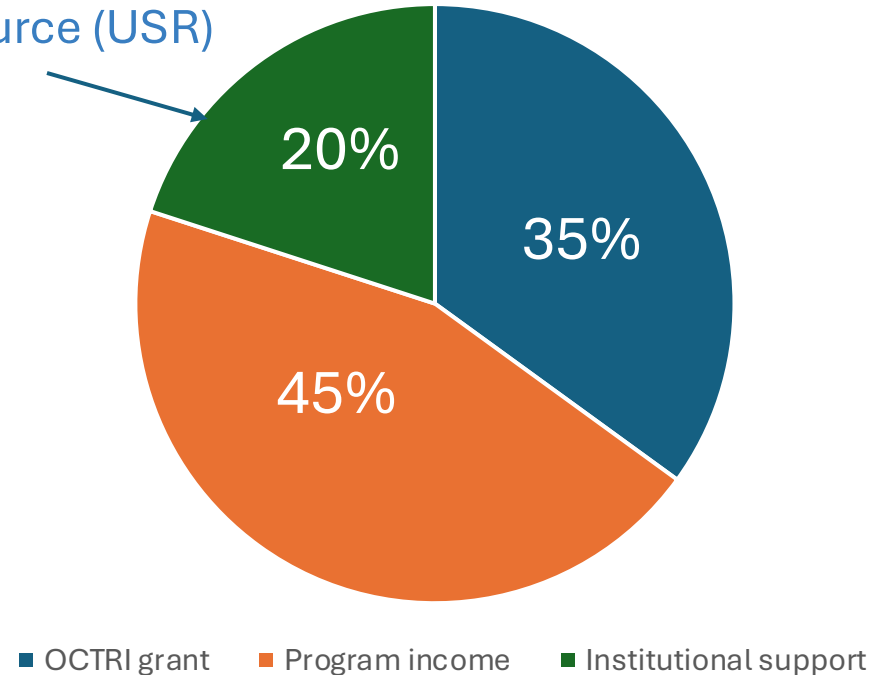


# OCTRI Clinical and Translational Research Center (CTRC)

- 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:

University Shared Resource (USR)



# OHSU Innovates

Intellectual Property  
Protection and Transactions



Collaboration  
Management



Technology Funding



New Ventures



Entrepreneurial Education



# Research Data Service Overview

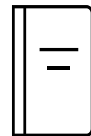
- One stop solution  
Research governance,  
Clinical Data  
knowledge and data management and delivery
- Develop Data Sets and Data Marts to meet custom research needs
- OHA Death Data
- Affiliate Data



4 Analysts



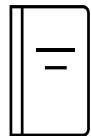
8 Engineers



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](mailto: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 [irb@ohsu.edu](mailto:irb@ohsu.edu).**



# Animal Research at OHSU

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), (8<sup>th</sup> Edition, 2011)
- Guide for the Care and Use of Agricultural Animals in Research and Teaching (1988), (4<sup>th</sup> Edition, 2020)
- American Veterinary Medical Association Guidelines for the Euthanasia of Animals (1963), (9<sup>th</sup> 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
- Evaluates 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.

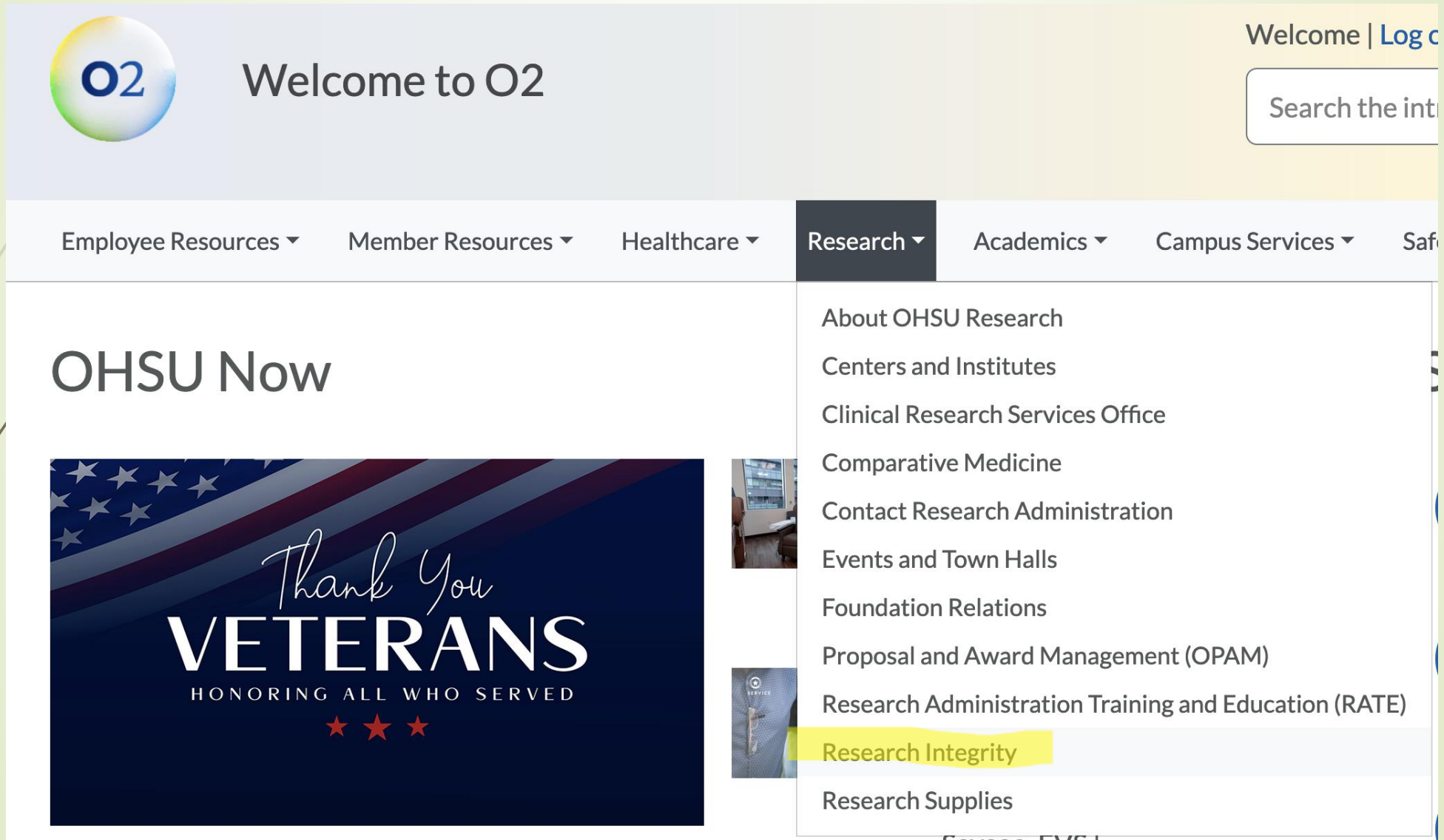
- IACUC Committee

- Meets monthly and has regulatory authority.

- Department of Comparative Medicine

- Veterinarians, veterinary technicians and staff that take care of your animals every day.

# Your protocol



The screenshot displays the OHSU O2 website interface. At the top left is the O2 logo, a blue and green sphere with the text 'O2' inside. To its right is the text 'Welcome to O2'. In the top right corner, there is a 'Welcome | Log out' link and a search bar with the placeholder text 'Search the internet'. Below the header is a navigation bar with several dropdown menus: 'Employee Resources', 'Member Resources', 'Healthcare', 'Research', 'Academics', 'Campus Services', and 'Safety'. The 'Research' menu is currently open, showing a list of links: 'About OHSU Research', 'Centers and Institutes', 'Clinical Research Services Office', 'Comparative Medicine', 'Contact Research Administration', 'Events and Town Halls', 'Foundation Relations', 'Proposal and Award Management (OPAM)', 'Research Administration Training and Education (RATE)', 'Research Integrity' (highlighted in yellow), and 'Research Supplies'. On the left side of the main content area, there is a section titled 'OHSU Now' featuring a large graphic with an American flag motif and the text 'Thank You VETERANS HONORING ALL WHO SERVED' with three red stars below it.

O2 Welcome to O2

Welcome | Log out

Search the internet

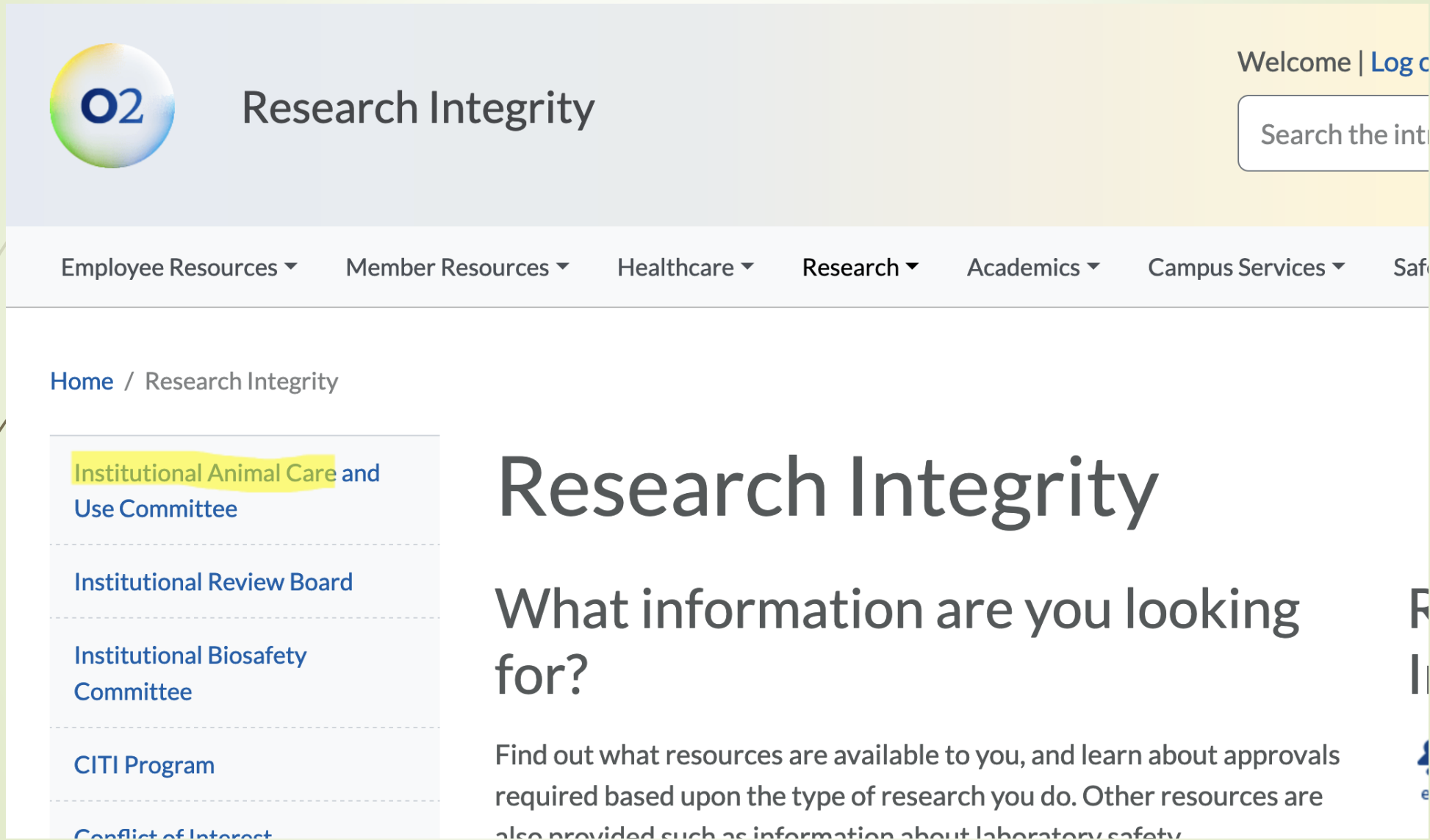
Employee Resources ▾ Member Resources ▾ Healthcare ▾ Research ▾ Academics ▾ Campus Services ▾ Safety ▾

OHSU Now

Thank You  
**VETERANS**  
HONORING ALL WHO SERVED  
★★★

About OHSU Research  
Centers and Institutes  
Clinical Research Services Office  
Comparative Medicine  
Contact Research Administration  
Events and Town Halls  
Foundation Relations  
Proposal and Award Management (OPAM)  
Research Administration Training and Education (RATE)  
**Research Integrity**  
Research Supplies

# Your protocol



The screenshot shows the Research Integrity website. The header features the O2 logo and the text 'Research Integrity'. A navigation bar includes links for Employee Resources, Member Resources, Healthcare, Research, Academics, Campus Services, and Safety. A search bar is located in the top right corner. The main content area has a breadcrumb trail 'Home / Research Integrity' and a list of links on the left: Institutional Animal Care and Use Committee (highlighted), Institutional Review Board, Institutional Biosafety Committee, CITI Program, and Conflict of Interest. The main heading is 'Research Integrity' followed by the question 'What information are you looking for?'. The introductory text states: 'Find out what resources are available to you, and learn about approvals required based upon the type of research you do. Other resources are also provided such as information about laboratory safety.'

O2 Research Integrity

Welcome | [Log out](#)

Search the internet

Employee Resources ▾ Member Resources ▾ Healthcare ▾ Research ▾ Academics ▾ Campus Services ▾ Safety ▾

[Home](#) / [Research Integrity](#)

- [Institutional Animal Care and Use Committee](#)
- [Institutional Review Board](#)
- [Institutional Biosafety Committee](#)
- [CITI Program](#)
- [Conflict of Interest](#)

## 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 also provided such as information about laboratory safety.



# Your protocol

[Home](#) / [Research Integrity](#) / Institutional Animal Care and Use Committee

Institutional Animal Care and  
Use Committee >

[Getting Started: Institutional  
Animal Care and Use  
Committee Protocols](#)

[eIACUC 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 Department of Comparative Medicine](#)

## Research Integrity systems



## Helpful links

- [Department of Comparative Medicine](#) - For Marquam Hill and South Waterfront



# Your protocol

- **Lots** of trainings necessary
- Policies available from O2 site
- Standard procedures available from within eIACUC
- 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



# Your protocol

- 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”