OREGON CLINICAL & TRANSLATIONAL RESEARCH INSTITUTE

Regulatory Consultation and Assistance Program (RCAP)

REQUEST FOR APPLICATIONS

The Oregon Clinical and Translational Institute (OCTRI) is accepting applications for funding regulatory consultation services.

PROGRAM OVERVIEW

The RCAP program aims to streamline the pathway to commercialization by providing OHSU sponsor-investigators with an expert regulatory review and analysis early in the project development life cycle.

The scope of support will help teams transition from the ideation phase of their project into proof-of-concept. Regulatory consultants can provide an overview of FDA rules and procedures specific to moving your technology or project towards commercialization. Teams at this stage may need help in the following areas:

- Assessment of commercialization pathway
- Support with device or study design
- Advisement on product or protocol development
- Development of design control systems: process and documentation considerations
- Strategic knowledge of how and when to engage with the FDA
- Navigating ongoing regulatory obstacles

Individual grants, up to $7,000, will be awarded on a rolling basis. Cursory regulatory evaluation will be conducted by OCTRI. Projects that are deemed to be ready for dedicated regulatory services will be awarded a one-time grant to hire one of the OCTRI-vetted consultancy groups, or any regulatory professional that meets the OHSU independent contractor requirements*.

Link to OHSU policy for procuring contractor services

APPLICATION PROCESS OVERVIEW

1. Submit your application through REDCap by clicking here. Please use the template below as guidance for your uploaded documentation.
2. Meet with the OCTRI review committee. Projects with an identified need for regulatory support will be pre-selected for grant funds.
3. Awardees will procure a SOW from their vendor of choice. The SOW and budget (not to exceed $7000) will be submitted to OCTRI.

CONTACT INFORMATION

To learn more about this grant opportunity, please contact:

Claudia Nakama
Alliance Manager
nakama@ohsu.edu

ADDITIONAL REGULATORY RESOURCES

Did you know? OCTRI has an office of Regulatory Knowledge and Support (RKS) providing expertise in local and federal regulatory compliance.

For more information, visit the OCTRI Clinical Research Development and Consultation page.

REVIEW CRITERIA

- Must have submitted an invention disclosure with Technology Transfer
- Should be able to communicate a business development plan or thoughts on a commercialization pathway

ELIGIBILITY

This regulatory support funding opportunity is open to all current employees and students of OHSU whose affiliation will last through the duration of the project. Funds will be awarded based on current readiness and need for regulatory support.

QUESTIONS?

Please direct all questions to Claudia Nakama (nakama@ohsu.edu, 503-418-7609).

RCAP APPLICATION TEMPLATE

Principal Investigator (name and title):

Project title:

Project Background/Abstract (<250 words):

If known, include any of the following for drug development:

- Target indication
- Any CMC data and development plans
- Any nonclinical data
- Any outline or thoughts relating to the clinical development strategy

If known, include any of the following for devices, diagnostics, and/or digital health:

- Thoughts on risk identification and classification
- Information on predicate devices
- Does design control documentation exist? (Please don't include the actual documentation)

Preliminary data:
From feasibility trials or prototyping. Brief explanation on method, results, and discovery/design implications (<200 words).

Team members:
List team members, expertise, and project role (No biosketches)

List of past and current funding related to the project needing regulatory support:

Supplementary information (if applicable):

- What are your current regulatory questions?
- Have you received previous regulatory advisement? If so, attach any strategy reports or landscape review.