



**Translational research:** moving knowledge and discovery gained from the basic sciences to its application in clinical and community settings

The **Institute of Translational Health Sciences** ([www.iths.org](http://www.iths.org)) is a regional inter-disciplinary consortium funded through the NIH-NCRR Clinical Translational Science Award (CTSA) to the University of Washington.

The goal of the **ITHS** is to make a positive impact on human health locally and globally by enabling and sustaining innovative translational research and research collaborations across disciplines and professions. Achievement of this goal requires collaboration between many groups in academia, industry, non-profit agencies, government, and the community. *Everyone from basic scientists to community-based participatory researchers can be involved in translational research.*

## Preclinical Research Development Network

The goal of the PRDN is to implement collaborative research programs that facilitate the identification and translation of novel therapeutic innovations into viable investigational products ready for human testing .

We have a robust **consulting program** that provides expert scientific and regulatory guidance to ITHS investigators seeking to transition their research innovations into the clinic.

- The Drug and Device Advisory Committee (*DDAC*) reviews proposed innovations and provides up to 8 hours of free consultation per project to discuss specific preclinical development plans, focusing on tasks needed to efficiently move the drug to the clinic according to FDA guidelines.
- Typical consulting services include: review of manufacturing process(es), design or review of toxicology data, relevant animal models, analytic methods, pharmacokinetics and ADME biomarker assay development and validation.
- DDAC will provide assistance to investigators and small companies in preparing grants for translational drug development. Longer-term support of DDAC activities is included as an expense in the grants.
- DDAC will also provide assistance in developing regulatory assistance (IND, IDE) in support of clinical trials.

### For More Information

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### ITHS Ignition Awards

- These awards support preclinical translational research and are intended to generate preliminary data to serve as a basis for submission of new research grant applications. There are currently three types of Ignition Awards;
  - Nonhuman primate models of human disease
  - Pharmaceutical studies
  - GMP manufacturing for cell and protein therapeutics

### ITHS Coulter Fellowships

- We sponsor MBA students to consult with investigators on market analysis and business development plans in collaboration with institutional Tech Transfer offices and UW Center for Innovation and Entrepreneurship.

# ITHS Core Groups That Support Translational Investigators

## ○ **Portal Program**

Provides the “gateway” to all things ITHS. Portal requests are directed to other applicable “cores” to best assist ITHS members and potential members

## ○ **Preclinical Research Development Network**

Gathers collaborative network of experts and resources from academia and biomedical industry to facilitate public/private partnerships that support translational research; offers drug & device development support from discovery through Investigational New Drug (IND) application or Investigational Device Exemption (IDE)

## ○ **Translational Technologies & Resources**

Offers central information source to enhance access and use of existing technologies and resources across ITHS partner institutions and WWAMI region, provides consult about which technologies may be appropriate for your project; fosters development of new technologies and resources

## ○ **Clinical Research Center Network (CRCN)**

Manages an integrated network of clinical research centers across multiple ITHS sites in the Puget Sound region

## ○ **Center for Biomedical Statistics (CBS)**

Offers core of biostatisticians and analysts to support statistical design and analysis options for proposed studies, including the preparation of grant proposals; provides assistance with data management

## ○ **Biomedical Informatics (BMI)**

Provides consultation on accessing and integrating diverse research data including electronic medical record data, electronic case report form data, and high throughput instrumentation data (e.g. genomic or proteomic data)

## ○ **Regulatory Support & Bioethics**

Provides support for ethical translational collaborative research within the ITHS; education, training and consultation related to research regulation (e.g., IRB, HIPAA) and other research ethics issues

## ○ **Community Outreach & Research Translation (CORT)**

The WWAMI States Practice-Based Research Network, American Indian and Alaska Native Communities, and Group Health Cooperative have formed a unique partnership to: increase community participation in all stages of research, foster research relevant to community needs, form and facilitate research network capabilities, and promote uptake of useful research findings in diverse health care settings in the WWAMI region

## ○ **Center for Scientific Review**

Manages a portfolio of pilot grants to support innovative research and integrate technologies into existing studies

## ○ **Evaluation Research**

Assesses the local and regional impact of ITHS initiatives; performs independent research on methods to facilitate the translational research process

## ○ **Research Education**

Provides formal (degree-granting) and informal training programs to facilitate the development and evolution of research skills in every phase of a translational investigator’s career

## ○ **Mentoring and Career Development**

Offers junior investigators training opportunities to support career development and advancement

## Benefits of ITHS Membership

- Eligible for all pilot grants and other ITHS funding
- Access to educational programs
- Facilitated access to translational technologies and resources
- Mentorship to further your research career
- Access to consultations
  - Biomedical informatics
  - Biostatistical
  - Regulatory support
  - Bioethics
  - Preclinical Research Development
- Ability to more readily find new research partners

## How can I contribute?

- With a unique resource that may benefit the research of others
- As a mentor for a junior investigator
- By reviewing pilot grant applications
- By presenting work in education and training

[www.iths.org](http://www.iths.org)

