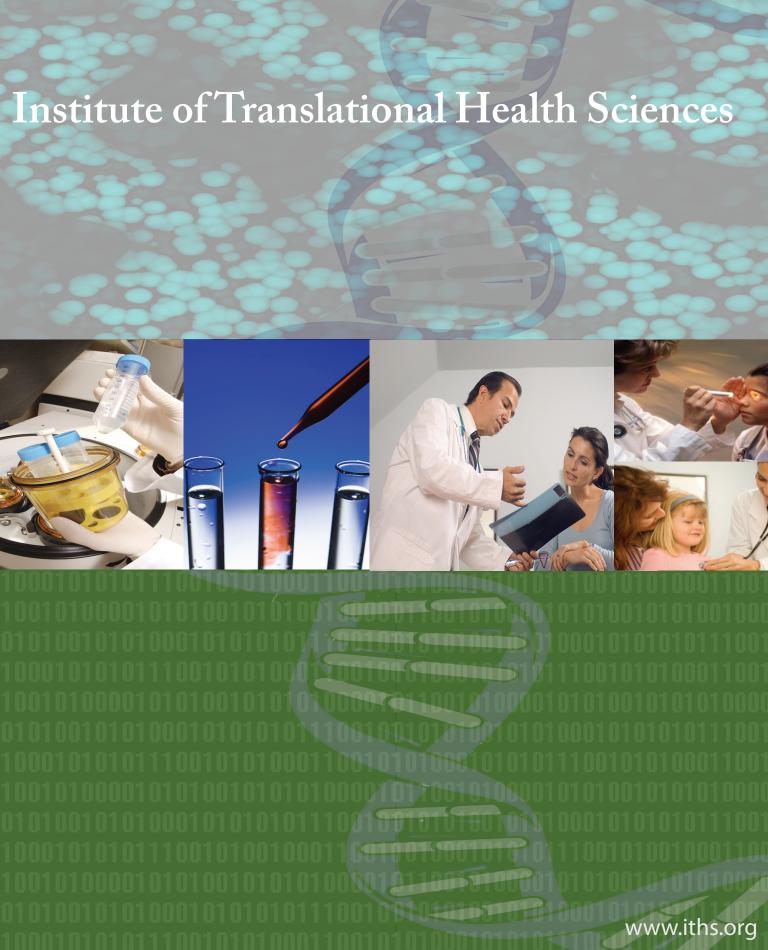
#### IV. REPORT OF THE CHAIR OF THE BOARD OF REGENTS

<u>University of Washington Medicine Board</u> <u>Annual Report on Operations and Governance</u>

Focus Topic: The Institute of Translational Health Sciences

Attachment



#### ITHS as a "Collaboratory"

The ITHS is a dynamic and interactive organization with a mission to create, enable, and sustain innovative translational research and research collaborations across disciplines and professions which will accelerate the development of concepts and tangible products that will improve human health.

#### Our common purpose is to:

- Foster innovative research and research partnerships
- Create and sustain research resources
- Ensure a translational research pipeline through robust education and career development programs

Develop an infrastructure that in itself can act as a laboratory for original research

#### **Contents**

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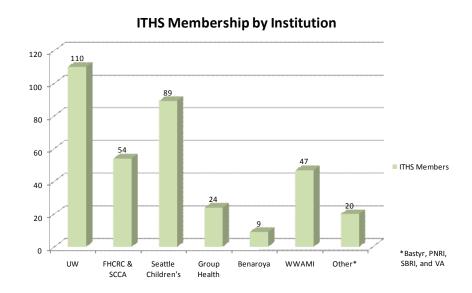
# OUR FIRST YEAR

The Institute of Translational Health Sciences helps researchers obtain the education, resources and collaborations necessary to translate discoveries into practice. The Institute is a partnership among the University of Washington (UW), Seattle Children's, the Fred Hutchinson Cancer Research Center (FHCRC) and other local institutions dedicated to improving human health. To achieve this goal requires collaboration between many groups: academia, industry, non-profit agencies, government, and most importantly the community. Any researcher or individual interested in translational research from any group is invited to become a member of the ITHS.

Here are some highlights of our first year, discussed in more detail in the pages of this report:

- Over 350 members representing 5 institutions as well as members in the WWAMI region (Washington, Wyoming, Alaska, Montana, Idaho). At the UW, all 6 Health Sciences schools are represented.
- Via our pilot project program we have awarded 47 grants for over \$500,000 to investigators representing 9 institutions: UW, FHCRC, Seattle Children's, VA Puget Sound Health Care System, Boise State University, University of Alaska, University of Idaho, Montana State University, University of Wyoming.
- Developed the ITHS-Coulter Fellowship program as a new targeted category of the fellowship program at the UW Business School's Center for Innovation and Entrepreneurship.
- Created new education programs: an annual Bootcamp rapid introduction to research, and a monthly clinical research education seminar series.
- Obtained unanimous approval of a business plan for developing a practice-based research network in the WWAMI
  region and launched the first pilot project (teratogenic drug use in young women).
- Developed joint operations among three therapeutics manufacturing units at UW and FHCRC to improve quality and reduce administrative costs.
- Finalized a collaboration between ITHS Biomedical Informatics Core, UW Medicine, and Microsoft related to
  exploration of their Amalga software suite in the context of data integration and use of Electronic Medical Record
  data for research.
- The ITHS and UW School of Medicine Research Funding Service joined efforts and will develop a career development program with didactic sessions for students and mentors as well as a grant writing mentoring program.

Our Portal service has responded to questions from over 100 investigators regarding resources, grant applications, collaborations, and getting started in translational research. Read more about our work, then join us by visiting us at www.iths.org.



# Who We Are



Mary L. "Nora" Disis, M.D., overall Principal Investigator of the Institute, is the Associate Dean for Translational Health Sciences at the UW School of Medicine, Professor of Medicine and Adjunct Professor of Pathology and Obstetrics and Gynecology at UW and a Member of the Fred Hutchinson

Cancer Research Center. She is also Director of the Center for Translational Medicine in Women's Health at UW. Dr. Disis is an expert in breast and ovarian cancer immunology. Her research interest is in developing vaccine and cellular therapy for breast and ovarian cancer. She holds several patents in the field of targeted cancer therapy.



Bonnie W. Ramsey, M.D., is a co-PI of the Institute. At Seattle Children's Research Institute, Dr. Ramsey is Director of the Center for Clinical and Translational Research, She is also Professor and Vice Chair for Research in the Department of Pediatrics and holds the Endowed

Chair in Cystic Fibrosis (CF) at the UW School of Medicine. She is internationally recognized for her work in developing new therapies for patients with CF.



Martin A. "Mac" Cheever, M.D., a co-PI, is Director of Solid Tumor Research for the FHCRC and SCCA. He is a Member of the FHCRC and Professor of Medicine at the UW. Dr. Cheever oversees the cancer center's initiative to establish translational and clinical research programs for

all solid tumors. He is an internationally renowned tumor immunologist and a leader in the field of adoptive T-cell therapy for cancer treatment.



Kim A. Margolin, M.D., is an FHCRC co-PI, a Member of the FHCRC, a Physician/Clinical Investigator in the SCCA, and a Professor of Medicine at the UW. Dr. Margolin is a leader in the clinical investigation of melanoma and renal cell cancer.

#### **Leadership & Administration**

Mary "Nora" Disis, M.D. (UW School of Medicine/FHCRC) Bonnie Ramsey, M.D. (Seattle Children's/UW SOM) Martin "Mac" Cheever, M.D. (FHCRC/SCCA) Kim Margolin, M.D. (Seattle Cancer Care Alliance/UW SOM) Cathryn Booth-LaForce, Ph.D., F.A.P.S., R.Y.T. (UW School of Nursing) Linda Hyman, Ph.D. (Montana State University) James Presson, M.Ed. (UW School of Medicine) Christina Surawicz, M.D. (UW School of Medicine) W. Michelle Terry, M.D. (Seattle Children's)

#### **Biomedical Informatics**

Peter Tarczy-Hornoch, M.D. (UW School of Medicine) James Brinkley, M.D., Ph.D. (UW School of Medicine) Nicholas Anderson, Ph.D. (UW School of Medicine)

#### **Center for Biomedical Statistics**

Patrick Heagerty, Ph.D. (UW School of Public Health & Community Medicine)

#### **Center for Scientific Review**

Cathryn Booth-LaForce, Ph.D., F.A.P.S., R.Y.T. (UW School of Nursing)

#### **Clinical Research Center Network**

Carla Greenbaum, M.D. (Benaroya Research Institute) Margaret Heitkemper, R.N., Ph.D., F.A.A.N. (UW School of Nursing) Steven Kahn, M.B., Ch.B. (VA Puget Sound Health Care System/UW SOM) Douglas Ramsay, D.M.D., Ph.D. (UW School of Dentistry) Margaret Rosenfeld, M.D., M.P.H. (Seattle Children's/UW SOM) Lupe Salazar, M.D. (UW School of Medicine/FHCRC)

#### **Community Outreach and Research Translation**

Laura-Mae Baldwin, M.D., M.P.H. (UW School of Medicine) Dedra Buchwald, M.D. (UW School of Medicine) Eric Larson, M.D., M.P.H. (Group Health)

#### **Evaluation Research**

Fredric Wolf, Ph.D. (UW School of Medicine) Doug Brock, Ph.D. (UW School of Medicine) Lynne Robins, Ph.D. (UW School of Medicine)

#### **Pre-Clinical Research & Development**

Lynn Rose, Ph.D. (Seattle Children's/UW SOM) Kim Folger Bruce, Ph.D. (Seattle Children's)

#### **Regulatory Support & Bioethics**

Ann Melvin, M.D., M.P.H. (Seattle Children's/UW SOM)

#### **Research Education**

Benjamin Wilfond, M.D. (Seattle Children's/UW SOM)

#### Pamela Mitchell, Ph.D. (UW School of Nursing)

Jeffrey Probstfield, M.D. (UW School of Medicine) Timothy De Rouen, Ph.D. (UW School of Dentistry/School of Public Health

and Community Medicine)

Susan Heckbert M.D., Ph.D., M.P.H., (UW School of Public Health and Community Medicine)

#### **Strategic Development**

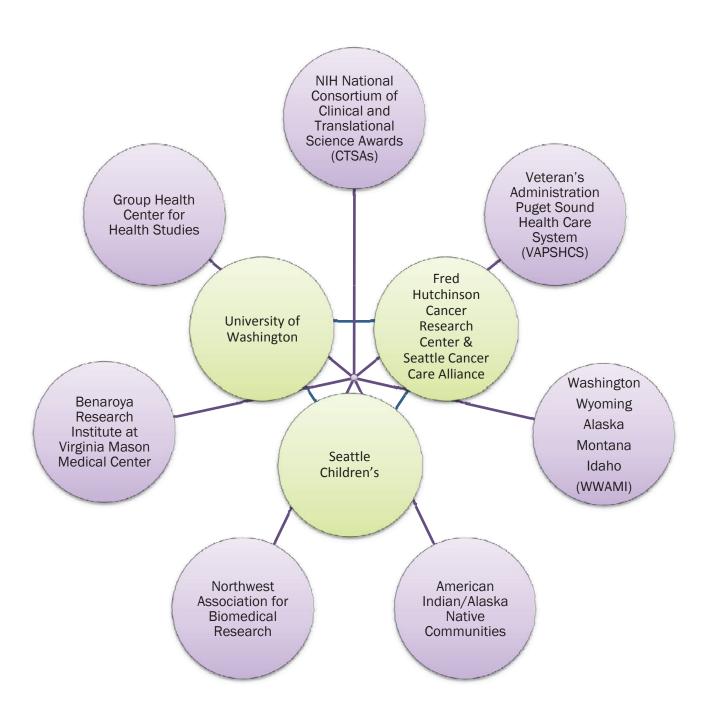
Havivah Schwartz, Ph.D. (UW School of Medicine)

#### **Translational Technologies & Research Resources**

Janell Baldwin, M.B.A. (Fred Hutchinson Cancer Research Center) Roger Bumgarner, Ph.D. (UW School of Medicine)

David Eaton, Ph.D. (UW Office of the Provost/School of Public Health and Community Medicine)

# ITHS Institutions & Partners



# OUR ORGANIZATION

Evaluation Research Core		
Strategic Development Core		
Pre-Clinical Research Network	Biomedical Informatics Core	Community Outreach and Research Translation Core
Center for Biomedical Statistics	Clinical Research Center Network	Translational Technologies and Research Resources Core
Regulatory Support and BioEthics Core	Research Education Core	Center for Scientific Review
Leadership and Administration Core		

### Foster innovative research and research partnerships

**Pre-Clinical Research Network.** Via education, consultation and funding, PCRN helps investigators prepare innovative ideas for human testing and commercialization.

**Biomedical Informatics.** BMI gives investigators biomedical informatics toolkits (both physical and intellectual) to manage and interpret complex data, and to allow data to be shared in a facile manner across ITHS sites and core functions. The BMI core also conducts research in bioinformatics data integration, clinical experimental management systems, ontologies and bioinformatics tool design.

**Community Outreach and Research Translation.** Using resources adapted from Group Health Center for Health Studies, research networks will be built in Native American/Alaska Native communities as well as in WWAMI clinical practice sites. The networks will perform and participate in ITHS research.

**WWAMI Translational Research Consortium.** Pilot program to create a research network among NCRR-funded programs to enhance collaboration and leverage resources in the Washington–Wyoming–Alaska–Montana--Idaho region.

#### **Create and sustain research resources**

**Center for Biomedical Statistics.** CBS provides investigators and trainees with statistical guidance and education regarding design and analysis options. CBS also collaborates with Biomedical Informatics on data collection and quality assurance review. CBS will engage in methodological research on topics inspired by interactions with ITHS trainees and investigators.

**Clinical Research Center Network.** A network of centers that offer physical locations where patients may be seen for research purposes; sample collection and storage; and capacities for therapeutic and specimen collection studies.

#### Translational Technologies and Research Resources.

This core supports and enhances access to existing resources and fosters the development of new technologies and research partnerships. Key initiatives include providing an online database of resources, developing educational seminars in technology applications or novel technologies, and reducing institutional barriers to accessing shared resources.

**Regulatory Support and BioEthics.** The RSB Core provides assistance and education to help investigators improve quality and compliance with federal, state and institutional regulations. A new pool of research coordinators is available, as is assistance with developing or implementing data and safety monitoring plans and study-related documents. RSB also conducts research on bioethical issues in translational research and offers 24/7 on-call research bioethics consultation.

# Ensure a translational research pipeline through robust education and career development programs

**Research Education.** This core offers TL1 (pre-doctoral) and KL2 (post-doctoral) programs, as well as a Master's tuition support program. The core will develop an ongoing training program in Clinical and Translational Research that will span from TL1 to established researchers. New programs include the week-long Clinical Research "Bootcamp."

**Center for Scientific Review.** CSR manages a series of review panels for pilot projects and ITHS resources. The core offers review services with other centers and programs. Young investigators learn grant review via the CSR.

**Mentoring and Career Development**. ITHS Scholar Program (open to all) to track junior investigators, offer them specific didactic training, create multidisciplinary mentoring committees, and support their career advancement.

#### **Overall Foundation and Evaluation**

**Leadership and Administration.** This core houses the overall direction, financial management and administration for the Institute. In addition, this core acts as an incubator for new programs such as Mentoring and Career Development and the WWAMI Translational Research Consortium.

**Evaluation Research.** This core qualitatively and quantitatively assesses the local and regional impact of ITHS initiatives and performs independent research on methods to facilitate the translational research process.

**Strategic Development.** To help the Institute unite toward common goals, this core provides an overall strategic mission filter, and a *Toyota Lean* continuous performance improvement program, in addition to a Portal service that helps investigators navigate the translational research environment.

# 2008 Environment Survey

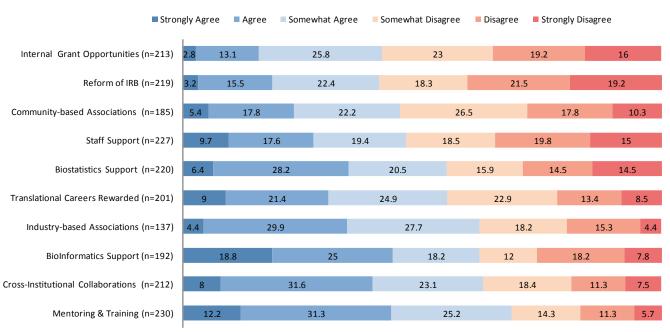
The ITHS is designed to be responsive to the needs of clinical and translational researchers in our environment and conducts annual and ad hoc surveys to assess research needs and priorities. The ITHS Evaluation Research Core's first annual environment survey from early 2008 demonstrates this effort. The survey recorded satisfaction, barriers and prioritization related to 10 key aspects of clinical and translational research. 240 investigators, trainees and research staff responded. They highlighted critical needs, particularly internal pilot research opportunities and staff support to assist in the conduct of research. Over 90% of the respondents rated these two areas as requiring improvement in the next 5 years. One respondent wrote, "Because of the extraordinary increase in work derived from regulations...we have opted to avoid human studies unless they are strictly and absolutely necessary, or somebody else is the PI and we just collaborate." Although there was considerable satisfaction with existing mentoring and biostatistical support, over 80% of respondents prioritized improvement in these areas. These four areas—pilot funding, staff and regulatory support, mentoring, and biostatistical support—formed key targets for the Institute's initial work.

#### In our first year, we:

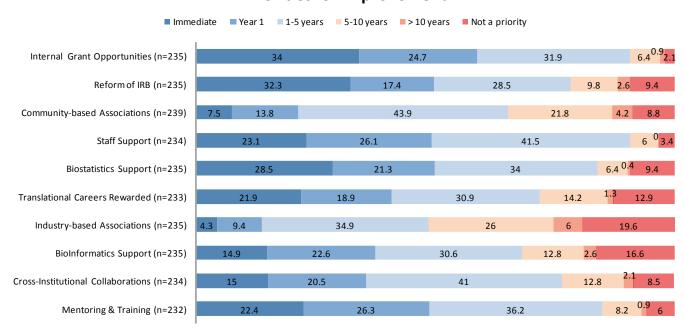
- Funded 47 grants for over \$500,000 (p.10)
- Developed a Research Coordinator pool and a variety of consulting services to assist with study design, regulatory guidance, and tools (p.12)
- Created the Center for Biomedical Statistics (p.13)
- Developed a mentoring program (p.17)

Among additional priorities, the most frequent recommendations coalesced around the theme of collaboration, with respondents expressing a desire for a "true collegial network of research in Seattle," and advocating that we "start to build a sense of being a team and of learning how to be excellent together, not just as individuals." ITHS programs and resources are designed to foster new collaborations among translational researchers and experts who can help them take their discovery into practice.

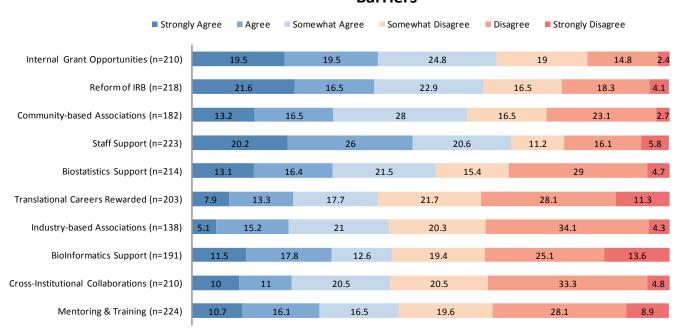
#### **Areas of Satisfaction**



#### **Priorities for Improvement**



#### **Barriers**



<sup>&</sup>quot;I have trouble finding clinical collaborators - I don't know how to find and meet the people doing certain kinds of clinical work. Sometimes they find me, and we work together, but I haven't been able to find them. This is as much a problem finding clinicians at UW as in other institutions." (2008 Environment Survey respondent)

# CREATING COLLABORATIONS

#### **Regional Collaboration: WWAMI Translational Research Consortium**

The five WWAMI states (Washington, Wyoming, Alaska, Montana and Idaho) are home to several academic research institutions. The WWAMI Translational Research Consortium has been created to identify and develop opportunities for leveraging NCRR-funded and other research infrastructure across the WWAMI states, and to facilitate collaborative, non-duplicative research and training in translational research. In addition to developing collaborative research proposals that draw on the strengths at participating institutions, the Consortium will explore opportunities to share core resources, pilot funding, and translational research training.

- The Consortium is an equal partnership of research programs and members.
- Initial Consortium activities throughout the region will include cataloguing and "advertising" resources and training opportunities
  in translational research; developing mechanisms for sharing core resources, pilot funding, and translational research training
  opportunities; and encouraging collaborative research proposals.

The Consortium Steering Committee meets monthly by teleconference and annually in person. Members include: Laura-Mae Baldwin, M.D., M.P.H., University of Washington; Caroline Bohach, Ph.D., University of Idaho; George Happ, Ph.D., University of Alaska – Fairbanks; Allen Harmsen, Ph.D., Montana State University; Linda Hyman, Ph.D., Montana State University; Mike Kavanaugh, Ph.D., University of Montana; Matthew McEchron, Ph.D., University of Wyoming; Jun Ren, Ph.D., University of Wyoming; Ken Roberts, Ph.D., Washington State University; John Slattery, Ph.D., University of Washington; Denny Stevens, M.D., Ph.D., VA Medical Center, Boise, Idaho; Dennis Valenzeno, Ph.D., University of Alaska – Anchorage.

#### **National Collaboration: CTSA Consortium**

The ITHS is a member of a national consortium of Clinical and Translational Science Award (CTSA) grantees, sponsored by the National Center for Research Resources. The national consortium fosters collaborative projects among member sites to improve the national environment for clinical and translational research.

**Dr. Nicholas Anderson**, Acting Assistant Professor of Biomedical Informatics at the University of Washington, in collaboration with Dr. Jim Cimino and Mr. Michael Kamerick at the University of California San Francisco and Dr. Julie Rainwater at University of California, Davis, has been awarded an NIH Clinical and Translational Information Exchange Environment Pilot Grant to direct an information exchange environment across three CTSA sites.

This two-year contract will involve adapting the National Center for Biomedical Computing i2b2 (integrating Bench to Bedside) architecture to support cross-institutional translational research across the CTSA sites at these institutions. In partnership with Recombinant Data Systems, this team will pilot a federated query framework that supports knowledge discovery for small to medium sized groups of clinical investigators across these sites. Further information about this project can be gained by visiting the project website at www.i2b2cictr.org.

"This collaboration is an exciting opportunity to bridge technical, clinical, and cultural environments across three unique and geographically distributed institutions." (Nicholas Anderson)

#### **Collaborations with Research Centers, Institutes and Programs**

As a collaboratory, the ITHS aims to help establish and sustain complementary cooperative networks and research programs, to improve the structures and resources that support and shape the lives of translational researchers across institutions. We share expertise; develop research, training and community collaborations; and leverage infrastructure. In the last year, the ITHS has assisted with the development of several new research programs and program proposals, including the Northwest Institute for Genetic Medicine (profiled below). We will continue to support further applications. Other examples include:

- Washington Chronic Kidney Disease Collaborative Network (Jonathan Himmelfarb, P.I.)
- Center for Intracellular Delivery of Biologics (Patrick Stayton, P.I.)
- · Northwest Health Disparities Research Center to Reduce Kidney Disease (Bessie Young, P.I.)
- Health Promotion Research Center (Jeffrey Harris, P.I.)
- Center for the Study of Health and Risk Behaviors (Mary Larimer, P.I.)
- Center for Research on the Management of Sleep Disturbances (Margaret Heitkemper, P.I.)

#### Local Collaboration: Northwest Institute for Genetic Medicine

There is often a gap between basicscience research and clinical studies at academic institutions and research at biotechnology companies. The Northwest Institute for Genetic Medicine (NWIGM), under the direction of Dr. Gail Jarvik, recently received a \$5.3 million, four-year grant from the Life Sciences Discovery Fund (LSDF) to bridge that divide by facilitating the design, development, and execution of translational genetic studies. Study findings from the institute may help prevent adverse outcomes of medications and surgery, predict the most effective treatment for patients, and prevent disease in high-risk subjects.

Several ITHS leaders and faculty were part of the team that developed the proposal for the NWIGM and now participate in its leadership, including Drs. Michael Bamshad (Center for Clinical Genomics), Eric Larson (Group Health Center for Health Studies), Peter Tarczy-Hornoch (Biomedical Informatics), and Bruce Weir (Biostatistics). NWIGM seeks to



Left to right: Drs. Gail Jarvik, Bruce Weir, Debbie Nickerson, Michael Bamshad, Eric Larson.

advance genetic research and provides a way to connect others interested in genetic medicine to crucial ITHS resources. For example, the mutual leveraging of NWIGM and ITHS has allowed both to avoid redundant services while expanding ITHS capacity for research into genetic medicine and giving NWIGM the research resources and structural support it needs to operate effectively.

"Without ITHS-fostered relationships and the ITHS infrastructure, the [LSDF] grant would not have been written." (Gail Jarvik)

# Fostering Innovation

#### **Small Pilot Project Grant**

Pilot Grants are designed to assist investigators in obtaining preliminary findings, testing "proof of concept," or conducting other research activities in preparation for developing competitive, full-scale grant applications. Typical awards are in the \$10,000 range, and projects are usually one year in length.

Examples of projects include:

- An investigation into the immunologic basis for the emergence of a dominant unit in double cord blood transplantation
- An evaluation of the brain local function of patients who are undergoing hunger response that correlates brain activity with serum signs of hunger
- · A plan to develop an automated, low-cost, optical imaging method to assist in wound healing assessment
- · A project translating an evidence-based intervention into Spanish for a high-need HIV population



Elahe A Mostaghel, M.D., Ph.D successfully proposed a pilot project to establish the feasibility of using a metabolomic approach in patients undergoing testosterone suppression to identify a blood-based metabolic profile of the tissue response to androgen

suppression, as well as a metabolic profile indicative of increased cardiovascular risk. Dr. Mostaghel is an Assistant Member at the FHCRC and an Assistant Professor at the UW School of Medicine. She completed her residency in internal medicine at the University of California at San Francisco and a fellowship in medical oncology at the University of Washington. Clinically, she cares for patients with genitourinary cancers including prostate, bladder and testicular cancer.



Angela J. Peck Campbell, M.D., is using her pilot grant to test the development and feasibility of the self collection of respiratory samples for CF patients to perform at home and mail them for virus testing. Dr. Campbell is an attending physician at Seattle Children's

Hospital, Acting Instructor in the Department of Pediatrics at the University of Washington, and Research Associate in the Clinical Research Division at Fred Hutchinson Cancer Research Center. Dr. Campbell's research focuses on factors that influence the acquisition of respiratory virus infection and disease progression among immunocompromised children and adults, with the goal to facilitate new diagnostic, preventive, and treatment strategies for respiratory virus infections.

#### **ITHS Coulter Translational Fellowship**

In the planning stages for the Clinical and Translational Science Award, we identified a gap in support for the scientist seeking to commercialize or license a biomedical innovation. Together with the Coulter Foundation, the Institute established the ITHS-Coulter Translational Fellowship to fund commercial analysis of up to four new biomedical projects per year. The ITHS-Coulter Fellowship is a new targeted category of the Fellowship Program in the UW Business School Center for Innovation and Entrepreneurship Fellowship Program, which supports second-year MBA students for a summer internship to develop marketing analysis, a marketing plan, and other materials for scientists seeking to translate their ideas for commercialization.



Rodney Ho, Ph.D. Pressurized Olfactory Drug Delivery System for CNS Delivery: Many neurological, analgesic, and cancer drugs do not reach the central nervous system (CNS) at safe and effective concentrations. With traditional oral or intravenous dosing, highly lipid soluble drugs must be delivered in high concentrations, at doses that may be toxic to the liver and other organs. Dr. Ho has developed a novel pressurized olfactory drug delivery (PODD) system that provides a unique opportunity for direct nose-to-brain delivery of CNS drugs. The ITHS-Coulter award was given to Michael Hite, an MBA student who performed a market analysis and drafted a business plan for Dr. Ho's invention. Dr. Ho is Associate Dean, Milo Gibaldi Endowed Professor of Pharmaceutics and Director

of the DNA Sequencing and Gene Analysis Center at UW. His research interests are in elucidating mechanisms of protein and drug disposition, and genetic basis of inter-individual variation in therapeutic responses.

#### **Ignition Award Program**

To foster preclinical work that has a high potential for translation to the clinic, the ITHS has developed the Ignition Award program, designed to provide support for generating preliminary data that will serve as the basis for submission of subsequent grants or clinical studies. Particular emphasis and priority are given to applications directed at the development of novel therapeutics such as small molecules or biologics. Proposals may be submitted by investigators from the UW, Fred Hutchinson Cancer Research Center, Seattle Children's, and other institutions within the WWAMI region.

In our first year, the ITHS co-sponsored an Ignition Award with the Washington National Primate Research Center. In 2008-2009, the Ignition Award will be a partnership with the UW School of Pharmacy, to support work that explores innovative areas of drug delivery, transport, metabolism, pharmacokinetics, or pharmacogenetics. Awards will be up to \$40,000.

#### **Implantable Recurrent Brain-Computer Interfaces for Therapeutic Applications**

Eberhard Fetz, Ph.D., received an Ignition Award to implant a microchip, called a novel brain-recurrent interface, that records activity in the brain and delivers a stimulus to the muscles. His original NIH research grant did not cover the costs of all the experiments needed and that the translational grant helps cover. The two-year Ignition Award of \$100,000 was cosponsored by the ITHS and the Washington National Primate Research Center.

Dr. Fetz's research has two main potential applications. The neurochip provides an artificial connection between the brain and the muscles and thus bridges lost connections that might occur as a result of spinal injury. Additionally, the neural activity can produce plasticity by connecting two adjacent sites and introducing a stimulus across the connections, a process that strengthens weak connections, such as those that might occur as a result of stroke.

The ultimate goal of the research is to produce a more clinically applicable process: an electrode that sits on the brain rather than inside of it. This surface contact approach is being tested on monkeys to determine if the activity the pads record is specific enough. Dr. Fetz and his group are preparing an RO1 application and plan to use the data collected from the Ignition Award research as preliminary evidence on feasibility.



Dr. Chet Moritz (left) and Dr. Eberhard Fetz (right) in their lab.

"For my lab it is a godsend to have this support." (Eberhard Fetz)

# CREATING RESEARCH RESOURCES

#### **Streamlining operations among existing resources**

A key aspect of ITHS operations is to serve as a "living laboratory" to study the translational research process itself. One approach is the Toyota Lean method of evidence-based continuous improvement. Lean is a data-driven approach to optimizing productivity by eliminating wasted effort and resources. Lean methods are inclusive, engaging staff, leaders, managers, and customers in the improvement process. With the support of Seattle Children's, the ITHS has begun to integrate Lean into our overall strategic development.

At the UW Clinical Research Center, Lean has been used to remove inefficient processes by implementing new systems that also resulted in better planning tools for the nurse managers:

- Pre-populated printed reports and barcode stickers replaced handwritten logs and plastic cards
- A visual grid displaying subjects, rooms, and research nurses replaced a daily schedule listing visits in a column
- Nursing overtime and per diems reduced by over 50%
- · Inpatient and outpatient no-shows decreased
- Improved access and workflow for blood draws and added capability to do physicals
- Returned or recycled surplus equipment and over 150lbs. of excess and unusable forms

Planning is underway for additional Lean efforts for the Clinical Research Centers at the UW and Seattle Children's.



The creation of the ITHS also provided the opportunity to streamline other resources and develop new collaborations:

Collaboration among therapeutic manufacturing units. By coordinating personnel and procedures among three independent Good Manufacturing Practice (cGMP) facilities at the UW and FHCRC, the units achieve savings and reduce redundancy, especially in site management and the associated regulatory burden. The cGMP units offer investigators a comprehensive quality program for therapeutic product development conducted in Biosafety Level 2 and 3 cleanroom suites. Experienced research personnel offer regulatory oversight and extensive assistance, including product development consultation and training for investigator staff.

**Nutrition, Body Composition and Bioenergetics Labs.**Collaboration with the UW Clinical Nutrition Research Unit has allowed the ITHS to broaden the scope of services for



body composition testing, including a Bod Pod and extended staffing. Other services include a staffed research kitchen, nutrition assessment and dietary intake analysis, a DXA machine and equipment for VO2max testing and energy expenditure measurements.

Streamlined review at Clinical Research Centers. For investigators who plan to see patients for research purposes, it is now faster and easier to gain access to the Clinical Research Centers (CRCs) at the UW Medical Center and Seattle Children's. By encouraging early discussion and eliminating redundant review of studies that had already obtained approval from select external scientific peer review committees, the new ITHS Center for Scientific Review has reduced start-up time. In the previous year, 71% (UW) and 85% (Children's) of applications were approved with contingencies. In the first eight months using the new processes, contingency approvals dropped to 6% (UW) and 26% (Children's). 88% (UW) and 69% (Children's) of applications now gain approval on initial review.

In addition to the CRC units at the UW Medical Center and Seattle Children's, the CRC Network includes the UW Regional Clinical Dental Research Center, Benaroya Research Institute at Virginia Mason Hospital, and the CRC at the VA Puget Sound Health Care System. The CRC Network offers inpatient and outpatient facilities, personnel skilled in therapeutic and specimen collections studies, and short-term specimen storage.

#### **Creating new resources**

In its first year, ITHS provided funding, leadership and infrastructure for several new research resources. One such innovation is the ITHS Portal, which helps investigators navigate our rich and dense translational research environment. The Portal is also the entry point to ITHS resources; get started by submitting an inquiry at www.iths.org or contact ithsnav@u.washington.edu.

Consultation during proposal and protocol development. All ITHS cores (page 5) assist investigators with new proposals by offering guidance on study design, regulatory preparation, data and safety monitoring, basic data management, community-based research, bioethics, evaluation research methods, drug and device development, and translation from preclinical work to clinical trial or commercialization.

Center for Biomedical Statistics. Faculty and staff biostatisticians collaborate with investigators on grant preparation, choosing statistical methods, determining sample size, randomization and blinding, electronic data capture, high-dimensional data storage, multicenter study coordination, data and safety monitoring, data analysis and cleaning and manuscript review.

**Biomedical Informatics.** The BMI core provides investigators with research access to Electronic Medical Records (see Amalga highlight below), and in collaboration with the Center for

Biomedical Statistics, BMI provides basic toolkits for electronic case forms, adverse event reporting, and data management. BMI is also researching methods in data integration, as in Dr. Anderson's national collaborative project (page 8).

Regulatory support and training and a Research Coordinator Core. Expert guidance is available to investigators in need of guidance in completing IRB and other regulatory applications, developing or implementing data safety monitoring plans and developing study related documents. A new Research Coordinator pool assists investigators with study start-up, implementation or close-out.

24/7 research bioethics consult service. ITHS bioethicists provide advice to ITHS members, research participants, families and communities, and IRBs who have questions that could benefit from in-depth conversation and analysis about ethical issues related to the development, implementation, or analysis of clinical research studies.

#### **ITHS Biomedical Informatics and Microsoft Amalga**

In September 2008, Microsoft, the University of Washington and the ITHS announced a new collaboration. For the full press release, go to: http://www.microsoft.com/presspass/press/2008/sep08/09-30UWAmalgaPR.mspx

The UW and ITHS will use Microsoft Amalga, the unified intelligence system, in a research protocol designed to provide clinical and translational researchers with faster and more complete access than they previously had to electronic data stored on disparate systems. In the UW's complex academic systems, gaining access to aggregate views of data is time- and labor-intensive and hinders translational research with long lags between the time a researcher has a need for a particular data set and when access to the data set is provided. Microsoft Amalga is designed to provide ITHS researchers with the ability to comprehensively access, search and perform analysis on data stored in UW medical record systems, UW research laboratory systems and study data management systems.

For example, subject to institutional review board and Health Insurance Portability and Accountability Act (HIPAA) regulations, researchers will be able to quickly assess whether the UW patient population has the numbers to support a study testing a particular hypothesis or if there are new patients eligible for recruitment into a trial. Microsoft Amalga also will enable researchers to prospectively collect study-specific data that is not in the university's electronic medical record (EMR), collect biological research specimens for the study and link them to the study or patient — under approved research studies with appropriate consent — and generate reports appropriate for biostatistical analyses.

"The Amalga tool will improve the ability of ITHS to provide our researchers with access to all of the data they need when they need it, allowing them to conduct their work faster and more effectively." (Peter Tarczy-Hornoch, BMI Director)

# New Resource Spotlight

#### **ITHS Translational Technologies and Resources**

New technologies are changing the way translational research is conducted. It is now essential that any comprehensive translational research program provide investigators with access to the most recent technologies for analyzing gene expression, (re)-sequencing DNA on a large scale, and characterizing genetic variability in the human population. The Seattle area is fortunate to have several leaders in the development and implementation of genomics and transcriptomics technologies. Funding from ITHS and other groups has helped create a new resource to advance the application of these technologies in health research.

#### **Center for Clinical Genomics**

The study of human genetics has been infrequently applied to clinical research, but under the direction of Dr. Michael Bamshad and with ITHS support, the Center for Clinical Genomics (CCG) fills this gap. The CCG provides study design expertise and the infrastructure to collect, organize, and maintain a collection of clinical information and biologic materials from individuals with various conditions who have been identified during routine clinical care at the UW Medical Center, Seattle Children's, the Fred Hutchinson Cancer Research Center and Group Health.



Left to right: Sofia Husain, Mike Bamshad, Sarah Ruuska

CCG provides the following services:

- Assistance with experimental design of the genetic component of clinical studies
- Development and writing human-subject protocols
- Design of data capture forms and questionnaires
- Collection and tracking of phenotypic information
- · Logistical coordination among regulatory boards, clinical centers, and research programs
- Identification of suitable technologies for processing and analyzing genetic material
- Identification of resources and colleagues from the UW Medical Center, Seattle Children's, and the Fred Hutchinson Cancer Research Center who can make available such technologies
- DNA extraction from a variety of tissues
- Tissue banking and long-term storage
- Support for management of clinical, sample storage, and genetic analysis data

Among the CCG's first 12 projects are the following two examples:

Genetic modifiers of cystic fibrosis (CF). Researchers at Seattle Children's are studying a group of 1,700 CF patients living throughout the United States to better understand health problems associated with CF disease. A major health problem in children with CF is a bacterial lung infection called Pseudomonas aeruginosa (Pa). Investigators are examining factors, such as nutritional status and genetics, that may that influence time to Pa acquisition as well as the severity of the infection. This study may lead to the ability to predict the onset of infection and the development of preventive measures. The CCG is processing blood obtained from CF patients and banking DNA for future studies. The CCG is also providing guidance for the design of studies looking at genetic factors that may affect many other CF outcomes.

StarNet. StarNet is a science education curriculum developed by the UW Departments of Genome Sciences and Medicine, Division of Medical Genetics. The StarNet curriculum involves high school students in designing and implementing a research investigation, a case-control study aimed at detecting the association of genetic and environmental factors with smoking behavior. For this study anonymous adults complete a questionnaire and give a blood sample for DNA. Under the direction of their classroom teachers, students are carrying out several aspects of this investigation, including formulating hypotheses, helping design the questionnaire, genotyping samples, and analyzing data. The CCG is responsible for recruiting, enrolling, administering the questionnaire and collecting and processing blood samples from 250 smokers and 250 non-smokers living in the Puget Sound area.

# INNOVATION THROUGH ACCESS

#### **ITHS Technology Access Grants**

One of the most vexing challenges for investigators wanting to incorporate new technologies into their translational or clinical research program is obtaining funds for "proof of concept" experiments. Funding agencies nearly always require an investigator to have preliminary data demonstrating that the new technology is available to them, yet resources to obtain these data are seldom available in existing grants. This is especially problematic for new investigators, who have neither the resources nor the experience to acquire such preliminary data. To help overcome this hurdle, the ITHS has established a fund to help investigators access technology resources and services for the purposes of gaining critical "proof of principle" experiments. Technology Access Grants offer up to \$10,000 to cover research services.

The goals of the Technology Access Grants Program are to:

- Encourage the utilization of the latest technologies and instrumentation into translational and clinical research.
- Foster collaborations between awardees and technology service providers.
- Promote the career development of junior faculty members in the ITHS.

In 2008, twelve grants were awarded, including the recipients featured below.



Tueng Shen, M.D., Ph.D., an Assistant Professor of Ophthalmology at UW, is hoping to revolutionize the approach to eye disease monitoring and treatment in the future. Using funds from the ITHS Technology Access Grant and collaborating with Electrical

Engineering assistant professors Brian Otis and Babak Parviz, Dr. Shen has utilized new imaging technologies in the Center for Nanotechnology to develop an artificial cornea, or contact lens, that will be able to sense and wirelessly report intraocular pressure and other measures of eye health.



Anne M. Stevens, M.D., Ph.D., is an attending physician at Seattle Children's Hospital and Assistant Professor at the UW School of Medicine. Her research interest is in the role that maternal cells play in the pathogenesis of autoimmune diseases.

The Technology Access Grant has enabled her to isolate single maternal cells in tissues, cut them out with a laser microscope, and isolate their RNA and DNA for analysis.



Kristina Utzschneider, M.D., is an attending physician at VA Puget Sound and an Assistant Professor of Medicine at UW. She is researching insulin sensitivity and glucose metabolism in conditions of chronic liver disease. With the support of a Technology

Access Grant and in conjunction with the VA Memory Wellness Program, she is measuring liver fat using magnetic resonance spectroscopy imaging techniques to quantify the amount of fat in the liver before and after 4 weeks on either a high fat/high saturated fat diet or a low fat/low saturated fat diet in older subjects.

"With the support of a Technology Access Grant...I will be able to learn much more about what kinds of maternal cells are in the tissues and what functions they may be serving to help or harm the child." (Anne Stevens)

# RESEARCH EDUCATION

The explosion of biological knowledge and technology outpaces the current health care delivery system. The ITHS KL2, TL1, and Tuition Fellows education programs help create the interdisciplinary clinical and translational research workforce of the future.

### **KL2 Multidisciplinary Clinical Research Career Development**

The KL2 program helps post-doctorate scholars from all health professions acquire depth in a specific area of research, and also breadth of knowledge about the full spectrum of clinical investigation. Most Scholars obtain a Masters degree from the School of Public Health or the School of Pharmacy.

#### **TL1 Multidisciplinary Predoctoral Clinical Research**

The ITHS TL1 training program provides core curriculum and interdisciplinary clinical and translational research experience to pre-doctoral students in the health professions through either a summer program or a year-long certificate option.

#### **ITHS Tuition Fellows**

The ITHS Fellows Program supports physicians and other health-care professionals who wish to become independent clinical researchers. Each year the program provides tuition support for four quarters to five fellows whose training will lead to an MS or MPH degree in Epidemiology or Health Services.



Dan Doherty, KL2 Scholar Pediatrics, UW School of Medicine

Daniel Doherty, M.D., Ph.D., is an Assistant Professor of Pediatrics. He is a developmental pediatrician focusing on Joubert Syndrome (JS)

and related cerebellar malformation disorders. This project involves collecting medical records and blood samples from multiple families with JS and carrying out a genome-wide scan for regions of halotype sharing in pedigrees with consanguinity. The study aims to find mutations leading to JS in specific functional and positional candidate genes. His work has been published in *Nature Genetics* (July 2007).



Amelia Gavin, KL2 Scholar UW School of Social Work

Amelia Gavin, M.S.W., M.P.P., Ph.D., is an Assistant Professor in the School of Social Work. Her training is in both political science and social work. Her

research efforts include investigating health disparities among African Americans, particularly the role of socioeconomic position across the life course in the incidence of depression, and the association between depression during the prenatal period, childhood socioeconomic position, and preterm delivery when African American women report life event stress.



Helen (Trez) Buckland, TL1 Trainee (year-long) UW School of Nursing

H. Teresa "Trez" Buckland, M.Ed, Ph.C., is a Clinical Assistant Professor in the UW School of Public Health and

a Project Coordinator in the School of Nursing. Her training is in health education and counseling. She is researching the definition of happiness as experienced by young adults, ages 18-35, with schizophrenia or schizoaffective disorder while also investigating the potential of Appreciative Inquiry, a strength-based methodology, as a treatment strategy.



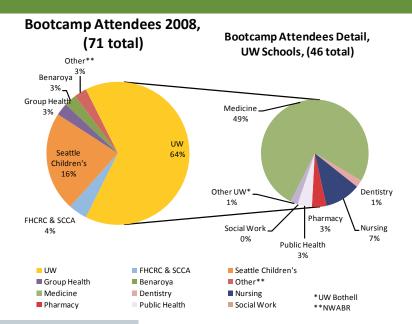
**Bart Scott, ITHS Tuition Fellow** FHCRC, General Oncology and Hematology

Bart Scott, MD, is an Assistant Professor of Medicine at the University of Washington School of

Medicine and an Assistant Member of the Clinical Research Division at the Fred Hutchinson Cancer Research Center. His clinical expertise is in myeloid malignancies and the focus of his research is the design of clinical studies for patients with myeloid malignancies. He is currently investigating the field of stem cell transplantation and novel therapeutics for myeloid malignancies.

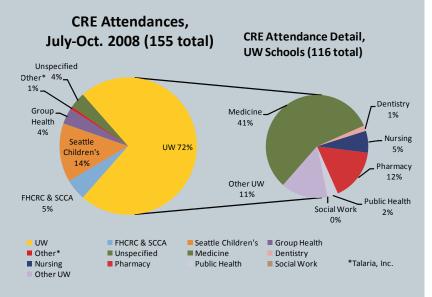
### ITHS Clinical and Translational Research Bootcamp

Incoming and novice researchers often lack a general orientation in clinical and translational research. To address this need, ITHS developed an intensive one-week clinical and translational research Bootcamp that consists of a series of minicourses to introduce specific subject areas such as biostatistical concepts, clinical epidemiology and study design, ethical issues in research on human subjects, grantsmanship, randomized clinical trials, regulatory issues, and scientific writing. The Bootcamp includes seminars with successful investigators. The lectures will be available via streaming video. The first Bootcamp was held September 15-19, 2008, and the program will be held annually.



#### **ITHS Clinical Research Education (CRE) Series**

Staying abreast of industry regulations and standards is a necessary part of any successful clinical research agenda. The ITHS CRE offers a new monthly seminar series for investigators, scholars, and research staff who wish to gain continuing education in research regulations and conducting studies in compliance with Good Clinical Practice standards.





#### **Mentoring and Career Development**

To assist junior investigators in becoming self-sustaining and successful in their translational health sciences careers, the ITHS created a Mentoring and Career Development program. Junior faculty, fellows and postdocs are invited to contact the ITHS Portal to be connected with a mentor, participate in pilot grant reviews through the ITHS Center for Scientific Review, and learn about ITHS career development events. Among our first events were a Grantwriting Workshop and a Mentor-Scholar Retreat. Attendees at ITHS career development events have represented 8 institutions and all 6 UW Health Sciences Schools.

# COMMUNITY PARTNERS

The ITHS Community Outreach and Research Translation (CORT) core aims to increase community participation in all stages of research, foster research relevant to community needs, and promote uptake of research findings in diverse health care settings. CORT joins three large communities.

#### Group Health Center for Health Studies

Group Health Center for Health Studies (CHS) is the research arm of Group Health, a large consumer-governed health maintenance organization with a well-organized provider group. CHS is also a member of the national HMO Research Network.CHS evaluates prevention and treatment interventions for the health problems of its service community, organizes delivery systems to improve the health of entire populations, and translates scientific knowledge into clinical practice. This work has led CHS to develop tools and methods that will be adapted to the needs of American Indian/Alaska Native communities and WWAMI practices.

#### American Indian/Alaska Native communities

Washington, Wyoming, Alaska. Montana, and Idaho have a population of over 400,000 American Indian and Alaska Natives. We are working to engage and form collaborative research partnerships with American Indian and Alaska Native communities in the WWAMI region. We aim to help create new health research networks involving these communities and develop a bi-directional relationship between American Indian and Alaska Native communities and other ITHS members to ensure the relevance of translational research for clinical practice and community members.

#### **WWAMI**

The educational and practice network in the WWAMI region (Washington, Wyoming, Alaska, Montana, Idaho) serves and trains physicians for a widely dispersed and largely rural region in the Pacific Northwest covering 27% of the US land mass. Compared with 19% of the overall U.S. population, 26% of the population in the WWAMI region lives in rural areas, and over half of these individuals live in small or isolated rural areas. We are working to engage and form collaborative research partnerships within the WWAMI region's clinical practices based in primary care training programs.

#### American Indian/Alaska Native Community Partner Profile: The Makah Tribe

The ITHS Community Outreach and Research Translational (CORT) core is strengthening existing partnerships and developing new connections between the UW and American Indian/Alaska Native communities. The Makah Indian reservation is located on the northwestern point of the Olympic Peninsula in Washington State. It covers 47 square miles of forests, mountains, wetlands and beaches. The reservation is remote; its closest cities are Forks, approximately 60 miles south, and Port Angeles, over 100 miles west. There are approximately 2400 Makah tribal members, of which over one-half live in Neah Bay.

Makah reservation residents, both tribal and non-tribal, receive health care at the small but bustling Sophie Trettevick Indian Health Clinic. The clinic is staffed by 37 employees and provides family medicine, pharmacy, laboratory, x-ray, and dental care on site. Through its existing telehealth partnership with UW's Native People for Cancer Control, cancer education, support groups, and case management services are provided to community members.

The Makah Tribe is an active partner of the ITHS CORT. CORT activities with the Makah Tribe include the exploration of a partnership with the UW Rheumatology Clinic, including research and health services and a partnership with the UW Rural Adult Nurse Practitioner Program. The Sophie Trettevick Indian Health Clinic is also a potential pilot site for an ITHS data sharing project with CORT and the ITHS Biomedical Informatics Core.

#### WWAMI Partner Profile: Idaho State University Family Medicine Clinical Research Center

In 2008, the UW Family Medicine Residency Network unanimously approved a pilot project to develop a practice-based research network in the WWAMI region. Focused on teratogens and contraceptive adequacy, the pilot study was launched in collaboration with fifteen WWAMI region-based practices. Network practice members have provided input on study tools (such as data abstraction forms and worksheets and a coding manual) and methods for the pilot project. The Network's Steering Committee includes Drs. Rex Force (Pocatello, ID) and Janelle Guirguis-Blake (Tacoma, WA) from the practice sites. Additional practice representatives serve on a network Advisory Committee: Drs. Jacintha Cauffield (Vancouver, WA), Deb Gould (Yakima, WA), Ron Healy (Anchorage, AK), and Rob Monger (Cheyenne, WA).



The Department of Family Medicine at Idaho State University (ISU) opened its doors in 1992 and has been affiliated with WWAMI ever since. Shortly thereafter the clinical research arm of the department was christened. Rex W. Force, Pharm.D., a clinical pharmacist recently out of a research fellowship at Ohio State University was hired with the mandate of developing a research program. Under his leadership, the ISU Family Medicine Clinical Research Center has sought opportunities to participate in multicenter clinical trials measuring cardiovascular outcomes, studying heart failure, and researching cardiovascular risk reduction. Recently, the Center has begun participating in a trial evaluating treatment in type 2 diabetes. Dr. Force also collaborates with researchers from ISU's College of Pharmacy in the area of drug use review and pharmacoepidemiology.

"The ITHS has created fantastic opportunities for collaboration. The research network of the WWAMI Residencies allows for an exciting exchange of ideas and experiences as well as more opportunity. This isn't possible when when programs work independently." (Rex Force)

#### **Northwest Association for Biomedical Research**

To heighten public awareness of the benefits of research, the ITHS also partners with the Northwest Association for Biomedical Research, a non-profit created in 1989 whose diverse membership spans academic, industry, non-profit research institutes, health care and voluntary health organizations. All NWABR programs are dedicated to promoting the understanding of biomedical research and its ethical conduct.

With ITHS support, NWABR has been able to expand the Speakers' Bureau, speaker trainings, and science cafe programs. These programs demystify science by bringing scientists face to face with students and the public. New community partnerships with Gilda's Club, Seattle CityClub, and Union Church strive to create salient community forums addressing clinical trials and the biomedical research process. NWABR also helps connect national CTSAs by recommending adoption of common metrics to evaluate the impact of community forums addressing low participation rates in clinical trials. NWABR is the recipient of a new five-year Science Education Partnership Award (SEPA).



# **ADVISORY BOARDS**

#### **Oversight Committee**

Paul Ramsey, M.D. (UW School of Medicine)

Thomas Baillie, Ph.D., D.Sc. (UW School of Pharmacy)

Dennis Dyck, Ph.D. (Washington State University)

Tom Hansen, M.D. (Seattle Children's)

Leland Hartwell, Ph.D. (Fred Hutchinson Cancer Research Center)

Maxine Hayes, M.D., M.P.H., Ph.D. (Washington State Department of Health)

Marla Salmon, D.Sc. (UW School of Nursing)

Martha Somerman, D.D.S., Ph.D. (UW School of Dentistry)

Patricia Wahl, Ph.D. (UW School of Public Health)

Edwina Uehara, Ph.D. (UW School of Social Work)

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Kathleen Bracy, M.P.A. (UW School of Medicine)

William Bremner, M.D., Ph.D. (UW School of Medicine)

Martin Cheever, M.D. (Fred Hutchinson Cancer Research Center)

James Hendricks, Ph.D. (Seattle Children's)

Bruder Stapleton, M.D. (Seattle Children's)

Myra Tanita (Fred Hutchinson Cancer Research Center)

Steve Zieniewicz, M.P.H. (UW Medical Center)

#### **External Advisory Board**

Thomas Boat, M.D. (University of Cincinnati, Ohio)

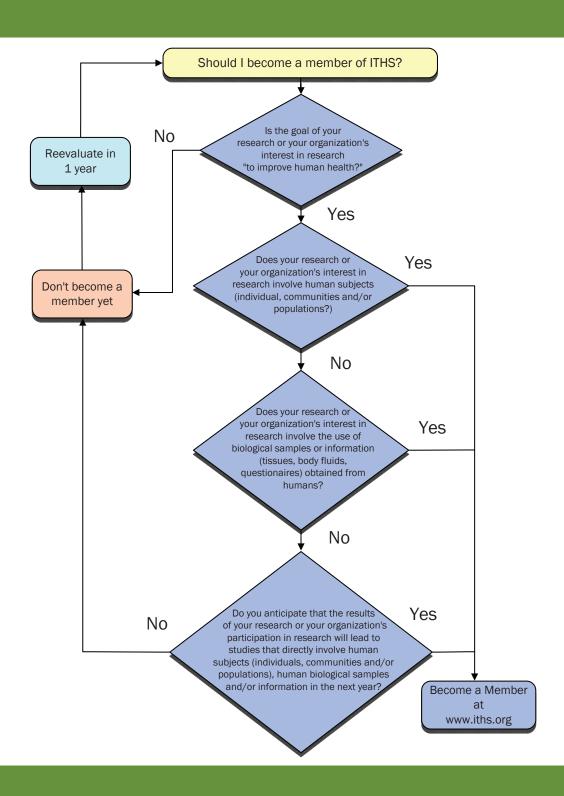
Kathleen Dracup, D.N.Sc. (University of California, San Francisco, California)

Kim (Herbert) Lyerly, M.D. (Duke University, North Carolina)

Cassandra Manuelito-Kerkvliet, Ph.D. (Antioch University, Washington)

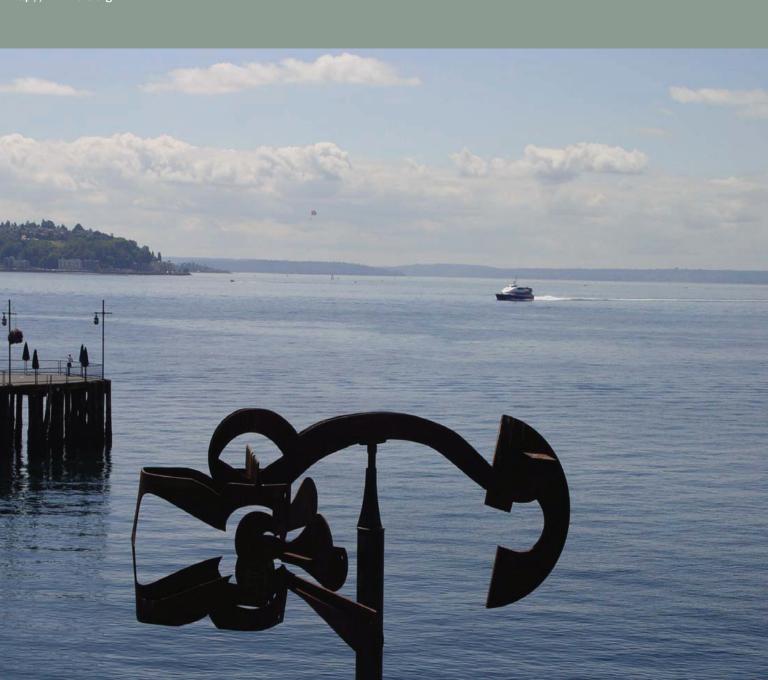
Edward Shortliffe, M.D., Ph.D. (Arizona State University, Arizona)

# Should You Become a member?



#### **Institute of Translational Health Sciences**

University of Washington 815 Mercer Street Building C2, Mailstop 358051 Seattle, WA 98109-4714 206-616-4547 iths@u.washington.edu http://www.iths.org



# Institute of Translational Health Sciences



# ITHS Core and Program Structure

### Administration: Portal and Program Incubator

# Innovative Research and Research Partnerships

Pre-clinical Research
Network

**Biomedical Informatics** 

Community Outreach and Research
Translation Core

# Research Resources

Clinical Research Center Network

Translational
Technologies and
Resources Core

Center for Biomedical Statistics

Regulatory Support and Bioethics Core

# **Education and Career Development**

**Short Courses** 

TL1

**Tuition Support** 

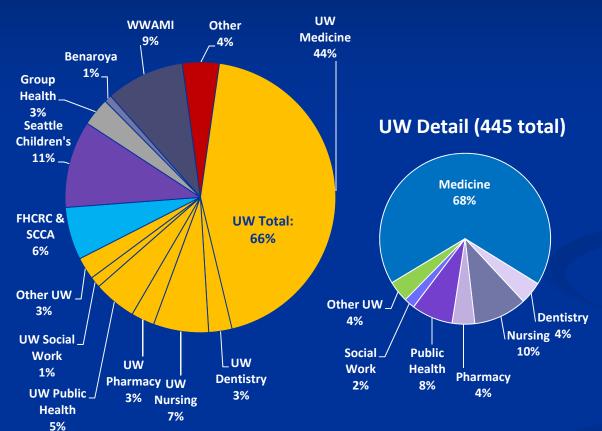
KL2

Overarching Mentoring Programs

Strategic Development and Evaluation

# ITHS Membership: Demographics

# ITHS Membership (682 total)



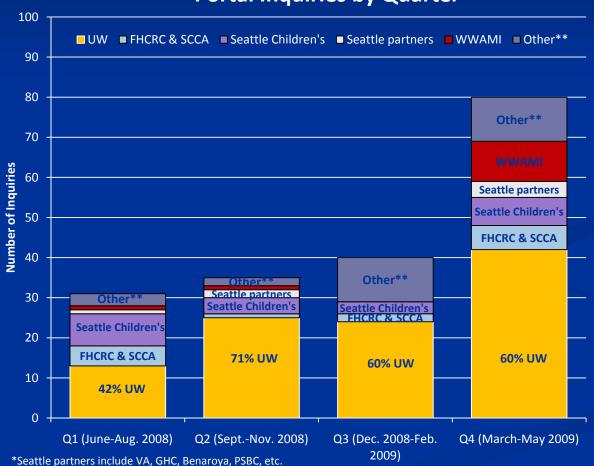


\*In this graph, the Medicine data include researchers who are affiliated with SOM but whose primary location is elsewhere (e.g., SCCA, Children's). This expanded definition enhances consistency between our member data and the SOM reports, which do not distinguish between primary and secondary affiliations.

# **ITHS Consult Services**

### **ITHS Portal Service**

#### **Portal Inquiries by Quarter\***



### Sample inquiries:

- Support development and continuation of research programs (e.g., 2 LSDF proposals funded -Jarvik, Stayton)
- Find collaborators and mentors
- Find technical resources and services for project
- Help with a proposal
- Find research training
- Find funding

<sup>\*\*</sup>Other includes international and small business inquiries and questions from the general public.

# Regulatory and Bioethics Support

- 1. Research bioethics consultation
- Data safety and monitoring plan (DSMP) development
- 3. Regulatory consultation visit program
- Drug and device (preclinical) development
- 5. Investigational new drug applications preclinical regulatory support
- 6. Therapeutic manufacturing (Biosafety level 2 & 3, regulatory support, etc.)

- Cross-institutional investigator clinical research training program
- 8 junior investigators thru educational monitoring program
- Established a research coordinator core
- Supported 4 IND submissions
- Supported 2 SBIR submissions

## Research Lab Services

- 1. Lab instrumentation and techniques
- 2. Scientific instrumentation data access
- 3. Bionutrition and body composition consultation

# Working in the Community

- 1. Conducting practice-based research
- Building partnerships with American Indian/Alaska Native communities

- Created an institutional technology inventory with searchable web tool
- Support Center for Clinical Genomics
- Technology Resource
   Coordinating Committee
- Combining and enhancing core resources
- Established WWAMI Practice
   Based Research Network
- Launched pilot of Data-Quest at key WWAMI practice sites

# Study and Data Management

- 1. Study data management tools
- 2. Computing and IT support for clinical and translational research
- Accessing electronic medical record (EMR) data
- Evaluation (surveys, interviews, etc.) support
- 5. Biomedical statistics
- 6. Research coordinator pool

- Launched the Center for Biomedical Statistics
- Informatics consults, >1500 hrs,
   4 funded grants
- Electronic tools for clinical trials management
- Amalga collaboration with Microsoft
- 110 biostatistical consults,
   >1000 hours

# **ITHS Resources**

# Directory of Technology Resources

#### **Directory Of Technology Resources**

We facilitate access to laboratory and clinical research resources across the greater Pacific Northwest region. Below are resources provided by our member institutions. You may also directly browse Fred Hutchinson shared resources and Seattle Children's resources.

If you prefer, browse resources by location.

To add a new resource, submit a resource center for consideration.



Animal/Living Organisms (bacteria, yeast, nematodes, flies, plants, fish, mice, etc.)

- BioMolecular Imaging Center
- CEEH Analytical Cytology Core (Facility Core 3)
- Center for Nanotechnology
- Center on Human Development and Disability
- Keck Microscopy Facility
- Mouse Behavioral Core
- Mouse Metabolic Phenotyping Center
- Small Animal Tomographic Analysis Facility (SANTA)
- · Transgenic Resources Program
- UW Superfund Basic Research Program
- · Washington National Primate Research Center

Biological Macromolecule Analysis (proteomics, x-ray crystallography, NMR spectroscopy, etc).

- · BioSpectroscopy Core Research Facility

### Highlights to date:

- Currently 52 UW resources listed plus resources in region
- Includes 22 resources for data management/statistical analysis/informatics
- 8 resources have biological sample archives
- Collecting WWAMI resources for entry

www.iths.org

### Clinical Research Resources

- 1. Benaroya Research Institute Clinical Research Center
- 2. Bionutrition research
- 3. Body Composition/Bioenergetics and Exercise Core Labs
- 4. Center for Clinical Genomics
- 5. Pediatric Clinical Unit at Seattle Children's Hospital
- 6. Therapeutic Manufacturing Gene and Cell Therapy Laboratory
- University of Washington's Regional Clinical Dental Research Center (RCDRC)
- 8. UW Clinical Research Center (CRC)
- 9. VA Puget Sound Health Care System Clinical Research Unit

# **ITHS Grant Programs**

### **Small Pilot Project Grants**

Twice yearly 10K

### **Technology/Resource Access Grants**

Three times/yr 10K

# **Ignition/Primate Center Award**

Annually 100K

### **ITHS Pediatric Small Grants**

Annually 20K

## **ITHS Ignition/Pharmacy Award**

Annually 20-40K

- In first 20 months, ITHS awarded 75 grants for \$1.23M to investigators representing 9 institutions
- Funding level 20-35% depending on mechanism
- Training program for grant review
- Mentor program for those grants that miss funding

# **ITHS Educational Programs**

# Degree and Certificate Programs

**Predoctoral Multidisciplinary Clinical Research** 

**Training** - offered as both a summer and a 12-24 month certificate-degree program.

Postdoctoral Clinical Research Career Development -

multidisiplinary program, up to 5 years in length.

ITHS Tuition Support Fellowship - provides tuition support for MS or MPH degree in Epidemiology or Health Services from the School of Public Health and Community Medicine.

# New Seminars and Short Courses

ITHS monthly Clinical Research Education Series - A seminar series for investigators and research staff that features 23 clinical and translational research topics to be presented over two year cycle.

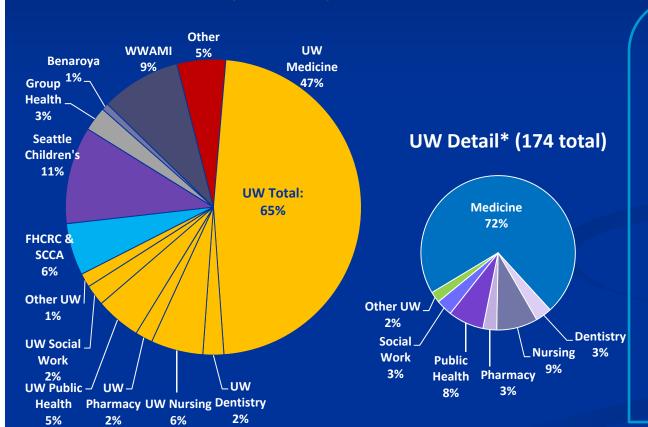
ITHS monthly Career Development Series for Scholars - A seminar series for scholars that features topics such as grant-writing, writing for publication, presenting at scientific meetings, and more.

ITHS annual Boot Camp - A yearly camp, held in September, that provides an orientation to clinical and translational research for incoming and novice researchers or those with clinical and translational research interests.

**Educational Clearinghouse** 

# **Mentoring Program**

# ITHS Scholar Members by Institution (263 total)



- Multi-disciplinary mentoring teams
- Mentor the mentor program
- Training in grant review
- Grant writing assistance
- Career development seminar series
- Grant writing course

# **ITHS** Research

- Bioethics of specimen repositories
- CPI optimizing translational research
- Discovery to health application...