|  |
| --- |
| *Instructions: Tailor this template to your project, specifying ITHS resources that might be used in your research. Brief descriptions of individual ITHS resources are included at the end of this support letter template, and more information is available on our website (*[*http://www.iths.org*](http://www.iths.org)*). Our Research Navigator (**ithsnav@uw.edu**) can offer personalized guidance to ITHS resources and can help you design a stronger Letter of Support.* *Many ITHS resources are provided at no cost to researchers, whereas others are offered on a fee-for-service basis. Before submission, we strongly encourage consultation with ITHS staff to discuss services, scope of work, and, as applicable, cost estimates related to your project.* ***Please allow at least 5 business days for your letter to be processed.*** *Submit your draft via the* [*ITHS Letter of Support webform*](https://www.iths.org/investigators/forms-templates/letters-of-support/)*. We will return a signed PDF version of the letter to the contact e-mail you provide.* *All information that you submit via this Letter of Support will be managed in accordance with the* [*privacy and security policy*](http://www.iths.org/privacy) *for this website (*[*www.iths.org*](http://www.iths.org)*).*  |

|  |  |
| --- | --- |
| **DATE SIGNED LETTER IS NEEDED:** | [INSERT DATE] |
| **CONTACT INFO for letter delivery/ questions:** | [INSERT NAME, PHONE, EMAIL] |
| **FOA NUMBER, TITLE, OR LINK** | [INSERT LINK OR FOA NUMBER] |
| **PROJECT ABSTRACT**[PLEASE PROVIDE A BRIEF SUMMARY OF THE PROJECT] |

[INSERT ADDRESS THAT SHOULD APPEAR ON THE LETTER]

RE: [INSERT TITLE OF APPLICATION, FUNDING ORGANIZATION, RFA # AS RELEVANT]

Dear [NAME OF ADDRESSEE],

As Associate Dean of Translational Science at the University of Washington (UW) School of Medicine and Director for the Institute of Translational Health Sciences (ITHS), I am pleased to write this letter in support of your project, “[PROJECT TITLE].”

ITHS develops and maintains resources and educational programs that support the spectrum of translational research activities. ITHS is a partnership between UW, Seattle Children’s, and Fred Hutch and supports translational research at institutions across the five-state Washington, Wyoming, Alaska, Montana, and Idaho (WWAMI) region. ITHS is funded by an NIH Clinical and Translational Science Award (CTSA). The national CTSA consortium is dedicated to improving human health by fostering translation of knowledge from basic science to clinics and communities.

If your project is funded, ITHS can support your research through a range of resources and services. Among our programs are: expert consultations in biomedical informatics, biomedical statistics, and bioethics; research coordination and regulatory support; access to community-based research programs; and specialized resources such as technology development, therapeutic manufacturing, dedicated patient rooms and staff supporting clinical research. Our Research Navigator is available for personalized guidance to our portfolio of services, educational programs, funding opportunities, and other research resources.

A few specific ITHS programs relevant to your research are described below.

[INSERT RELEVANT ITHS RESOURCES HERE – SEE SAMPLE PARAGRAPHS AT THE END OF THIS TEMPLATE]

As you are aware, clinical research often requires investigators to obtain regulatory approval through Institutional Review Boards or other regulatory bodies, and access to some ITHS services will require appropriate regulatory documentation. In addition, some ITHS services have associated costs; you will be provided with specific cost estimates prior to accessing these services. ITHS staff will work with you to determine the availability and costs of our resources and to guide you through any approvals that may be required from ITHS administration.

We wish you success with your application and look forward to a fruitful collaboration.

Sincerely,

John K. Amory, MD, MPH, MSc

Director, Institute of Translational Health Sciences

Associate Dean for Translational Science

Professor of Medicine

University of Washington School of Medicine

DESCRIPTIONS OF SPECIFIC ITHS RESOURCES

*Outlined below are some specific ITHS programs that are available to support your research. To ensure a strong and specific letter, please select resources applicable to your project and insert them into the letter above. We encourage you to adapt descriptions according to the needs of your project and add a sentence or two about the relevance of the resource to your proposed work.*

*Contact our Research Navigator at* *ITHSNav@uw.edu* *for assistance identifying and connecting with services and resources that might benefit your project. Please be aware that services require lead time to provide initial consultation, prepare a budget estimate, or facilitate connections with potential collaborators/resources across the WWAMI region. ITHS services provide initial consultations at no cost to investigators and can work with you to budget hours for direct service or in a consultative/training capacity.*

**CLINICAL RESEARCH AND REGULATORY SUPPORT**

[**Research Coordination Center**](https://www.iths.org/rcc): In partnership with the UW School of Medicine, ITHS has established the UW Medicine Clinical Trials Office (CTO). CTO provides an array of clinical research support services for both investigator and industry initiated interventional trials and non-interventional clinical research studies. The CTO’s Research Coordination Center (RCC) is a multidisciplinary team of research coordinators, regulatory specialists, and study monitors providing creative research staffing solutions for projects that involve human research participants. We offer support in completing IRB and other regulatory applications, study monitoring, study start-up, and protocol implementation. Our team is experienced in creating customized REDCap databases to electronically collect data for clinical trials, administer surveys, and create longitudinal studies. RCC staff can also provide training to your staff to help you develop a strong research team.

**Multisite Trial Support:** As a CTSA program hub, ITHS is a [partner in the Trial Innovation Network (TIN),](https://www.iths.org/investigators/services/trial-innovation-network/%29) a collaborative national initiative that provides consultations and infrastructure to support multisite clinical trials. TIN services include: central IRB review enabling compliance with the NIH single IRB policy; assistance finding partner investigators for domestic and international trials; feasibility assessments; study design consultations; and clinic and data coordinating centers. The ITHS TIN liaison will assist you in preparing and submitting your study proposal to the TIN.

[**Recruitment Resources**](https://www.iths.org/investigators/tools-resources/recruitment-resources/): Difficulty recruiting participants is a key reason for delays in clinical trials. To help investigators overcome challenges with recruitment, ITHS has developed a repository of recruitment resources including feasibility assessment tools, recruitment toolkits, and patient registries. In partnership with UW School of Medicine, ITHS provides a free, passive patient recruitment service website ([Participate in Research](https://www.iths.org/participate/)) where potential volunteers can identify research opportunities including observational, therapeutic, and diagnostic studies. We also facilitate UW investigators’ access to [ResearchMatch](https://www.researchmatch.org/), a national recruitment registry that helps match volunteers with research studies of interest.

[**Recruitment Support Service**](https://www.iths.org/investigators/services/recruitment-support-service/): The ITHS Recruitment Support Service (RSS) offers both pre- and post-award guidance on study-specific recruitment and retention strategies throughout the lifespan of a study. This team brings together extensive experience in clinical trial design and implementation, biomedical statistics, research participant protections, and biomedical informatics. The RSS team can assist with feasibility assessment, budget review, early-stage study design, and planning related to participant accrual and retention. As you prepare to implement your study, we can assist with the development of a comprehensive recruitment plan and materials. The RSS team also offers support for active studies to boost recruitment, meet accrual milestones, and retain enrolled volunteers.

**CONSULTING AND MENTORING**

**Statistical Services:** Statistical support from ITHS is coordinated through the UW [Center for Biomedical Statistics](https://www.biostat.washington.edu/research/centers/cbs) and the [Biostatistics, Epidemiology, and Analytics in Research (BEAR) Core at Seattle Children’s](https://www.seattlechildrens.org/research/resources/bear/). These teams provide guidance on design and analysis options for study proposals for Phase 1 through Phase 3 trials. We have experience in both animal research and clinical trials. Consultations include advice on identifying optimal study designs that are appropriately powered and cost efficient for study objectives; sample size and power estimations to detect clinically or biologically meaningful effects; and randomization strategies. We also offer guidance on translating scientific hypotheses into actionable analyses, choosing appropriate statistical methods, analyzing and reporting data, and coordinating data for multicenter studies. ITHS Biomedical Statistics teams also work with Biomedical Informatics to ensure timely and thorough data collection and quality assurance review.

[**Biomedical Informatics (BMI)**](https://www.iths.org/bmi): ITHS offers a variety of biomedical informatics services including access to Electronic Health Record (EHR) data, biospecimen acquisition and management tools, computing and IT support, and study data management tools. Our team of expert consultants can work with researchers to determine how to best manage biospecimen data, manage data in multisite research studies, extract clinical data from EHRs, develop algorithms to screen patients for eligibility in clinical studies, develop custom queries to extract and derive clinical variables, states, phenotypes, and outcomes, and automate transfer and ingestion of extracted EHR data into customized databases. In addition to available enterprise data, investigators can access [DataQUEST](https://www.iths.org/dquest/), a tool to harness primary care data for over 250,000 patients across Washington and Idaho.

BMI has developed [Leaf](https://www.iths.org/investigators/services/bmi/leaf/), a self-service tool that provides UW Medicine investigators with a user-friendly interface for querying live data from UW Medicine EHRs. Leaf can assist with cohort identification, feasibility assessment, and chart abstraction.

BMI supports [REDCap](https://www.iths.org/redcap) access and technical support for non-commercial use by institutions across the WWAMI region. REDCap is an electronic data capture system that can be used to administer surveys, collect data for clinical trials, track adverse events, conduct remote e-consent of patients, and to create longitudinal studies.

The [**Technology Development Center**](https://www.iths.org/investigators/services/technology-development-center/) has clinical, regulatory, reimbursement, and commercialization experts to assist investigators seeking to commercialize a small molecule, biologic, diagnostic, medical device, or digital health application. Services include customer discovery coaching, market opportunity assessment, commercialization planning, regulatory strategy and filings, FDA pre-submission support, as well as helping connect investigators with mentors and investors.

The [**Drug and Device Advisory Committee**](https://www.iths.org/investigators/services/technology-development-center/ddac/) (DDAC) assists academic investigators seeking to move a drug or device through preclinical testing and into the clinic. DDAC provides consultation on preclinical development plans, focusing on tasks needed to efficiently move an innovation to the clinic in accordance with FDA guidelines. DDAC can also provide insight into associated costs and complications that investigators might anticipate during the process. Committee members have extensive industry experience, with expertise in regulatory affairs, toxicology, animal models, pharmacokinetics, and assay development and validation.

[**Clinical Research Grant Consultation**](https://www.iths.org/investigators/services/clinical-trials-consulting/): The Scientific Success Committees (SSC) is available to review clinical study design and feasibility, giving investigators feedback early in project planning. SSC members include highly experienced clinical investigators as well as experts in biostatistics, bioethics, and community engagement. The committee can offer guidance in all aspects of study design, including development of research questions, approach, outcome measures, feasibility, clinical appropriateness, and statistical planning.

The [**Dissemination and Implementation (D&I) Program**](https://www.iths.org/community/partners/d-i/) helps investigators identify strategies to accelerate adoption of guidelines or interventions and refine research plans and products for successful implementation in real-world settings. We can help investigators select methods and tools to scale up and spread their research findings, identify appropriate clinical or community-based settings, and connect you with key stakeholder representatives and potential research partners. We can also assist with identifying valid measures, tools, and study design to evaluate the effectiveness of implementation practices.

The [**Research Bioethics Consultation Service**](https://www.iths.org/investigators/services/bioethics/) provides advice on any ethical issues that may arise during the development, implementation, or analysis of clinical and translational research. The team has expertise in bioethics, medicine, and law and offers investigators a forum for in-depth conversation and analysis to help improve the quality of their research.

[**Team Science**](https://www.iths.org/investigators/services/team-science/) provides research teams with strategies and tools that help them build stronger relationships and function more effectively. We provide facilitation and consulting services for teams, centers, and individuals. Our training includes online training, an Annual Team Science Boot Camp, executive coaching, and Lean project management training. We also offer tools to support the recognition of interdisciplinary research and collaboration in academic career advancement.

[**RESEARCH FUNDING**](https://www.iths.org/funding/)

ITHS offers funding for novel, innovative, and collaborative translational and clinical research. [New Interdisciplinary Academic Collaborations Awards](https://www.iths.org/investigators/funding/trpa-academic-collaborations/) encourage the development of new, interdisciplinary collaborations between investigators in projects addressing critical transitions in translational research. [Academic/Community Partnership Research Awards](https://www.iths.org/investigators/funding/trpa-academic-community-partnerships/) foster collaborations between academic and community investigators. [Early-Stage Product Development Awards](https://www.iths.org/investigators/funding/early-stage-product-development-award/) support translation of clinically relevant research discoveries toward development of commercial products that improve human health.

Early stage investigators can also apply for critical, just-in-time support for research proposals through [Voucher Awards,](https://www.iths.org/investigators/funding/ei-voucher/) providing in-kind support for ITHS services, or [Catalyst Awards,](https://www.iths.org/investigators/funding/ei-catalyst/) granting direct cost support for research supplies or services.

**ITHS RESEARCH UNITS**

[**Adult Translational Research Unit**](https://www.iths.org/investigators/units/tru/):The Clinical Trials Office’s Translational Research Unit (TRU) offers investigators clinical support and infrastructure needed to conduct research. The TRU offers access to dedicated research space with patient rooms, specially trained nursing staff, a CLIA-certified laboratory processing room, and state-of-the-art equipment. Nursing support may include IV infusions, monitoring of adverse events, frequent vital signs, EKGs, and high volume and closely timed blood draws. Space is available for consenting patients, administering questionnaires, and conducting physical examinations.

The TRU also provides mobile on-call nurses to travel to inpatient units within UWMC or Harborview to complete needed clinical activities. This service ensures that all research protocols can be accommodated during anticipated and unanticipated admissions while a patient is enrolled in a research study. These mobile TRU nurses can also be sent to ambulatory clinics at UW or other settings where clinical research is conducted for the convenience of the participants and investigators.

[**Pediatric Clinical Research Center**](https://www.iths.org/investigators/units/pcrc/): The Pediatric Clinical Research Center (PCRC) at Seattle Children’s provides space and resources to conduct clinical and translational research in children less than 21 years of age. PCRC offers dedicated research space with patient rooms, Good Clinical Practice (GCP)- and Pediatric Advanced Life Support (PALS)-certified nursing staff, and state-of-the-art equipment. Nursing support may include IV infusions, monitoring of adverse events, frequent vital signs, EKGs, and high volume and closely timed blood draws. Nurses are available to travel to Seattle Children’s inpatient units to ensure that research protocols can be accommodated during anticipated and unanticipated admissions while a patient is enrolled in a research study. Research nurses can also be sent to ambulatory clinics at Seattle Children’s or other settings where clinical research is conducted for the convenience of the participants and investigators.

[**Regional Clinical Dental Research Center**](https://www.iths.org/investigators/units/rcdrc/): The Regional Clinical Dental Research Center (RCDRC) provides facilities, resources, and personnel to conduct translational and clinical research related to oral diseases. Facilities include two oversized dental operatories and a biomedical laboratory for initial specimen processing and an area for coordinator activities. Personnel support includes research project coordination, regulatory management, participant recruitment, dental hygiene/dental assisting services, and study design and implementation consultation. RCDRC personnel are available to provide research services in other units and clinics and are experienced in the logistics of conducting field research, with flexible scheduling available.

[**Gene and Cell Therapy Lab**](https://www.iths.org/investigators/units/gctl/): The Gene and Cell Therapy Lab (GCTL) provides researchers with infrastructure, training, and technical expertise to facilitate translation of promising cell-based therapies. The GCTL can be contracted to manufacture gene- and cell-based clinical products for therapeutic applications that are compliant with standards set by FDA and state and local regulatory bodies. GCTL is a Current Good Manufacturing Practices (cGMP) facility that maintains its good standing with regular audits and regulatory filings. GCTL can also train and qualify researchers to work within GCTL facilities to be a part of the team manufacturing cell products.

[**COMMUNITY PROGRAMS**](https://www.iths.org/community/)

The Community Engagement Program offers expertise and resources for translational research with community partners and facilitates academic, community, and clinical research partnerships. Our team of experts can work with investigators to develop effective engagement plans, assess training needs and research capacity, and provide ongoing technical support. We provide guidance on returning study results to communities and tools for improving adaptation and adoption of evidence-based discoveries in a variety of settings. We also offer assistance with protocol development, grant proposal preparation, and implementation of funded projects.

ITHS has established collaborative pathways for academic- and community-based research with clinicians and clinical organizations, patients or individuals in the community, and community-based organizations in the WWAMI region, including rural populations with adverse health outcomes. Investigators can partner with the WWAMI-region Practice and Research Network ([WPRN](https://www.iths.org/investigators/find-collaborators/primary-care-research-network/)), a network of about 100 primary care practices that offers investigators tools and connections to conduct collaborative research in community-based primary care clinical settings. The Northwest Participant and Clinical Interactions ([NWPCI](https://www.iths.org/investigators/find-collaborators/clinical-research-centers/)) Network is a consortium of clinical and translational research centers dedicated to providing local access to high-quality research across the ITHS partners and the WWAMI region. NW PCI enables investigators to collaborate with clinicians and clinical organizations, access a broad range ofinpatient and outpatient populations, and conduct their clinical research in real-world settings.

**[EDUCATION AND TRAINING PROGRAMS](https://www.iths.org/education/)**

Researcher education and training is an important part of the ITHS mission. We have a number of educational programs that could support your project.

The [**Career Development Series**](https://www.iths.org/education/professional-development/cds/) is a bi-monthly seminar series targeted to early-stage investigators. The series focuses on practical tools necessary for a successful career in research and academia. Topics have included grantsmanship, scientific writing, data visualization, mentoring, team science, and presentation skills.

The [**Clinical Research Education Series**](https://www.iths.org/education/professional-development/rc/cres/) is a continuing education and training series for research coordinators, other research staff, and investigators focused on clinical research topics such as informed consent and single IRBs. Sessions are held five times per year and include speakers from Fred Hutch, Seattle Children’s, UW, and the WWAMI region.

The [**Networking to Enhance Development (NED)**](https://www.iths.org/education/professional-development/rc/annual-research-coordinator-ned-conference/) Conference is an annual, day‐long professional development event held in Seattle. It is intended for professionals at all experience levels who perform clinical research operations duties in the health sciences fields. Participants attend general sessions and choose relevant breakouts to expand their knowledge and skills in clinical research operations. The NED Conference is a collaboration between UW, Fred Hutch, and Seattle Children’s.

[**KL2 Program**](https://www.iths.org/education/KL2): The ITHS KL2 Multidisciplinary Clinical Research Career Development Program provides protected time, funding, and mentorship to foster training of early career clinical and translational researchers. The program offers up to three years of support for scholars holding a research or health professional doctoral degree applicable to clinical research. The KL2 program is tailored to the research and career development needs of each scholar through a flexible curriculum. Investigators are trained in-depth in a specific area of research, while also learning the full spectrum of translational research. The program encourages all types of clinical research, including patient-oriented research, translational research, small- and large-scale clinical investigations and trials, epidemiologic and natural history studies, health services research, and health behavior research.

[**TL1 Program**](https://www.iths.org/education/TL1): The ITHS TL1 Multidisciplinary Predoctoral Clinical Research Training Program provides one year of early career development for health science and related doctoral students, with an emphasis on preparing them as translational scientists who excel in interdisciplinary teams. The curriculum is based on nationally developed core competencies for clinical and translational research and incorporates didactic coursework, mentored training, work-in-progress research discussions, and conferences.

[**ITHS/WRF Summer Commercialization Fellowship**](https://www.iths.org/education/graduate/commercialization-fellowship/): ITHS/WRF Summer Commercialization Fellows explore the commercialization potential of early-stage technologies emerging from research labs at ITHS partner institutions. Fellows work with inventors, technology managers, and experts in market research, customer discovery, regulatory and clinical affairs, and venture investment to develop the business aspects of the project. The program has supported startup company launches, identification of licensing opportunities, and expanded research goals.