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| *Instructions: Please tailor this template to your project and be specific about how ITHS resources will be used in your research. Detailed descriptions of individual ITHS services are available on our website (*[*http://www.iths.org*](http://www.iths.org)*) or at the end of this support letter template. Our Research Navigator is available to provide you with personalized guidance to ITHS resources and can help you design a stronger Letter of Support. Please contact the Navigator at* *ithsnav@uw.edu**.**Before submission, we strongly encourage consultation with ITHS staff to discuss ITHS services’ scope of work within your project. This will help with customizing the template below and, as needed, provide cost estimates to include in your proposal budget.* ***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)*).*  |

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| --- | --- |
| **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 by offering a number of resources and services. Among our programs are: expert consultations in biomedical informatics, biomedical statistics, and bioethics; regulatory support; access to community-based research programs; and specialized resources such as therapeutic manufacturing, patient rooms, and clinical research staffing solutions. 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,

Mary L. (Nora) Disis, MD, FACP

Associate Dean, Translational Science, University of Washington School of Medicine

Professor, Medicine

Member, Fred Hutchinson Cancer Research Center

Director, Institute of Translational Health Sciences

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 only select resources applicable to your project and insert them into the letter above. We encourage you to adapt 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* *if you have any questions or to learn more about ITHS resources.*

***Clinical Research and Regulatory Support***

[**Research Coordination Center**](https://www.iths.org/rcc)**:** The 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 subjects. 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.

[**Data Safety Monitoring Services**](https://www.iths.org/dsm)**:** ITHS offers data and safety monitoring of clinical trials, which may be necessary to ensure participant safety and compliance with approved protocols. We can establish and facilitate data monitoring committees and independent medical monitors, as well as review and develop data safety monitoring plans.

[**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 has developed [Participate in Research](https://www.iths.org/participate/), a website where potential volunteers can search studies posted by research teams. We also facilitate UW researchers’ 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 project-specific guidance on study recruitment and retention throughout the lifespan of a study. This team brings together extensive experience in clinical trial design and implementation, biomedical statistics, human subjects protections, and biomedical informatics. The RSS team can assist with feasibility assessment, budget review, study design, and planning related to participant accrual and retention. As you prepare to implement your study, they 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.

**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 CTSA 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. *[You may want to request an additional letter of support directly from the TIN. Contact the ITHS Research Navigator (**ithsnav@uw.edu**) for additional information.]*

***Consulting and Mentoring***

**Statistical Services:** Statistical support from ITHS is coordinated through the UW [Center for Biomedical Statistics](https://www.iths.org/CBS) and the [Children’s Core for Biomedical Statistics](http://www.seattlechildrens.org/research/cores/ccbs/). These teams provide guidance on design and analysis options for study proposals for Phase 1 through Phase 3 trials. They 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. They 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 Medical Record (EMR) 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 manage data in multisite research studies, extract clinical data from EMRs, develop algorithms to screen patients for eligibility in clinical studies, and automate transfer and ingestion of extracted EMR data into customized databases.

BMI has developed [Leaf](https://www.iths.org/investigators/services/bmi/leaf/), a self-service tool which provides UW Medicine researchers with a user-friendly interface for querying live data from UW Medicine EMRs. Leaf can assist with cohort identification, feasibility assessment, and chart abstraction. Through the BMI group, researchers can also access [DataQUEST](https://dataquest.iths.org/), a tool to harness primary care data across Washington and Idaho for research.

BMI supports [REDCap](https://www.iths.org/redcap) access and technical support for academic institutions in 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, and create longitudinal studies.

[**Early-stage Drug and Device Development**](https://www.iths.org/prd)**:** Academic researchers seeking to move a drug or device through preclinical testing to the clinic can access the Drug and Device Advisory Committee (DDAC). DDAC reviews propose innovations and provide consultation on preclinical development plans, focusing on tasks needed to efficiently move the drug to the clinic in accordance with FDA guidelines. The group can also provide insight into associated costs and complications that investigators might anticipate during the process. DDAC members have extensive industry experience, with expertise in regulatory affairs, toxicology, animal models, pharmacokinetics, and assay development and validation.

[**Clinical Trials Consulting**](https://www.iths.org/investigators/services/clinical-trials-consulting/)**:** To support researchers in overcoming challenges associated with conducting clinical trials, ITHS has developed a Clinical Trials Mentoring Program (CTMP). The CTMP offers guidance and recommendations to researchers on the steps to design and implement high-quality clinical trials, incorporating expertise in biostatistics, protocol design, regulatory issues, data collection, and monitoring.

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

[***ITHS Funding***](https://www.iths.org/investigators/funding-opportunities/)

ITHS offers funding for novel, innovative, and collaborative translational and clinical research. [Collaboration Innovation Awards](https://www.iths.org/investigators/funding-opportunities/iths-collaboration-innovation-awards/) 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-opportunities/iths-academiccommunity-partnership-research-awards/) foster collaborations between academic and community investigators. The [Research Innovation Award](https://www.iths.org/investigators/funding-opportunities/iths-research-innovation-awards/) targets clinical or translational research that can be used as a vehicle to develop new methods, policies, or procedures that will aid in the conduct of research.

ITHS also offers awards to help early stage investigators with critical support that may be needed for a project through [Voucher](https://www.iths.org/investigators/funding-opportunities/iths-early-investigator-voucher-awards/) and [Catalyst Awards](https://www.iths.org/investigators/funding-opportunities/iths-early-investigator-catalyst-awards/).

***ITHS Research Units***

[**Adult Translational Research Unit**](https://www.iths.org/investigators/units/tru/)**:** The ITHS Translational Research Unit (TRU) offers investigators the support and infrastructure needed to conduct clinical and translational 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 PALS-certified nursing staff, psychometry services, 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. The PCRC also offers a study facilitator who can assist research teams with protocol development, study start-up, and recruitment tracking.

[**Regional Clinical Dental Research Center**](https://www.iths.org/investigators/units/rcdrc/)**:** The Regional Clinical Dental Research Center (RCDRC) provides space and resources to conduct translational and clinical research related to oral diseases. Facilities include two oversized dental operatories and a biomedical laboratory for initial specimen processing. Personnel support includes research project coordination, regulatory management, participant recruitment, dental hygiene/dental assisting services, and study design and implementation consultation. The RCDRC personnel are available to provide research services in other units and clinics. They 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 for dissemination and implementation of clinical and translational research findings. The program can provide consultation on how to engage community partners in research as well as connections with community partners for your research project. They provide guidance on returning study results to communities and tools for improving adaptation and adoption of evidence-based discoveries in diverse settings. The program assists with protocol development, grant proposal preparation, and implementation of funded projects related to community-based research. Expertise in the engagement of community-based organizations, patients, clinicians, and clinical organizations is available to help researchers new to community-driven or -engaged research and experienced researchers seeking innovative methods and solutions.

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.  Researchers 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 more than 60 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 creates infrastructure for investigators to collaborate with community-based clinicians, access diverse inpatient and outpatient populations, and conduct their clinical research in real-world settings.

*[If you would like to partner with network sites, we recommend connecting with WPRN or NWPCI Network at least eight weeks before your submission deadline to identify sites, develop the study budget, and obtain a network-specific letter of support. Contact the ITHS Research Navigator (**ithsnav@uw.edu**) for additional information.]*

[***Education and Training Programs***](https://www.iths.org/ED)

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

The [**Career Development Series**](https://www.iths.org/news-events/calendar/cat_ids~84/) is a 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, and presentation skills.

The [**Introduction to Clinical Research Boot Camp**](https://www.iths.org/?p=30555) is a two-day intensive, immersive workshop that trains investigators and research staff in translational research topics such as study design, study start-up, and research compliance. The workshop is open to all disciplines and provides an excellent opportunity to learn the fundamentals of translational science and an introduction to clinical research.

The [**Clinical Research Education Series (CRES)**](https://www.iths.org/?p=19518) is a continuing education and training series for research staff and investigators interested in clinical research topics. This 90-minute event is held in Seattle four times per year and includes speakers from Fred Hutch, Seattle Children’s, and UW. Regional partners participate in workshops at local sites simultaneously by way of live video feed and coordinated local workshops.

The [**Networking to Enhance Development (NED)**](https://www.iths.org/?p=19520) Conference is an annual, day‐long professional development conference for research coordinators held in Seattle. 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. It is intended for professionals at all experience levels who perform clinical research operations duties in the health sciences fields at any of our partner institutions.

[**KL2 Program**](https://www.iths.org/education/KL2)**:** The ITHS KL2 Multidisciplinary Clinical Research Career Development Program provides protected time, funding, and rigorous 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 clinical 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 through didactic coursework, mentored training, work-in-progress research discussions, and conferences. Trainees master the first twelve of fourteen CTSA core competencies for clinical and translational research during this program.

[**ITHS/WRF Summer Commercialization Fellowship:**](https://www.iths.org/education/graduate/mba-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.