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## UW ICTR Learning Health System Demonstration Project 2024-2025 Program Announcement

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A Learning Health System (LHS) helps bring research into healthcare practice, providing necessary evidence at moments when stakeholders see an opportunity to make healthcare more efficient and effective. The establishment of a Learning Health System aligns with the goals of the Agency for Healthcare Research and Quality (AHRQ), as the LHS uses data to track changes in healthcare and applies proven strategies to enhance patient safety and care. An integral component of this system is the Plan-Do-Check-Act (PDCA) cycle. This cycle helps transform data into knowledge, apply that knowledge, and feed information on results back into the data pool. This process is key to fostering an LHS, encouraging culture shifts that support real-world clinical trials, and ultimately accelerating the delivery of precise, evidence-based care to improve patient health outcomes.

However, implementation of these LHS principles has been slow, leading to growing health inequalities and soaring healthcare costs. The slow uptake of evidence-based practices in everyday care has resulted in notable delays in enhancing health outcomes. Achieving the LHS's promise of clinical and operational improvements and widely applicable knowledge requires a culture shift and process overhaul. This shift begins by creating a cooperative environment where health systems, clinicians, researchers, patients, payors, vendors, government, and other important stakeholders can work together. This environment needs to be disciplined but adaptable, using real-time clinical data to drive PDCA cycles and continuously test and improve patient care quality and safety.

The University of Wisconsin has been active in LHS activities since 2013, beginning with evidence-based quality improvement programs. In 2022, UW Health bolstered its partnership with the University of Wisconsin-Madison's Institute for Clinical and Translational Research (ICTR) to advance the LHS. The focus of ICTR LHS is on data-driven technologies, aiming to unite our ICTR experts in team science, implementation science, biostatistics with pragmatic study design, clinical informatics, protocol development, and other consultants with the operational teams in our health system. This Program Announcement invites teams to identify significant questions and care gaps that could be addressed using an informatics, data-driven workflow with a focus on healthcare outcomes aligned with the quintuple aims and UW Health strategic priorities.

The Program Announcement introduces support for the development of ICTR's LHS initiative by funding a large-scale, pragmatic healthcare demonstration project that is a priority for UW Health. The project must include a clinical champion as the Principal Investigator, and a detailed plan for rapid and effective implementation into clinical practice of a patient intervention. Pragmatic comparative effectiveness trials are preferred but quasi-experimental quality improvement projects are also acceptable.

The successful grantee will use the results of this award to demonstrate a data-driven and collaborative Learning Health System that improves healthcare delivery and grows the LHS infrastructure in a sustainable manner. The following criteria must be met:

- **Continuous Quality Improvement in the Quintuple Aims.** The National Academy of

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Medicine<sup>1</sup> and AHRQ acknowledged the need for continuous improvement in health outcomes and healthcare delivery by proposing an LHS. A LHS aims to progress healthcare delivery to rapidly "Learn from What We Do and Do What We Learn." Stakeholders and researchers in the LHS should work closely with health systems operations to allocate the resources for collecting real-world data that may be analyzed to provide real-world evidence that serves the quintuple aims of any health system: (1) addressing health inequity and justice gaps and advancing health equity; (2) reducing costs; (3) improving patient health; (4) enhancing the patient care experience; (5) and reducing clinician burnout.

- **Data-Driven Decision-Making** is used, drawing upon methods in data science. The National Institutes of Health (NIH) defines data science as “the interdisciplinary field of inquiry in which quantitative and analytical approaches, processes, and systems are developed and used to extract knowledge and insights from increasingly large and/or complex sets of data.” The proposed team and computing infrastructure should provide the resources to collect real-world data on UW Health patients and follow its LHS governance workflow and required collaborators to collect real-world evidence to inform operational decisions that can lead to process redesign and change management in clinical practice. The strategic goal of a *data-driven* LHS is to improve health outcomes by leveraging data science to incorporate rapid methods needed for process redesign and overcome the delays in implementation that currently plague healthcare. Experts in implementation science and systems engineering should work closely with the health system’s enterprise analytics team and ICTR’s Clinical and Health Informatics Institute (CHI<sup>2</sup>).
- **Integration of UW Health Key Strategic Priorities into the Demonstration Project:** Proposals should align with the current UW Health Strategic Playbook.:

1) **Design our Future Work and Workforce:** UW Health will leverage the ingenuity of our people to redesign how we will deliver care and work in the future. We will build a culture that attracts and retains diverse, skilled, and innovative individuals, and enable their success through opportunities for learning and advancement.

Strategies:

- I. Understand the competencies and capabilities required to remain competitive in the future and prioritize our workforce needs.
- II. Advance our talent with professional development designed to meet current and evolving industry and organizational needs.
- III. Redesign how we do our work and innovate to meet our future goals.

2) **Excel in Value-Creating Care:** UW Health will be the provider of choice in primary and specialty care. We will deploy innovative care models that are simple and efficient to use. We will advance the pursuit of better health outcomes, exceptional patient experience, lower cost, and greater equity while improving provider and team member well-being.

Strategies:

- I. Develop and scale care models that enhance access, quality and efficiency.
- II. Coordinate care across our system so patients seamlessly receive the right care at the right place at the right time.
- III. Enhance the coordination of care with referring providers to improve access.
- IV. Address social determinants of health (SDOH) in our local communities through effective partnerships with community organizations.

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3) **Be the Destination for Specialty Care:** UW Health will draw patients regionally and across the nation and globe for programs built on our exceptional clinical capabilities that deliver outcome excellence, experience, and value. We will lead in offering the latest diagnostic and therapeutic options for patients in these programs.

I. Define and scale our regional and destination programs.

II. Strengthen UW Health's regional presence to spur growth and support care in the appropriate setting.

III. Excel in the research, development, and clinical translation of innovative diagnostics and treatments.

Additionally, project scale is a major consideration; ideally, demonstration projects should involve many patients that impact the health system. These include projects that examine the comparative effectiveness of two interventions that are already available in clinical practice (i.e., clinical equipoise), and should include sustainable infrastructure built into the budget for the LHS.

*Note: If your research question involves an intervention that is novel and has not demonstrated efficacy, or an intervention lacking data on efficacy, or if you are in the early stages of developing an intervention, please consider the ICTR Pilot Awards Program opportunities described in its Funding Opportunities website.*

## AWARD

Two awards will be granted this year; each award provides **up to \$125,000** for up to **12 months** of direct cost support.

## ELIGIBILITY OF CLINICAL CHAMPION (Demonstration Project Principal Investigator)

- The Clinical Champion must be employed by UW-Madison (*either sole appointment, or joint-appointment with VA Hospital, UW Milwaukee*) and have the title of:
  - Assistant, Associate or Full Professor (tenure track, CHS, or clinical) with clinical effort in a UW Health Department/Division.
  - Whereas residents, fellows, post-doctoral associates are **NOT** eligible to serve, they are eligible to serve as co-Investigators.
- At least 20% effort salary support (up to NIH annual salary cap: \$221,900 + fringe per year) must be included in the budget for the Clinical Champion as the Principal Investigator (PI). The sponsoring Department/Division Chair must provide a letter of support agreeing to at least 20% effort buyout on a 1.0 FTE appointment from this award for the PI's effort.

## ADDITIONAL REQUIREMENTS:

- Studies that meet the criteria [for human subjects research](#) must undergo Institutional Review Board (IRB) review and approval or exemption determination. They may additionally require [clinicaltrials.gov registration](#), or [UW Health/School of Medicine and Public Health Research Operations Committee \(UROC\)](#) endorsement if study meets criteria for each oversight for the award. Funding will be released after all required items have been completed. Since funding will not be awarded upon submission of the protocol to the IRB, the study team must:
  - Indicate ICTR as the study sponsor and include "Learning Health System demonstration project" in the study description.

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- Enter the funding source in the “other funding” section of the application in ARROW.
- On the ARROW page for ICTR Scientific Review (if displayed), select application has already undergone peer review to receive exemption from ICTR Scientific Review Committee.
- Assess the suitability of your proposal as research versus Quality Improvement/Quality Assurance. The criteria for granting waivers of consent, as well as criteria when assessing QA/QI versus research can be found at the following links: (1) [QI/QA vs. Research: QI Decision Tree](#); and (2) [Waiver of Consent: HRP-410 Checklist](#).
- The clinical champion should identify a health systems operations dyad partner and provide a letter of support from the individual.
- *If awarded*, research teams are required to participate in a 90-minute facilitated Collaboration Planning process as part of the [ICTR Team Science](#) initiative. In addition, the PI will serve as one partner in a dyad working relationship with a health operations leader/executive with corresponding content/ operational expertise. **These roles will need to be identified and delineated in the Letter of Intent.**

**KEY DATES AND DEADLINES**

**LETTER OF INTENT (mandatory) DUE January 27, 2025**

Program Announcement	October 28, 2024
LOI Due	January 27, 2025
D&I, Budget estimations for other ICTR services, consults with LHS leaders Due (for accepted LOIs)*	February 3 - March 28, 2025
Full Application Due	June 9, 2025
Peer-Review and LHS Steering Committee Review Period	June 16-August 18, 2025
IRB approval, Clinicaltrials.gov registration, UROC endorsement	Prior to award start date
Demonstration Projects Notification of Award	August 28, 2025
Demonstration Project Start Date	September 1, 2025
Team Science Collaboratory Kickoff Meeting	ASAP after start date
LHS Component Consultations	September 8, 2025 – October 31, 2025
Quarterly meetings with LHS leadership	September, January, May, August
1-year Presentation to Community Stakeholders	September 2026

Letters of Intent (LOIs) must be submitted as a **single PDF/Word document via email** to [lhs@ictr.wisc.edu](mailto:lhs@ictr.wisc.edu).

Note: The LOI will be reviewed by Director (Majid Afshar) and Associate Director (Anne Gravel Sullivan) of the LHS to ensure alignment with the health system priorities, LHS focus, and clear delineation of clinical champion and operational lead prior to an invitation for a full application.

**The Letter of Intent - please include the following:**

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1. Clinical Champion/PI and Operational Dyad with Name, contact information, and department/division
2. Title of your proposal.
3. Names and roles of key personnel.
4. Specific aims and *brief* overview of UW Health LHS Demonstration Project should include enough detail to identify **both** scientific and design/methods reviewers.
5. Please indicate all contributors, collaborators and/or invested groups for this demonstration project and how they will be involved in this project. The clinical champion should describe the role with the dyad partner in UW Health operations leader/manager. The Clinical Champion must have an appointment with UW Health to be considered for the LHS award.
6. Identify the **Learning Health System components and Quintuple Aims** your Demonstration Project will address.

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Select proposals that are determined to meet the criteria for a UW Health-based LHS demonstration project will be encouraged to submit a full application. Prior to submission of a full application, project PIs will be required to hold consultations with the D&I Launchpad, as well as meet with LHS Program leadership to discuss budget estimates for any ICTR services that may be included in the project proposal (see below for services/expertise available). The purpose of these consultations is to assess and provide feedback on the demonstration project's design to proactively identify facilitators that can help mitigate barriers to swift IRB approval/exemption, as well as optimize project scalability and provide budget estimates.. Questions about the application process may be directed to the LHS Leadership at [lhs@ictr.wisc.edu](mailto:lhs@ictr.wisc.edu).

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## APPLICATION REQUIREMENTS

The full application is due on **June 9, 2025**

### Please note the application instructions:

- A complete application includes **items 1-10** below
- Please insert page numbers on the full application
- Narrative: Maximum length of 6 pages, 11-point Arial font with ½” margins
- **Submit the full application via the application survey link in RedCap** by 5 pm on June 9, 2025.

### Full Application Components (1-10):

1. **Face Page**
2. **Scientific Abstract:** Provide a concise description of the proposed demonstration project written for scientific audiences that includes how the project will address one or more of the Quintuple Aims. (800 word maximum.) The abstract is an opportunity to express to our **LHS Steering Committee** how you anticipate that this project can, in the long-term, impact the health of patients and serve the need of the following Quintuple Aims: (1) advancing health equity; (2) reducing costs; (3) improving patient health; (4) enhancing the patient care experience; and (5) reducing clinician burnout.

The aims-grounded scientific abstract should **tell a story** that addresses how the demonstration project will enhance healthcare efficiency to achieve the Quintuple Aims as a framework from the Institute for Healthcare Improvement for achieving value-based care.

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Your scientific abstract must include:

- Scientific rationale supporting your proposed demonstration project meeting the criteria of data-driven decision-making strategy, and alignment with UW Health key strategic areas.
- Scientific aims and demonstration project design. The investigator should describe the need for the project by the participating health system (UW Health), and how they will leverage ICTR resources in informatics (CHI<sup>2</sup> and their clinical research data services) Team Science, Protocol Development, D&I Launchpad, and biostatistics and research design (BERD). Also describe how completion of the project will be achieved using a rapid PDCA cycle (consult with D&I to help).
- A description of the magnitude of the health problem: how many individuals are affected and the scope of the issue locally and nationally? How will the project, in the context of the health system, improve health and advance health equity and enter our digital era of healthcare?
- An explanation of how the costs of healthcare are impacted and whether/how this project addresses health inequities and advances health equity. Identify at least two of the Quintuple Aims on which the project focuses and detail what questions the project will address.
- The longer-term policy implications of your LHS project. How might your LHS project inform and improve the LHS workflow for the health system?

**3. Health System Collaboration and Alignment:** Provide a concise description of the primary patient audience(s) targeted by the demonstration project and how the project will improve care at UW Health. Provide a case for how your project aligns with UW Health system priorities and will improve health care outcomes in an effective, cost-efficient, and sustainable way. (800 word maximum.) The application must include:

- A description of the core problem your proposed project solves within one or more clinical settings at UW Health. Using the SBAR model (Situation, Background, Assessment, Recommendation), briefly describe each component of the problem the project is designed to address, then the proposed solution/recommendation.
- An explanation of whether your project is intended to improve or grow an existing UW Health service or would it create an entirely new service. When writing this section, applicants should address or answer the following:
  - A description of how the proposed project would incorporate existing UW Health and/or UW resources. For example, how many staff members (physicians, nurses, administrators, facilities services, IT engineers, coders, etc.) will be needed at startup and to maintain daily project operations? What new equipment, supplies, software, etc. are needed?
  - A description of the operational effort (significant, moderate, minimal) and support resources required to accomplish project goals? (e.g. IT, project management, business planning, risk management)
  - A description of the ways the proposed project would directly or indirectly impact other areas of the organization. Would cost, workload, staff well-being be affected either by the initial setup or ongoing operation of this project?

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- Does the proposed project depend on the implementation of other work? Or does other work depend on the implementation of the project work proposed? If so, please describe the dependency type.
- What would the consequences be if the proposed project is not funded?

**4. Community/Patient Engagement:** Provide a concise description of how the primary patient audience(s) targeted by the demonstration project will be involved in its design and/or implementation processes. 500 word maximum. The application must include:

- A list of patient/partner collaborators. Who are the intended beneficiaries of this project and how will patient, family or community members, contributors and/or invested stakeholders be involved; what roles will they play? How will the experiences of the patient and provider included in the outcomes?
- A plan for dissemination of study findings to the patient/community partners affected by the proposed project and implementation within one year of the project's end. (e.g. by presentation to a Patient Advisory Board, other).

**5. Biosketches for Key Personnel:** Please use the new NIH Biosketch format as described here: <https://grants.nih.gov/grants/forms/biosketch.htm>

- **Special note for Clinical Champion/PI applicant:** The Personal Statement of the NIH Biosketch must include detail on how the proposed research represents an independent area of investigation for the applicant and integration with the health care system. Letters from the faculty supervisor and department chair or dean expressing support of at least 20% effort buyout on a 1.0 FTE with funds from this award with an outline of the PI's proposed role with healthcare operations and clinical workflow should be included. A letter of support from the operational dyad is also required.

**6. Budget (\$125,000 for 12 months of direct support) Requirements:**

- Use the budget template which is bundled with the face page in the application materials.
- Budget Justification is required (maximum 2 pages).
- When creating your budget, please note the following parameters:
- **Indirect costs are *not* allowed.**
- Investigator salary support is allowed for at least 0.20 FTE of a 1.0 FTE appointment.
- Estimates for any ICTR services used, as identified in consultation with LHS Program leadership, should be included in the budget.

**7. Narrative Requirements:** The narrative should not exceed 6 pages and should address each of the following components (**sections a-f below**).

- a. **Specific Aims.** Each proposal should include LHS aims that align with the Quintuple Aims.

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- b. **Background and Significance.** When writing this section, applicants should address the following:
- What is the UW Health priority the Demonstration Project will address?
  - What is the estimated hospital/health system benefit of the LHS project and how big is the impact of the planned intervention?
  - Identify the care or quality gap, e.g., do the existing data or workflow in the healthcare delivery and patient need the LHS framework?
- c. **Investigator.** Please explain how the PI, study team, and health partners are especially suited to this project (i.e., their expertise), including clinical operations involvement
- d. **Environment.** Will the clinical environment in which the work will be done contribute to the probability of success? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements? What is the sustainable infrastructure build that will result? Will any digital health advancements be invoked and what are the data-driven resources?
- e. **Approach.** Describe the overall strategy, methodology, and analyses to accomplish the specific aims of the project. Include preliminary studies, if appropriate.
- Identify and describe the program/ treatment/intervention to be implemented and evaluated. Be sure to provide sufficient detail on the intervention itself and the pragmatic design for the intervention with reference to the publications providing evidence on the established efficacy of the intervention and need for a quality improvement evaluation or comparative effectiveness trial.
  - Describe the pragmatic data-driven approach and evaluation framework that informs the design and the outcomes being tested (e.g., the LHS model that will be used).
  - Describe the setting for your implementation, including readiness and capacity to implement the intervention as well as hospital partners and committees involved for approvals.
  - Describe the implementation strategies you will use and your consultation results with D&I launchpad.
  - Describe any consultations or expertise input accomplished to date. A priority is for quasi-experimental or pragmatic randomized clinical trials with an EHR-embedded approach. Sample size calculations should be included.
  - Rapid Plan Do Check Act (PDCA) Cycle: Include a plan for how a rapid PDCA cycle will ensue with the project, particularly in the context of stakeholder involvement, after the intervention is deployed. When writing this section, applicants should consider the following:
    - What factors influence the timeliness of final implementation or de-implementation within the allotted 12-month period?
    - How will you match the rigors of science with the timeliness for business needs and operations of a healthcare delivery system?
    - How will the tools and materials from your project be disseminated?
- f. **Special Criteria.** Applicants must address how they will incorporate the following special criteria in their research project.



- **Investigator – Health Partner collaboration:** The project involves a partnership between a clinical champion (PI) and a UW Health operational leader. What processes and mechanisms will be used to ensure continuous alignment between the clinical champion and health operations leader over the course of the project?
- **Interdisciplinary collaboration:** The project involves developing a collaborative planning process and mechanisms to support interdisciplinary team involvement. What results came from ICTR's Team Science consultation to ensure interdisciplinary collaboration?

**The required application components below do not count against your 6-page narrative.**

8. **Timeline:** Earliest start-date for the award is September 1, 2025, and projects must be completed within 12 months of the start date. IRB approval, UROC endorsement, clinicaltrials.gov registration, and D&I Consultation should be completed before project work involving human subjects can begin.
9. **Literature citations:** Please attach a separate reference section.
10. **Letters of collaboration/support:** Please include *signed* (can be electronic) letters of support from the division chief/department chair for clinical champion and LOS from operational leadership (attesting to their willingness to support the project, as well as its acceptability, feasibility and resources UW Health will bring to the partnership). Also consider collaborators who are associated with the special criteria that you choose.

**POST-AWARD REQUIREMENTS, CONSULTATIONS AND MEETINGS**

**PRESENTATION:** The PI (clinical champion) is REQUIRED to meet with LHS leadership to coordinate LHS components with the ICTR Team Science Collaborative Planning process; Dissemination and Implementation Consultation; Protocols Development, ICTR Biostatistics, Epidemiology, and Research Design (BERD) Consultation; ICTR Protocol Development, and the Center for Health Informatics Institute (CHI<sup>2</sup>). LHS leadership will meet with awardee in the first month of the award with plans to complete these activities with the first two months of the award date with follow-up quarterly progress reports. See details below for each of these components.

In addition, the PI is required to present their research study and/or outcomes to patients and community members in an appropriate context (e.g. a Patient Advisory Council) within one year of receiving the award.

**MANDATORY APPROVALS: Institutional Review Board approval;** UW Health Hospital Operations Committees that are required for the Demonstration Project (i.e., Nursing, Clinical Decision Support, Center for Clinical Knowledge Management, Clinical AI and Predictive Analytics, Inpatient Providers, Epic Super-User, etc.)

**CONSULTATIONS:**

**D&I Consultation:** A [consultation](#) with the [Dissemination & Implementation \(D&I\) Launchpad](#) is required to ensure projects produce generalizable knowledge and address health inequities.

**Biostatistics and Epidemiology Research Design (BERD) Consultation:** A consultation with BERD scientists is **recommended if no expertise is available** to ensure projects are designed to produce data of sufficient volume and quality to be used in scientific research around the effectiveness and scalability of the project intervention(s).

**Protocol Development Consultation:** A meeting with the Protocols Development team regarding the project IRB submission and registration with ClinicalTrials.gov is required to facilitate swift and accurate navigation of the project through the necessary protocols for approval.

**Center for Health Informatics Institute (CHI<sup>2</sup>):** Consult with the Clinical Research Data Service (CRDS) to plan data extraction query and procedures.

**TEAM COLLABORATION KICKOFF AND DEBRIEF:** PIs are required to attend and help lead a project Team Collaboration Kickoff workshop and follow-up project Debrief facilitated by the Team Sciences group. The purpose of the Kickoff Collaborative Planning session is to bring together all LHS partner stakeholders to discuss project roles and responsibilities, as well as project timeline, process, research, and administrative functions. The purpose of the Debrief session is to assess the effectiveness of the interdisciplinary planning and execution, identify best practices, and discuss lessons learned from the project process.

**BIWEEKLY PROJECT TEAM MEETINGS:** Clinical Champion PIs and their LHS Clinical Operational Lead counterparts (Dyads) are recommended to meet at minimum every two weeks to ensure momentum behind project progress and to address any issues identified during project implementation.

**QUARTERLY PI/TEAM MEETINGS WITH ICTR LHS DIRECTOR/TEAM:** Quarterly meetings between the PI, Operational Co-lead/team and the ICTR LHS Director/Associate Director (Drs. Majid Afshar and Anne Gravel Sullivan) are required to ensure project activities, progress and outcomes are documented effectively for reporting purposes. More frequent check-ins may be required depending on the project progress and timeline. **Quarterly reports** of those activities and outcomes, as well as a **Summative Report** to be shared by the project team at each quarterly meeting.

1. Summary W. *The Learning Healthcare System*. Washington, DC: National Academies Press; 2007.