



## **iTHRIV Pilot Translational and Clinical Studies Program Request for Applications**

### **TIMELINE**

- **June 27<sup>th</sup>, 2022:** Request for Proposals Release Date
- **July 11<sup>th</sup>, 2022 at 12 pm ET:** Information Session: [Click here](#) to register
- **August 29<sup>th</sup>, 2022 by 5 pm ET:** Application Deadline
- **October 28<sup>th</sup>, 2022:** Anticipated notification of award
- **February 1, 2023:** Anticipated project start

### **OVERVIEW**

The iTHRIV Pilot Translational and Clinical Studies Program is a core component of the NIH-funded Clinical and Translational Sciences Award (CTSA), the integrated Translational Health Research Institute of Virginia (iTHRIV). iTHRIV is a statewide collaborative research network with a mission of using data to improve health. It is comprised of 4 research institutions: Carilion Clinic, Inova Health, the University of Virginia, and Virginia Tech.

The goal of the iTHRIV Pilot Studies Program is to support innovative approaches to clinical and translational research to foster collaborative research across the iTHRIV partner institutions. By providing teams with early-stage pilot funding, iTHRIV aims to provide resources to accelerate discovery, generate preliminary data, and support translational science through partnerships across the Commonwealth of Virginia.

Proposals can include the full range of translation from the laboratory to the clinical area.

Areas of particular interest include:

- Innovative uses of data science to improve health
- Research focused on health disparities
- Team science collaborations across two or more iTHRIV partner institutions

iTHRIV encourages and will also be accepting proposals which focus on understanding the *science of translation*, i.e., focused on understanding a scientific or operational principle underlying a step of the translational process, with the goal of developing generalizable principles to accelerate translational research. Examples might include, but are not limited to:

- Development of new research methodology and/or new technologies/tools/resources that will advance CTS and thus increase the efficiency and effectiveness of translation
- Early-stage development of new therapy/technology with generalizable application to an identified translational roadblock
- Demonstration in a particular use case(s) that the new methodology or technology advances translational science by successfully making one or more steps of the translational process more effective or efficient
- Dissemination of effective tools, methods, processes, and training paradigms
- Feasibility/proof of concept studies to support future CTS projects

- Novel approaches to enhance secondary analysis of existing data (e.g., projects using the [National COVID Cohort Collaborative \(N3C\)](#) Data Enclave)

iTHRIV has a total of \$200,000 to distribute and the number of projects funded will depend on the quality of proposals and funding request amounts. Projects are required to be completed within one year.

### **Budget Request Options:**

- Single-site iTHRIV Institution Investigator: can submit a budget of \$25,000 in direct costs, or
- Multi-site iTHRIV Institution Investigators (Requires a minimum of 2 iTHRIV institutions): can submit a budget of \$50,000 in direct costs

## **APPLICATION PROCESS**

### **Eligibility**

- All proposals must involve an interdisciplinary team. Multiple PIs or co-PIs are encouraged.
- Any faculty member eligible to serve as a PI on external grants and contracts at their iTHRIV institution may serve as the contact PI or Co-PI for an application.
- Multi-institutional projects must include at least 2 separate iTHRIV institutions (Carilion Clinic, Inova, UVA, VT).
- All projects involving human subjects or vertebrate animals must provide proper regulatory approvals prior to initiation of the research, but not prior to submission of the proposal.

### **Proposal**

Applications **MUST** be submitted **by 5:00 pm ET on Monday, August 29th, 2022.**

Complete proposals should be submitted through the online application [link](#).

**For full details and access to required forms, please visit our website: <https://www.ithriv.org/ithriv-request-for>**

Teams should submit a **single PDF** containing the following:

- Abstract (500 words or less)
  - Please Note: Use non-medical terminology to describe your research project and its potential impact. This abstract will help our community reviewers better understand the proposal.
- 5-page project description (includes all of the following categories)
  - Specific Aims
  - Impact
  - Research Plan
  - Description of Team
  - Plan for Community Engagement
  - Timeline
  - Plan for Follow-on funding

- Resource and Data Sharing Plan (1 page limit)
  - This should include your plans for dissemination of data from your project as well as plans for sharing any other resources including model organisms or genomic data sharing.
- NIH formatted budget and budget justification (templates located on the [website](#))
- NIH biosketch for each key personnel (please utilize the new **10/2021 version**)

\*References should be included but are not considered to be part of the 5-page project description.

## **Budget Guidelines**

- Project period is one year; no-cost extensions are not permitted.
- For multi-institutional projects: a separate budget and budget justification for each institution is REQUIRED.
- PI/ Co-PI effort is NOT required on the budget. Pilot awards are ideally suited to provide support for research staff, supplies, etc.
- Consortium agreements are not required between iTHRIV institutions.
- Publications costs are NOT allowed.
- One Community Engagement Studio is required for each project, and this should be budgeted in only one site budget for multi-institutional projects. Please include \$500 in the budget for a Community Engagement Studio (see section below for more details about Community Engagement Studios).
- Budget and budget justification templates provided must be utilized (templates located on the [website](#)).
- Anticipated funding dates: February 1, 2023 - January 31, 2024.
- Indirects are unallowable. Only direct costs should be included in the budgets.

Please contact the following individuals at each institution for grant management review and support for this proposal submission process (have institution sign off for VT, Carilion, and Inova):

- **Virginia Tech:** Sarah Whitt - [sklawr2@vtc.vt.edu](mailto:sklawr2@vtc.vt.edu)
- **Carilion Clinic:** Vera Hollen - [vlhollen@carilionclinic.org](mailto:vlhollen@carilionclinic.org)
- **Inova:** Lynn Evans-Riester - [Lynn.Evans-Riester@inova.org](mailto:Lynn.Evans-Riester@inova.org) or Bhruha Shah - [Bhruha.Shah@inova.org](mailto:Bhruha.Shah@inova.org)
- **UVA:** Contact the Grant Administrator for your Department or School

\*These grant administrators can then contact Kayla Calvo: [KRC7D@hscmail.mcc.virginia.edu](mailto:KRC7D@hscmail.mcc.virginia.edu) with any additional questions.

## **Regulatory Approvals**

- Awardees must obtain all applicable regulatory approvals (e.g. IRB, IACUC, or Radiation Safety) and meet all compliance requirements prior to receiving funds and maintain approvals during the entire length of the award.
- When applying for IRB/IACUC approval, indicate that this research is supported by the National Institutes of Health (iTHRIV Award number UL1TR003015). Funding source: NIH/NCATS.
- IRB/IACUC approval(s) must be kept current and active for the duration of the award period. Copies of all approval letters need to be sent to Medard Ng, PhD, Research Quality Manager - [HTN3U@hscmail.mcc.virginia.edu](mailto:HTN3U@hscmail.mcc.virginia.edu).

- Any multi-site non-exempt human subject research study will be required to follow the NIH mandate for use of a single IRB of record.
- All funded proposals which involve human subjects or vertebrate animals will require submission to and review of the project by NCATS prior to beginning the project. Teams who are awarded funding will meet with the Research Quality Manager for guidance through this process. The approval process can take several weeks to 1 month's time. In order to protect against delays, all applicants are urged to seek IRB or IACUC approval concurrent with the submission of the pilot application.
- If your project is an NIH-defined clinical trial (see below), you must register your project and report results on [clinicaltrials.gov](http://clinicaltrials.gov).

### NIH Clinical Trial Definition

A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes

- **Please Note:** iTHRIV has a four-way Master Research Collaboration Agreement in place between all institutions. This agreement should be utilized to expedite MTAs and DUAs between iTHRIV institutions.

### Proposal Review Process

iTHRIV Pilot Studies applications will receive an administrative review for completeness and eligibility, then all applications will be evaluated by reviewers from all four institutions and a community member. The top proposals will be reviewed and approved for funding by the iTHRIV Leadership Council.

Applications will be evaluated based on the following criteria:

- Does the project involve an innovative approach to an important clinical problem?
- Is the project supported by appropriate preliminary data supporting the feasibility of translation to the clinic?
- Does the project employ a team science approach and include personnel with the required expertise? Priority will be given to multi-site collaborative projects.
- Is the project likely to lead to follow-on funding and/or translation to clinic or does it solve a challenge to the translational science process?

### Community Engagement Studios

All iTHRIV funded pilot projects will be required to conduct a Community Engagement Studio during their project period. A Community Engagement Studio (CES) is a facilitated round table discussion that brings together health researchers and patients/consumers/other non-academic stakeholders.

Each Community Engagement Studio session assembles a customized panel of community experts who share their perspectives on a research topic.

Potential topics:

- Shaping a research question or proposal.

- Enhancing study design, implementation, or dissemination.
- Addressing potential barriers or challenges, such as recruitment or retention.
- Improving the cultural and linguistic appropriateness of research documents (e.g., recruitment materials, consent documents, or surveys).

iTHRIV CES gives community members an effective and active role in health care research and gives researchers an avenue to consult with patients/the public before, during, and after their research project takes place.

Community expert participants are compensated for their time in Community Engagement Studios. All pilot project applications must include costs for this in the budget (\$500).

Please Note: The iTHRIV team will assist in this process.

Please click [here](#) for additional information.

### **Information Session**

An optional information session about the iTHRIV Pilot Studies program and the proposal submission process will occur on **July 11<sup>th</sup>, 2022 at 12 pm ET on Zoom**: [Click here](#) to register in advance for this session. All applicants are strongly encouraged to attend this session.

### **Submission Process & Checklist**

**Proposals should be submitted by following this [link](#).**

Complete the online form and submit a single PDF where indicated on the form with all of the following elements:

- ☐ Abstract
- ☐ Project Proposal/Research Plan (5 page maximum)
- ☐ References
- ☐ Resource and Data Sharing Plan
- ☐ NIH biosketch for each key personnel
- ☐ Separate Budget(s) and Budget justification(s) for each institution

***Questions? Need help finding a partner for a project?***

**Contact iTHRIV: [iTHRIVAdmin@hscmail.mcc.virginia.edu](mailto:iTHRIVAdmin@hscmail.mcc.virginia.edu).**