Pilot & Translational Clinical Studies Program

Program Director: Sean Moore, MD
Program Manager: Jennifer V. Phillips, RN, CCRC
Financial Manager: Kayla Calvo

integrated Translational Health Research Institute of Virginia
What is iTHRIV?

CTSA Network: ~60 elite hubs

Regional CTSA hubs
- Children’s National/DC
- VCU Wright Center
- iTHRIV

NIH award: 2019-2023 (~$23M)
$200,000 per year for Pilot funding

Primary Goals:
1. Data science
2. Collaborative teams
3. Training the next generation

https://ncats.nih.gov/ctsa
OBJECTIVE

“Using Data to Improve Health”

• Help research teams transition from small seed grant funding to successful external project support and to advance translational approaches

• Interested in funding projects related to:
  • Innovative uses of data science to improve health,
  • Research focused on health disparities,
  • Team science collaborations across two or more iTHRIV partner institutions.
No proposals will be accepted after 5 pm ET on August 30th, 2021
1 year award
NIH approval will be required if selected for funding, process will begin in November 2021
ELIGIBILITY

- Interdisciplinary team required, multi-PI’s or Co-I’s encouraged
- Faculty member at an iTHRIV institution who is eligible to serve as PI on external grants
- Multi-institution projects MUST include at least 2 separate iTHRIV Institutions
- Health related research (translational or clinical)

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<th>Pilot Funding Year</th>
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SUBMISSION

- Submit a single PDF
- Application Coversheet
- Abstract (500 words or less)
- 5-page project description
- Resource and Data Sharing Plan
- NIH formatted budget and budget justification (one for each institution included in the project)
- NIH-Style biosketch for each key personnel

5-page Project Description

- Specific aims
- Impact
- Research plan
- Description of team science
- Plan for community engagement
- Timeline
- Plan for follow on funding/subsequent research studies

Templates available
https://www.ithriv.org/ithriv-request-for

Center for Open Science
https://www.cos.io/
https://osf.io/
Budget Guidelines

- Single-site iTHRIV Institution Investigator: up to $25,000 in direct costs
- Multi-site iTHRIV Institution Investigators: up to $50,000 in direct costs
- 1 year award (anticipated funding dates: Feb. 1, 2022-Jan. 31, 2023)
- Consortium agreements are not required between iTHRIV Institutions
- Publication costs are NOT permitted
- Indirects are unallowable
- Include $500 in the budget for a Community Engagement Studio
- NIH formatted budget and budget justifications required
- No-cost extensions will not be permitted
- Must follow all NIH funding rules
Proposal Review

- NIH Style Scoring
- Reviewers from each iTHRIV institution
- Final funding decisions made by iTHRIV Leadership Council

EVALUATION 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 clinic?
- Does the project employ a team science approach and include personnel with 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?
OTHER REQUIREMENTS

- If funded, appropriate IRB or IACUC approvals will be required
- NIH Approval for funded projects involving humans subjects or vertebrate animals will be required
- Any multi-site non-exempt research will be required to utilize single IRB
- Projects MUST be completed in one year
A Community Engagement Studio is a facilitated conversation between researchers and community members.

- The researcher presents his/her research project and then asks 3-4 questions of the community members.
- It lasts for about 1 ½ hours.
- Done virtually
- A report on how the input effected the project is shared with the participants.
- Compensation for participants is $50.
- iTHRIV staff will assist with the studio
- All funded proposals will be required to do 1 studio
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FREQUENTLY ASKED QUESTIONS

1. What does community engagement mean?
   • Identifying and communicating with stakeholders and end-users of the research process.

2. Are indirecst allowed to be included in the budget?
   • No

3. Are references considered part of the 5-page project description?
   • No, references are separate as are, the abstract, resource and data sharing plan, budget, budget justification, and NIH biosketches

4. Are PI’s or Co-I’s required to have effort on the grant?
   • No, PI effort is discouraged, with this limited funding iTHRIV anticipates the majority of the funding will be needed for supplies, support staff, statistical support, etc.

5. If this is a multi-institution project, are separate budgets and budget justifications required?
   • Yes, see question #2 for information regarding indirect rates.
FREQUENTLY ASKED QUESTIONS

6. Do proposals require review prior to submission by the grants and contracts office?
   • For UVA budgets (even if it is considered a sub-award) - No, but departmental research administrator review is highly recommended and a signature is required.
   • For all other institutions-follow institution guidelines and policies
   • Consortium agreements are NOT needed. Please contact Kayla Calvo (KRC7D@hscmail.mcc.virginia.edu) for further clarification.

7. If this is a multi-institution project, are the budgets required to be split evenly between institutions?
   • No, the budgets should be comparable to the work being done at each site.

8. Does any information about the Community Engagement Studio have to be included in the Research Plan?
   • No, but there must be a description about the overall plan for community engagement and $500 does need to be included in the budget and budget justification for the completion of a Community Engagement Studio.
OTHER QUESTIONS?

Contact us: iTHRIVAdmin@hscmail.mcc.virginia.edu

Please help us continue our support for clinical and translational research by citing our grant number in relevant publications:
National Center for Advancing Translational Science of the National Institutes of Health Award UL1TR003015/ KL2TR003016.