Request for Applications:
integrated Translational Health Research Institute of Virginia (iTHRIV)
2025 iTHRIV Scholars Mentored Career Development Program

Release Date: October 15, 2024

The integrated Translational Health Research Institute of Virginia (iTHRIV) is a transformational, cross-Commonwealth collaboration that leverages the latest advances in data science to accelerate innovation in health-related research and facilitate team science. Partners within iTHRIV include Carilion Clinic, the University of Virginia (UVA), and Virginia Tech. iTHRIV seeks to support highly qualified early career faculty for activities related to the development of a successful clinical or translational research career.

The iTHRIV Scholars Mentored Career Development Program aims to develop the next generation of clinical and translational researchers in principles of data science, the conduct of rigorous and reproducible science, and to promote team science as a means to enhance innovation and discovery in health-related research. iTHRIV announces the annual call for applications for this mentored career development program.

Eligibility:

- Applicants must have a *terminal* research or health-professional doctoral degree, including but not limited to M.D., D.O., D.V.M., Ph.D. or equivalent.
- Applicants must have a full-time faculty appointment at one of the iTHRIV partner institutions (Carilion Clinic, University of Virginia, or Virginia Tech) at the time of anticipated appointment to the program **(July 1st, 2025)**; the position cannot be contingent on obtaining appointment to the program. Faculty holding at least a 9-month appointment are eligible. **Please plan to provide the start date of your full-time faculty appointment according to your offer letter in your Letter of Intent if you are not currently in the role.**
- Applicants must be a U.S. citizen or non-citizen national, or have documented permanent resident status.
- Applicants and their home units must commit faculty member's effort, as outlined below, to mentored research and career development activities. **A letter of commitment from the applicant's unit or department head or chair is required with the Letter of Intent submission and must include a statement of commitment to protected time (the agreed upon amount) and a clear description of other activities (including the percent effort allocated to clinical responsibilities, on-call time, teaching, service, and/or administrative activities**).
- Applicants who have previously received a career development award or a national, independent research award (as a faculty PI) covering more than 2 full calendar months of support in a year (e.g. NSF, NIH, AHA) are **NOT** eligible.

Applicant's home unit (department/college/institute) must commit to allow for 75% release time for mentored research and career development during the Scholars two-year program (specific statement of protected time must be noted in the Letter of Intent). The home unit must also commit to provide the Scholar funding support for a third year of 75% protected research time in the event that extramural funding has not been achieved at the conclusion of the two-year program. Requests for reductions from 75% protected research time, but no less than 50%, will be considered for those in surgical specialties and must be submitted and justified with the applicant's Letter of Intent.

Applicants must identify at least one scientific mentor. The primary scientific mentor must

provide a letter of support to be included with the application. More than one scientific mentor is permitted and encouraged as appropriate for the proposal.

Proposals that demonstrate potential to integrate team science and data science in clinical or translational research are encouraged.

Program Description:
The iTHRIV Scholars Program is supported in part by the National Center for Advancing Translational Sciences of the National Institutes of Health under Award Number KL2TR003016. Scholars are selected annually to participate in the program. Early career faculty candidates pursuing a career in clinical research or translational research from all departments in all colleges, schools, and institutes at an iTHRIV partner institution that meet program eligibility criteria are encouraged to apply. In seeking excellence through diversity of experiences and perspectives, we encourage members of underrepresented populations as defined by NIH (https://diversity.nih.gov/about-us/population-underrepresented) to apply.

iTHRIV Scholars will be expected to contribute to a learning community through participation in weekly virtual educational sessions (currently Tuesday afternoons from 1-5 pm) with other Scholars. The iTHRIV Scholars Program focuses on the fundamental characteristics of a translational scientist with added emphasis on principles and practices of data science, the art and skill of writing good grants, scientific integrity and responsible research, peer mentoring, and professional development. Our Scholars consist of faculty from UVA, VT and Carilion Clinic and we use Zoom to gather together for our weekly sessions. **Attendance at these sessions is mandatory for the duration of the two-year structured program.** Each iTHRIV Scholar will furthermore enhance the skills specific to his/her research and career development through an individualized learning plan. **Applicants must include the integration of participating in the weekly iTHRIV Scholars Program sessions in their individual career development plan for their proposal.**

Individualized training should be detailed in the applicant's career development plan and may include:

- The composition of a personal mentorship team.
- Translational experiences, which are individually selected by Scholars to broaden the Scholars' perspective and ability to communicate with stakeholders outside of their immediate scientific field.
- Coaching to achieve professional development goals.
- Opportunities for individualized course work (e.g. Master of Science in Data Science, Masters of Science in Clinical Investigation, Certificate in Implementation Science, etc.).

All iTHRIV Scholars are required to complete Responsible Conduct of Research (RCR) training. See NIH's requirement for Training in the Responsible Conduct of Research (RCR), for more information on this policy. The iTHRIV Scholars Program incorporates RCR training into our weekly programming that fulfills this NIH requirement.

iTHRIV provides access to training in research informatics, data analysis and visualization, prediction modeling, open data resources and data sharing, the ethics and governance of big data, principles of commercialization, and scientific rigor and reproducibility. Applicants may consider the use of tools from the Center for Open Science (https://cos.io/) and the University Libraries of the partner institutions to enhance the reproducibility of their work.

During the two-year period of appointment to the program, iTHRIV Scholars are expected to pursue an extramural mentored career development award and/or independent research

funding **as soon as possible** with the goal of obtaining significant extramural funding by the end of the two-year program. *If funding is not achieved within the two-year appointment period, the applicant's home department or school or institute must provide funding support for 75% research protected time for a third year to achieve extramural funding.* ***A letter of commitment from the applicant's unit or department head or chair confirming this support is required at the time of Letter of Intent.*** If a national career development award or major independent research grant is funded before the end of program appointment, the iTHRIV Scholar is expected to continue to participate in iTHRIV Scholars programming, and financial support will transition to the extramural award (as allowed by the external award). Progress reports are required of all iTHRIV Scholars.

This program does not support any application which contains a foreign component as defined by NIH Policy. Per NIH Policy, the definition of a foreign component is the performance of any significant scientific element or segment of a project outside of the United States, either by the recipient or by a researcher employed by a foreign organization, whether or not grant funds are expended. Activities that would meet this definition include, but are not limited to, (1) the involvement of human subjects or animals, (2) extensive foreign travel by recipient project staff for the purpose of data collection, surveying, sampling, and similar activities, or (3) any activity of the recipient that may have an impact on U.S. foreign policy through involvement in the affairs or environment of a foreign country. Examples of other grant-related activities that may be significant are:

- collaborations with investigators at a foreign site anticipated to result in co-authorship;
- use of facilities or instrumentation at a foreign site; or
- receipt of financial support or resources from a foreign entity.

Foreign travel for consultation is not considered a foreign component. If you have any questions about the appropriateness of your research with consideration of this foreign component restriction, please reach out to the Program Manager, Amy Harrigan (acm6a@uvahealth.org).

Instructions for Proposal:

A Letter of Intent (LOI) is required and should be submitted via this form by 8:00 am on December 10, 2024. Please submit as one single PDF.

Applicant **must include** in LOI:

- The title of the proposal
- Name(s) of scientific mentor(s)
- A paragraph (100-word limit) describing the intended proposed mentored research project including topic and probable methods
- For applicants in surgical specialties ONLY, any request for deviation from the 75% protected time and salary/fringe support must be noted and justified in this LOI.
- A letter of commitment from the applicant's department head or chair, institute director, or dean which includes:
    - A statement confirming 75% protected time for mentored research and career development for the two years of program appointment
    - A statement confirming applicant's participation in our 4-hour weekly sessions for the two years of program appointment
    - If extramural funding is not achieved during the 2 years of formal programming, a guaranteed third year of **department/institutional funding** to support 75% protected research time as described above.
    - If an applicant does not have a current faculty appointment at an iTHRIV participating institute, a statement that the applicant's **full-time faculty**

appointment will begin no later than July 1st, 2025.

Full applications are due by 8:00 am on Tuesday, January 21, 2025.

A complete application adherent to NIH guidelines on fonts and margins, submitted as a single PDF, **must include**:

- NIH Biosketch and **other support** for the applicant
- NIH Biosketch and **other support** for the applicant's scientific mentor(s)
- NIH Biosketches for key contributors to the applicant's proposed research and career development
- Proposal **that is suited for the two-year time period of the award**, to include the following:
    - Career Development Plan **(6-page limit)**
        - Describe applicant background
        - Career goals and objectives
        - Mentoring plan
        - Proposed career development activities during the two years of the program, including **how the iTHRIV Scholars Program fits into the applicant's career development goals and objectives**
    - Specific Aims (research question(s)) **(1-page limit)**
    - Research strategy **(6-page limit)**
        - Include plan to assure scientific rigor and reproducibility (applicants may wish to consider resources offered by the Center for Open Science (https://cos.io/))
        - References cited (not included in the page limitations)

        Note: the research proposed in the application should be feasible to complete during the two years of the program.
    - List up to three additional areas of expertise (or individual faculty members) that would be welcome contributions to the proposed project or augment the applicant's career development plan.
- Budget and Budget Justification

    Note: Applicants will receive a REQUIRED budget template from us once their LOI has been reviewed and approved. Applicants are expected to work with their research/grants administrator on the budget and should ask questions when uncertainties arise. See page 5 for funding details.
- Letters of support **(6-page limit total for ALL letters)** from the following:
    - Department chair/head unit, which must include the following:
        - A statement confirming 75% protected time
        - Confirming participation in our 4-hour weekly sessions
        - A guaranteed third year of department/institutional funding to support 75% protected research time as described above.

        Note: This could be the same or updated version of the letter of commitment submitted with applicant's LOI.

- Primary scientific mentor, which must include the following:
  - Their commitment to the mentoring relationship, including a description of mentoring time and regular interactions with the candidate – the greater the specificity the better
  - A commitment to attend monthly Mentoring Hour discussions and other mentoring activities as available
- Co-mentors named in the application, which must include the following:
  - A description of their commitment to the candidate, including a description of the time and activities planned – the greater the specificity the better
- Consultants and contributors named in the application, which must include the following:
  - A description of their commitment to the candidate, including a description of the time and activities planned – the greater the specificity the better

- Description of Institutional Environment and Commitment **(1-page limit)**
- Human Subjects (see Addendum 1 below if applicable OR state N/A if not appropriate)
- Vertebrate animals (see Addendum 2 below if applicable OR state N/A if not appropriate)
- Biohazards (state N/A if not appropriate)
- Data Management & Sharing Plan
- Conflict of Interest Disclosure:
  - Indicate whether or not the research involves the evaluation or further development of intellectual property associated with the financial interests of the applicant, mentor(s), or other participants.
  - Describe the plan for management of any potential conflict if applicable.

Applications should be submitted electronically on or before **January 21, 2025 at 8:00 am**. No applications will be accepted after this date and time. Interested and eligible applicants that submit a LOI will be emailed instructions and a link to complete their full application submission.

Funds Available and Anticipated Number of Awards
The number of awards is contingent upon funding appropriations and the submission of a sufficient number of meritorious applications. Depending on specific circumstances, individuals may be invited to participate in the program with no funding support from iTHRIV.

Award Budget (contingent upon available funding)
Some faculty who are appointed to the iTHRIV Scholars Program could receive up to $30,000/year for research and career development-related expenses including supplies, Scholar travel, Scholar training and/or tuition, etc. for each year of the two-year appointment. These funds may not be used to support Scholar salary/fringe, however may be used to support other personnel costs related to Scholar research. No mentor salary/fringe costs are permitted. Additionally, some faculty who are appointed to the Scholars Program could receive up to $120,000 per year for the two-year appointment period for salary costs (exclusive of fringe) to support the iTHRIV Scholar.

Award Project Period
The project period duration is two years.

Key Dates:

- Request for Applications released: **Tuesday, October 15, 2024**
- Letter of Intent & Department Chair/Head Unit Letter of Commitment: **Tuesday, December 10, 2024 by 8:00 am** (required)
- Full Applications Due: **Tuesday, January 21, 2025 by 8:00 am**
- Interviews by Invitation: **During the months of March & April 2025**
- Notification of Appointment: **Anticipated May 15, 2025**
- Appointment Begins: **Anticipated July 1, 2025**

Information sessions will take place via Zoom on **October 29th at 12:30 pm** (as part of the iTHRIV Scholars Symposium, see link for event registration), **November 7th at 11:30 am** (Zoom link), and **November 12th at 9:30 am** (Zoom link).

Selection Criteria:

NIH Scoring criteria will be used to evaluate submitted proposals and determine candidates selected for interviews.

Each of the following areas will be scored using the NIH nine-point scale:

- Overall impact
- Candidate
- Career development plan/career goals & objectives/plan to provide mentoring
- Research plan
- Mentors/consultants/collaborators
- Environment and institutional commitment to the applicant

Additional Review Criteria:

  - Human Subjects
  - Vertebrate Animals
  - Biohazards
- Potential for Integration of Data Science and Team Science Principles
- Approach to Scientific Rigor and Reproducibility

Reviewer comments will be returned to applicants with the intent of providing feedback that will be helpful for all applicants (whether or not the proposal is funded) for future competitive proposals. Applications with sufficiently high scores will progress to the interview stage, meeting with iTHRIV Scholars Program leadership to discuss their project and career development plan. Both the scientific critique and the interview will factor into final selection.

Support for Applicants:

For any and all questions, contact the iTHRIV Training Programs Manager, Amy Harrigan (acm6a@uvahealth.org).

References for proposal content and selection criteria:

1. NIH Biosketch format, template: https://grants.nih.gov/grants/forms/biosketch.htm
2. Other Support information and template: https://grants.nih.gov/grants/forms/othersupport.htm
3. NIH Research Career Development Program:https://researchtraining.nih.gov/programs/career-development
4. NIH Scoring Guidance for Career Awards: https://grants.nih.gov/grants/peer/guidelines_general/scoring_guidance_training.pdf
5. Data Management and Sharing Plan: https://portal.ithriv.org/#/resource/1689

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Addendum 1- Human Subjects

Exempt Research: For human subject research which meet one of the eight categories of research that are **exempt** under 45 CFR Part 46, please include the following in your proposal:

https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-a-46104/index.html

1. **Justification for the exemption**

   The applicant should include a justification for the exemption. This justification should explain how the proposed research meets the criteria for exemption claimed. Do not merely repeat the criteria or definitions themselves.

2. **Human subjects involvement and characteristics**

   The applicant should include how humans subjects will be involved the proposed plan and the characteristics of those human subjects.

3. **Sources of materials**

   The applicant should include the specific sources of materials to be utilized in the research project. This could include types of data or specimens. Please include the plan for securing these sources of material.

Non-Exempt Research: For **non-exempt** research that involves human subjects (projects which do not meet the criteria for exempt are, the following sections should be included:

1. **Inclusion of Individuals Across the Lifespan**

   The applicant should include the proposed plans for inclusion of individuals of all age ranges. Individuals of all ages are expected to be included in all NIH-defined clinical research unless there are scientific or ethical reasons not to include them. The applicant should discuss whether individuals will be excluded based on age and provide a rationale for the minimum and maximum age of study participants, if applicable. Additionally, if individuals will be excluded based on age, provide a scientific or ethical rationale for their exclusion.

2. **Inclusion of Women and Minorities**

   The applicant should include the proposed plans for inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity. The applicant should describe the planned distribution and rationale for selection of subjects by sex/gender, racial and ethnic group, as well as describe the proposed outreach program for recruiting sex/gender, racial and ethnic group members.

3. **Recruitment and Retention Plan**

The applicant should include the proposed plan for recruitment and retention of all subjects involved in non-exempt research. The plan should describe both the planned recruitment activities as well as the proposed engagement strategies for retention.

4. Protection of Humans Subjects

The applicant should include a full description of the protection of human subjects. The following sections should be included:

1. Risk to Subjects
    a. Human subject involvement, characteristics, and design
        - *Briefly describe the overall study design.*
        - *Describe the subject population(s) to be included in the study; the procedures for assignment to a study group, if relevant; and the anticipated numbers of subjects for each study group.*
        - *List any collaborating sites where human subjects research will be performed, and describe the role of those sites and collaborating investigators in performing the proposed research.*

    b. Study procedures, materials and potential risks
        - *Describe all planned research procedures (interventions and interactions) involving study subjects; how research material, including biospecimens, data, and/or records, will be obtained; and whether any private identifiable information will be collected in the proposed research project.*
        - *For studies that will include the use of previously collected biospecimens, data or records, describe the source of these materials, whether these can be linked with living individuals, and who will be able to link the materials.*
        - *Describe all the potential risks to subjects associated with each study intervention, procedure or interaction, including physical, psychological, social, cultural, financial, and legal risks; risks to privacy and/or confidentiality; or other risks. Discuss the risk level and the likely impact to subjects.*
        - *Where appropriate, describe alternative treatments and procedures, including their risks and potential benefits. When alternative treatments or procedures are possible, make the rationale for the proposed approach clear.*

2. Adequacy of Protection Against Risk
    a. Informed Consent and Assent
        - *Describe the process for obtaining informed consent. Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. When appropriate, describe how potential adult subjects' capacity to consent will be determined and the plans for obtaining consent from a legally authorized representative for adult subjects not able to consent.*
            - ***For research involving children:** If the proposed studies will include children, describe the process for meeting HHS regulatory requirements for parental permission and child assent (45 CFR 46.408). See the HHS page on Research with Children FAQs and*

the NIH page on Requirements for Child Assent and Parent/Guardian Permission.

- *If a waiver of some or all of the elements of informed consent will be sought, provide justification for the waiver. Do not submit informed consent document(s) with your application unless you are requested to do so*

b. Protection against risk
- *Describe planned strategies for protecting against or minimizing all potential risks identified, including strategies to manage and protect the privacy of participants and confidentiality of research data.*
- *Where appropriate, discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects on participants.*
- *Describe plans for handling incidental findings, such as those from research imaging, screening tests, or paternity tests.*

c. Inclusion of vulnerable subjects (if relevant)
- *Explain the rationale for the involvement of special vulnerable populations, such as fetuses, neonates, pregnant women, children, prisoners, institutionalized individuals, or others who may be considered vulnerable populations. 'Prisoners' includes all subjects involuntarily incarcerated (for example, in detention centers).*
- ***Pregnant Women, Fetuses, and Neonates or Children***
  If the study involves vulnerable subjects subject to additional protections under Subparts B and D (pregnant women, fetuses, and neonates or children), provide a clear description of the risk level and additional protections necessary to meet the HHS regulatory requirements.
- ***Prisoners***
  If the study involves vulnerable subjects subject to additional protections under Subpart C (prisoners), describe how proposed research meets the additional regulatory requirements, protections, and plans to obtain OHRP certification for the involvement of prisoners in research.

3. Potential benefits of the proposed research to human subjects
   - *Discuss the potential benefits of the research to research participants and others.*
   - *Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to research participants and others.*
   - ***Note:** Financial compensation of subjects should not be presented as a benefit of participation in research.*

4. Importance of knowledge to be gained
   - *Discuss the importance of the knowledge to be gained as a result of the proposed research.*
   - *Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that reasonably may be expected to result.*

Addendum 2- Vertebrate Animal Research

Vertebrate Animals
For projects which involve live vertebrate animals as part of the project, please include the following in the proposal:

(1) Description of proposed procedures involving animals, including species, strains, ages, sex, and total number to be used;

(2) Justifications for the use of animals versus alternative models and for the appropriateness of the species proposed;

(3) Interventions to minimize discomfort, distress, pain and injury

(4) Justification for euthanasia method if NOT consistent with the AVMA Guidelines for the Euthanasia of Animals.