

West Virginia Clinical and Translational Science Institute

Research Scholar Handbook

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WVCTSI Research Scholar Program

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Research Scholar Program Mission

The mission of the West Virginia Clinical and Translational Science Institute (WVCTSI) Research Scholar Program is to support junior faculty in becoming independent investigators leading programs in clinical and translational research. The desired outcomes of the program are to enable investigators to develop peer-reviewed publications and submission of extramural grant applications, with the ultimate goal of transitioning to independent federal funding (e.g. NIH K- or R-type). This mission is accomplished through an organized program of financial support, faculty mentoring, professional development seminars, and opportunities for the faculty appointed as a Research Scholar (RS) to present their scientific work.

WVCTSI Research Scholar Program Goals:

- To provide mentored research experience in a productive scientific setting
- To provide salary support to ensure protected time to conduct research
- To provide opportunities for professional development in a structured and individually custom-tailored manner

WVCTSI Research Scholars will have access to numerous WVCTSI research services. These research services include pre- and post-award grant management support, biostatistics, bioinformatics, study design, clinical trials support, pilot funding, proposal development and networking opportunities with potential collaborators at WVU and partner institutions. A mentoring plan has been designed for Research Scholars with the objective that the Research Scholars will become independently funded investigators in clinical and translational science.

WVCTSI Research Scholar Program is administered through the Professional Development Core of the WVCTSI by the Program Director, Dr. A. Courtney DeVries; Co-Director, Dr. Joan M. Lakoski; and Program Manager, Sarah Haymond.

Program Details

Eligibility

The WVCTSI seeks candidates at the Assistant Professor level with a clinical or professional degree (MD, PhD, PharmD, PhD-physician/clinician scientist). Candidates must also be U.S. citizens or permanent residents. Applicants must be faculty at the West Virginia University or one of the WVCTSI Partner Institutions (West Virginia School of Osteopathic Medicine, Marshall University) and registered as a WVCTSI member.

Mentoring

An essential component of the Research Scholar Program is a mentoring team built around the individual scholar. Comprised of multiple faculty with expertise and experience appropriate to this role, this mentoring team will assist the RS by facilitating the development of clinical and translational research skills, promoting and guiding in career development and advancement, and facilitating the entry of the mentee into a successful academic research career with strong potential for extramural support. The primary mentor, and additional members of the mentoring team, should be experienced and established investigators in clinical and translation research at the time the RS applies for the program. The mentoring team should be composed of one primary mentor, and additional mentors, not to exceed a total of four.

Expectations include:

- The mentoring team will conduct regular and frequent team meetings with the mentee. There should be a minimum of one meeting of the primary mentor and the mentee per week, and at least one hourly documented meeting every other month of the full core mentoring team and the mentee. The Professional Development Core Program Manager, Sarah Haymond, should be kept informed of all scheduled meetings by the RS. WVCTSI staff will facilitate the scheduling of meetings and videoconferencing technology as needed.
- The mentoring team will work with the mentee to develop specific goals and objectives for substantive learning/skills/progress to be achieved and identify timelines for achieving program requirements and milestones. These goals and objectives will be formalized via a written annual plan, ideally in an Individual Development Plan (IDP) or Individual Opportunity Plan (IOP) format. Training will be provided to the RS (required) and to their mentors (should they be unfamiliar with this process; optional)
- The RS will meet quarterly with the WVCTSI leadership to discuss project goals, progress, and any other pertinent information.
- Unless one mentor is a biostatistician, the RS is required to consult with a biostatistician twice per year.

Professional Development for Mentors

WVCTSI will provide professional development opportunities for mentors through tailored workshops and seminars. It is the expectation that the mentors will attend as their schedule allows.

Logistical Requirement:

- The RS must be a WVCTSI member. Visit the WVCTSI web site at (<http://www.wvctsi.org/>) to become a member.

- In order to access WVCTSI services, the RS must have an iLAB account. To learn more about iLAB and setting up an account, please visit this [site \(accessible via the www.wvctsi.org\)](http://www.wvctsi.org).
- The RS must have and share their ORCID ID (www.orcid.org) with the Professional Development Manager, Sarah Haymond.

Program Activities

Orientation

Before the disbursement of scholar funds, the RS will attend an orientation of the program. The orientation will serve to provide the scholar with clear expectations and guidelines for being a WVCTSI Research Scholar. The objective of this orientation is for the RS to learn the expectations and program requirements including guidelines, procedures for the mentor/mentee relationship, professional development attendance, RS works-in-progress program, budgeting and purchasing procedures, and quarterly reports. The expectation of applying for extramural funding and generating peer-reviewed publications will also be discussed.

WVCTSI Research Scholar Works-in-Progress & Educational Seminars

The Research Scholar Works-in-Progress (RS WIPS) is an opportunity for scholars to present their research ideas and design, discuss and analyze data, and obtain feedback from their mentors, content experts, and program leadership. Presentations should be interactive and serve as a time to receive feedback and constructive criticism for planned and ongoing studies, help prepare research results to present at conferences or for publications, and guide future studies.

- All RS will present twice per year.
- Attendance is required by all research scholars.
- Attendance is expected by the mentoring team on the days that the RS presents.
- WVCTSI Professional Development core will provide a PowerPoint template and technology assistance as needed.
- One week prior to scheduled presentation, the RS will upload their presentation into the RS SOLE site for review and feedback from the program leadership.
- In addition, educational seminars and/or informal networking opportunities held monthly will provide professional development relevant to clinical and translational science. RS attendance is required.

Presentations

In addition to RS WIPs, research scholars are expected to present their research at WVCTSI-sponsored events that allow for the highlighting of WVCTSI-supported scientists, including the WVCTSI Annual Meeting. Research Scholars are also encouraged to submit poster presentations and abstracts at relevant national professional society conferences.

WVCTSI Principal Investigator (PI) Academy

The PI Academy is a program structured with curriculum and periodic training events to provide WVCTSI-affiliated faculty researchers conducting clinical trials, as defined by the NIH, with the appropriate infrastructure for successful trial management.

- Research Scholars are expected to join the PI Academy, attend the training events, and complete the PI Academy curriculum. For more information about this program please contact Meghan Reeves, WVCTSI Assistant Director of Investigator Development, at mreeves1@hsc.wvu.edu.

WVCTSI K and R Award Grant Writing Groups

- Research Scholars are required to participate in a K Award Grant Writing Group and submit an application for the NIH Mentored Career Development Training Award.
- If a RS has already applied for a K award, then participation in a R type Grant Writing Group is required to complete an application for an independent external research funding.
- K-Club Grant Writing Groups run over a 12-14 week period and meet for 6 sessions (programs are offered in advance of every NIH submission deadline).
- R03/R21 Grant Writing Groups run over a 5 week period and are offered prior to each NIH submission deadline.
- R01 Grant Writing Groups run over a 4-month period in advance of an NIH submission deadline and include a required submission of the proposal for review by the HSC Internal Study Section.

Tracking and Evaluation

Quarterly Reports

The WVCTSI must report outcomes of services to the funding agency for this federal award (NIH/NIGMS) to maintain funding and continue providing services. Because of this requirement, Research Scholars must complete quarterly reports to update the WVCTSI on the outcomes of their research. Currently, this quarterly report is completed online via Qualtrics. The typical schedule for reports to be submitted are mid-September (Q1), mid-December (Q2), mid-March (Q3) and mid-June (Q4).

- Research scholars will be notified, via email, of quarterly report requests and due dates; typically, notification will be provided 3 weeks in advance of a due date.
 - Items to include:
 - Updated CV
 - Professional Services provided
 - Honors or Awards received
 - Undergraduate students mentored
 - Graduate students mentored
 - Residents or Fellows mentored
 - Publications completed (submitted, in press, or in print)
 - External grant applications submitted
 - External grants awarded
 - Presentations given related to research scholar’s research project
 - WVCTSI services received
 - Key accomplishments related to research scholar’s research project
 - Issues encountered related to WVCTSI-funded project
 - Participation in workshops, seminars, professional develop training, or other continuing education activities
 - Study section participation
- Planned activities and next steps for the scholar’s research and professional development activities

Application and Selection Process

Those interested in becoming a WVCTSI RS will complete a two-part application process by first submitting a letter of intent and then a final application. Application will only be accepted from faculty appointed full time at the rank of Assistant Professor (Associate Professor will be considered on a case by case basis).

Letter of Intent

To better serve those applying for WVCTSI RS Program; Letters of Intent (LOI) will be required from interested Principal Investigators. The proposed projects should address health care needs of West Virginia. Examples include, but are not limited to, the following health care disparities:

- Addition and Resultant Emerging Epidemics (hepatitis C)
- Cancer
- Cardiovascular Disease
- Chronic Lung Disease
- Neuroscience

The purpose of the LOI is to facilitate review planning. Additionally, the LOI is a valuable feedback tool to further strengthen the full proposal applications. LOIs are due two months prior to the full application deadline and should follow this [template](#).

Call for full applications

After the Professional Development Core leadership has reviewed the LOI, candidates will be notified via email whether they have been selected to submit a full proposal application. Two months will be given for the completion of the full proposal application. For complete request for application (RFA) requirements, please visit this [link](#).

Biostatistical consultation

Prior to submitting full proposal applications, RS applicants are required to consult with a biostatistician. This will serve to ensure the statistical aspects of the proposed study are rigorous. Access to a biostatistician is available via iLAB request to the WVCTSI.

Review and Selection Process

Submitted applications will undergo peer review. Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the four scored review criteria, and additional review criteria. An application does not need to be strong in all categories to be judged likely to have major scientific impact.

Scored Review Criteria:

- Candidate
- Career Development Plan
- Research Plan
- Mentors

Additional Review Criteria:

- Protection for Human Subjects
- Budget and Period of Support
- Clinical and Translational Focus
- Potential for future funding

WVCTSI leadership, taking into consideration programmatic priorities and availability of funds, will make final funding decisions. Appeals of initial peer review will not be accepted for applications submitted in response to the RFA.

Award Notices:

The formal notification in the form of a Notice of Grant Award (NGA) will be provided to the applicant via email for successful applicants.

Professional Standards

Citing IDeA CTR

WVCTSI investigators are required to cite IDeA CTR support (NIH/NIGMS Award Number 5U54GM104942-05) in all publications and presentations. Language for citing can be found at <https://www.wvctsi.org/about-us/citing-wvctsi/>.

Compliance

Research Scholars are committed to promoting objectivity in research by establishing and maintaining ethical standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI); in accordance with 42 CFR Part 50 Subpart F. Grantees must be in compliance with all aspects of the 2011 revised regulation. Consult the NIH website. <http://grants.nih.gov/grants/policy/coi> for a link to the regulation and additional important information.

Press Releases

Research scholars are expected to notify WVCTSI Communication Specialist, Ian Moore, at imoore3@hsc.wvu.edu, prior to issuing press releases or other public advertisements concerning the outcomes of their WVCTSI-funded project. Additionally, research scholars are expected to participate in interviews, press releases, and social media updates as requested by the WVCTSI communication team.

Frequently Asked Questions

1. What purchases can be made with Research Scholar funding?

The WVCTSI Research Scholar program has adopted Federal Cost Principles (https://grants.nih.gov/grants/policy/nihgps/html5/section_7/7.9_allowability_of_costs_activities.htm) regarding allowable and unallowable costs. Some exceptions may be considered upon request, provided approval is received from the RS Program Manager and WVCTSI Finance Department.

2. May I make changes to my Research Scholar Budget?

An outline of proposed changes can be submitted to RS Program Manager, Sarah Haymond, and will be reviewed for consideration.

3. Is there a requirement that the primary mentor be faculty at WVU?

While we encourage and support the inclusion of mentors from other institutions, primary mentors are required to be from WVU or a WVCTSI partner institution. (Marshall University, WV Osteopathic School of Medicine, etc.)

4. May I change my mentoring team post-award?

Changes to your mentoring team will need to be discussed with the WVCTSI Research Scholar Leadership team. We recognize that the addition of a new mentor with specialized expertise can be of assistance for moving one's research project along.

5. May I change my project post-award?

The goals and objectives of your research project may change and evolve over time. However, unless there are unique situations or timely opportunities, the focus of your research project should not change without written approval from your mentoring team and the WVCTSI RS Leadership team.

6. What do I do if my department cannot honor the WVCTSI "protected research time" due to professional or clinical duties?

Should you be in a circumstance where there is a sustained loss in your protected research time, as the WVCTSI is a federal grant from the NIH we are obligated to address this issue. Both your department chair and your mentors should understand the protected research time is a commitment to you as a RS. Please notify the WVCTSI RS Leadership team of any difficulties you are encountering so that remedial steps can be taken to address this situation and ensure NIH compliance.

7. May I keep the Research Scholar award and items purchased with the funds if I resign from the university?

Upon resignation from WVU or a Partner's Institution, the policies and procedures of the institution must be honored in accordance with NIH guidelines. Assets purchased typically remain with the Institution.

8. Is the RS award automatically renewed for the second year?

A research scholar reappointment requires documentation of research progress to date and a detailed plan of activities for the coming year. Upon review of this report and discussions with the RS and mentors, and based on availability of funds, a RS reappointment is likely to be approved for a second year.

Useful Resources

- **West Virginia Clinical and Translational Science Institute**
<http://wvctsi.org/>
- **WVU HSC SOLE**
<https://sole.hsc.wvu.edu/login?ReturnUrl=%2f>
- **National Institutes of Health**
<https://www.nih.gov/>

Contact Information

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Signature Page

I have read and understand the WVCTSI Research Scholar Handbook. I agree to abide by the requirements outlined in this document as well as the requirements of the WVCTSI funding support.

Signature: _____

Name (printed): _____

Date: _____