CARILION CLINIC

Research Acceleration Program

GUIDELINES & APPLICATION INSTRUCTIONS

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Research Acceleration Program Statement

Carilion Clinic's Research Acceleration Program (RAP) offers funding for Carilion employees interested in pursuing clinical, biomedical, or behavioral research projects. Projects of particular interest are projects that would advance Carilion's care objectives, education and research excellence as well as strengthen Carilion's collaborative relationships across disciplines within Carilion and/or with research institutions within the region. While all innovative research proposals are welcomed, applicants are encouraged to pursue research in alignment with our Vision 2025 Research and Innovation Strategy.

- Expand, design, and invest in care delivery of the future.
- Grow and invest in clinical platforms that provide cutting-edge treatment capabilities
- Deepen academic partnership
 - Virginia Tech
 - Fralin Biomedical Research Institute
 - Virginia Tech Carilion School of Medicine
 - Radford University Carilion

The Research Acceleration Program has a threefold purpose. First, it is designed to foster a culture of independent research within Carilion and offer the opportunity for Carilion employees to develop research capacity by engaging in pilot projects. Second, the program is intended to provide seed funds for the purpose of producing preliminary data prior to applying for future extramural funding opportunities. Third, the program is intended to result in meaningful changes in patient care—defined broadly to include basic, clinical, and implementation science for the integration of evidence-based medicine into routine practice. RAP grants are not intended to be a source of ongoing support for an investigator's program of study.

This is a competitive program with the granting of awards determined by the quality of submissions (significance, innovation, approach) and the availability of funds. Submissions will be reviewed, and awards provided by the Department of Research and Development.

Eligibility criteria

Any Carilion employee may apply to the RAP program. Per the Carilion PI policy, general criteria to serve as a Principal Investigator must be met. Established investigators, as evidenced by prior extramural funding or a significant publication record in peer reviewed journals are encouraged to apply for Tier I grants.

Proposals that have been previously reviewed and scored but did not receive funding from an external funding agency are encouraged provided your proposal meets the Carilion Clinic priority areas as stated above. All submissions of this type should be accompanied by a copy of reviews as an appendix at the end of your proposal.

Submissions will only be considered for review if the potential principal investigator has no unresolved compliance issues with research oversight (e.g., IRB, Carilion Security Governance Committee, and Carilion Biosafety Committee).

Type of Grant Applications:

<u>Tier I:</u> Up to \$40,000

Tier II: Up to \$15,000

Tier III: Up to \$2,500

General Award Guidelines:

The Department of Research & Development (Research and Development) will announce a request for applications (RFA) in the second week of October. All grant applications are due on Monday, December 2nd at 5:00 pm EST. An email will be sent indicating that the application has been received. The Review Committee will evaluate all applications and announce successful awardees no later than January ^{22nd}, 2025.

Projects involving human subjects, chart reviews, behavioral interventions, translational studies, etc. will require Institutional Review Board (IRB) review (Tier I and II). Once a project is approved by the Review Committee, the Principal Investigator (PI) must obtain Carilion Clinic IRB approval or exemption. In general, the Review Committee requests that submission of your IRB application occurs 90 days following receipt of the award.

The duration of funding for any RAP project is up to two years. If IRB or IACUC (for animal projects) review is required, the project period begins upon receipt of IRB or IACUC approval. If awardees have a project not requiring IRB or IACUC review, the project period begins upon receipt of the Review Committee award letter.

To ensure that RAP projects are proceeding as planned, interim reports are required. These reports are due semi-annually. A final report is due 90 days after the project period and/or project has ended. Failure to submit reports may result in the withholding of remaining funds or denial of future submissions.

RAP Application Form

The <u>RAP application</u> is a web-based online REDCap form. The application mimics our Research and Development application. If you have questions on any sections of the form, you are encouraged to contact Research and Development for assistance. All personnel on the project must be included on this form. The Principal Investigator will sign the application with their mouse and click submit. If the application is completed by someone other than the Principal Investigator, click submit and Research and Development will obtain the PI signature. In addition, **Research and Development will obtain chair**/ section chief approval from the PIs department and all other departments involved in the project. Those involved in the project who are not Carilion employees must be listed on the application form with their professional email listed. In addition to the REDCap fillable form, you will also upload your project narrative and budget. The REDCap has an "other "upload option for information not included in your project narrative.

Project Narrative

The project narrative must adhere to the Project Narrative provided on the <u>Research and</u> <u>Development RAP25 website</u>. The narrative will be considered incomplete if any section is missing. If a particular section is not applicable, do not leave it blank; state it is not applicable and explain why.

The project narrative must be typed in 12-point font (Arial or Times New Roman) and singlespaced and with no smaller than $\frac{1}{2}$ inch margins on all sides. The narrative must be no more than 6 pages. Bio-sketches, graphs, and appendices are not counted against the six-page limit.

Supporting Documents

Biographical Sketches- NEW NIH format required

A biographical sketch is required for the PI as well as all investigators involved in the project. This includes investigators from other institutions and consultants. NIH recently changed the biosketch format and PIs are require to adhere to the new requirements. Please utilize the NIH Common Form for Bio Sketches using the <u>SciENcv</u> platform. This will require ONE of the following: an eRA Commons account, an ORCiD ID/account, or a login.gov account. A sample biographical sketch can be found on the RAP website. For questions or assistance creating an account, please contact Trish Winter at pjwinter@carilionclinic.org. Students and support personnel do not have to submit a biosketch. Biosketches should be attached to the Project Narrative as one combined PDF.

Support and Commitment Letters

If other institutions or individuals outside of Carilion are involved in the project, provide evidence of commitment. If an investigator is from another institution, that institution's sponsored programs office must submit the proper paperwork to Carilion's Research and Development before the application can be considered complete. Carilion Research and Development will require the following documents:

- Letter of Commitment from the institution's sponsored programs office.
- Statement of work that outlines what the institution's personnel are responsible for on the project.
- Budget breakdown and justification of the requested costs.

If a consultant is involved, a letter from the consultant that outlines the work that will be done as well as fee for this work must be included here.

Appendix

Although not required, up to ten pages of appendix material may be included in addition to the project narrative. The following material may be included in the appendix:

- Literature cited, references (please only those directly related to the project research)
- Abstracts of publications directly relevant to the project,
- Flow charts or images,
- Surveys, questionnaires, and data collection instruments,

- Detailed methods
- Documentation of Carilion's care objectives.

Institutional Review Board Application

If your work involves human subjects, IRB approval is required. A submission of the IRB application (including consent forms) must be completed through <u>PRIS3M</u>. If you have already received Carilion IRB approval prior to submitting your RAP application, please indicate this in the Project Narrative.

Information regarding the IRB application can be found on the Carilion Clinic IRB website.

Personnel and Project Budget

There is no specified limit on a particular category of expense; however, the budget request will be carefully considered in funding decisions The following expenses are allowable:

- Supplies, both laboratory and medical
- Patient-related procedures
- Equipment with a justification of how it is directly required for the successful completion of the research proposal (defined as any non-expendable item costing \$1,000 or more)
- Patient-related fees (reimbursements, medical costs, etc)
- Travel related to conducting the research project (e.g., mileage)
- Expenses related to printing or developing project-related materials (surveys, brochures, etc) and publication costs
- Fees for statistical analysis, clinical research coordinators (CRC), pharmacy support, or other staffing that would be required for the completion of your protocol (e.g. technician, nurse, therapist). NOTE: If a research coordinator is needed, it cannot be an admin person from a department **if** anything procedural related, information will be entered into EPIC, or if any procedure, etc. will be billed.
- Salary for support positions only (fringe benefits are unallowable and funds cannot be used for graduate related tuition). Graduate students that have 100 % tuition, fees and a yearly stipend paid by an academic department may be subject to restrictions that supersede the RAP program.
- Consultation fees for persons bringing critical information or skills to the study but who are not investigators and will not be included in any resulting manuscript or presentation.
- Costs up to \$1,800 for regional, national, and international meetings to present findings. This cost consideration is automatically awarded and is above and beyond the Tier cap. It does not need to be included in the proposed budget. Please note that it is ONLY available for two years and is not included in the one time no-cost extension request.

Salaries for the PI and investigators are **not** permitted on RAP budgets. The PI and any investigator must secure the time and associated salary necessary to complete the project from his/her respective department. Facilities and Administrative (F&A) fees (overhead, indirect costs) are not permitted on RAP projects.

In cases where collaboration is with an outside investigator, Carilion will require a subcontract/ research agreement with the outside investigator's institution. Under these agreements, the investigator's institution will be allowed funds from the grant for such expenses as supplies, patient-associated costs, lab fees and/or support staff. Salaries for any subcontractor investigator(s) will **not** be allowable. Note that any funds requested by the outside investigator will be included in the respective budget limit for Tier I and II grants. Agreements with any other institution will only be made upon the award of the project. Research and Development will work directly with the other institution's sponsored programs office to ensure all RAP requirements are met.

Budget Request and Justification

Complete the budget using the excel budget template found on the <u>Research and Development</u> <u>website</u>. Upon completion, upload the budget in your REDCap form where indicated. The budget justification for each budget item requested will be stated in the Project Narrative.

Personnel funds may be requested **only** for support positions. These include research assistants, students, and other support staff.

If you plan to have an external collaborator such as subcontracting partner on your project, please note that Graduate Research Assistants (GRAs) and undergraduate students are not allowed to use RAP funds for tuition and fees; however, students can be listed on projects as support staff and paid an hourly rate. Research Assistants and Graduate Research Assistants hourly rate is capped at \$20/hour.

Itemized Ancillary Services

Supplementary services such as research lab usage, imaging, laboratory tests, and technology services may be charged on RAP projects. Research and Development can provide the appropriate price for hospital services. Please specify which service is required on the budget form and describe the need for this service in the justification.

Materials and Supplies

On the budget form, provide a final total for supplies. A more descriptive list of specific items that will be purchased can be stated in your Project Narrative: Budget Justification.

Equipment (Capital)

Equipment at Carilion is defined as any non-perishable item \$1,000 or over. Any equipment must relate directly to the project, and all equipment purchased becomes the property of Carilion. This includes computer-based equipment as well. Note that each item of equipment must be justified carefully and state why each capital item would be better suited to carrying out the project than what is already on hand within the PI's department or division. Capital will only be allowed if it is essential to complete the project and no suitable alternative is available. A current quote from the vendor must also be included for all requests. Computer-related equipment, should be procured from Carilion TSG. Please note that the purchase of a computer will not be considered.

Consultant

If a consultant is required, indicate the name of the consultant, and give the hourly rate and/or agreed upon costs. Justify the reasons why the consultant is needed for the project to succeed.

Subcontractor

If employees from another institution (using their laboratory or other facilities) are involved, enter that information in the project narrative and funding amount in the Budget form. In the justification section, be sure to specify a breakdown of all costs (e.g., support staff, supplies, and travel). A letter of commitment from that institution's sponsored programs office must be submitted as an attachment to the application. This letter ensures that the subcontractor is aware of, and able to adhere to, the RAP guidelines and policies.

Travel

Mileage reimbursement may be requested if it will be required between sites or for obtaining resources related to the project. Travel for the PI or one research team member to attend a national or regional conference to present project findings is limited to \$1,800 and is not transferrable to a different budget line item post award.

Participant-related Fees

Participant-related fees such as procedure costs and participant stipends are allowable. Please contact Research and Development for costs associated with physician and hospital procedures, as Research and Development can often negotiate for a lower cost for research projects. Note that if a procedure is performed outside of standard of care, you must either budget for it or obtain a cost share approval from the department chair.

Additional Budget Concerns

As RAP funds are intended to underwrite research conducted by Carilion staff, overhead (F&A) is not allowed on any RAP project.

Be sure to show matching or donated amounts where these are made available by your department, or through other sources such as collaborating partners. This information should be included in the budget justification under the in-kind category.

Administration of Awards

A central goal of a RAP award is to support Carilion investigators in their pursuit of extramural funding for their projects. A strong part of this support is assisting the PIs in grant stewardship once the project has been awarded. After award, Research and Development personnel will work closely with each PI to ensure all RAP and Carilion guidelines on spending and reporting are followed.

Program Management

Upon notification of award and before the project begins, Research and Development personnel will meet with the funded PI to discuss the post-award procedures for both the PI and Research and Development.

All ordering requests for supplies, equipment, etc., as well as travel and personnel time expenses, must be routed through Research and Development. Research And Development personnel will approve these expenses and work with the Finance Department to ensure the expenses are charged to the correct project account.

Reporting Requirements

Following IRB approval, interim reports will be required every six months. A Microsoft Teams virtual meeting with the research and R&D teams will be scheduled six months after the project's start to review progress and address any potential issues the study team may have encountered. The written reports will outline the progress of the project to date as well as the benchmarks completed. Templates for interim reports will be sent to the PI.

A final, completion report is due 90 days after the project period and/or upon project completion. This report must include results of the project as well as a description of future extramural submissions. As applicants are expected to develop poster presentations, abstracts and/or articles based upon their findings, these accomplishments should be listed, and copies should be presented with the final report. The final completion form will be sent to the PI.

Budget Modification Requests

Once a project has been approved, Accounting will enter the budget into the Carilion Clinic Lawson system linked to an activity number. If, during the progress of the project, the PI finds that certain costs will not be required or that certain items will be more expensive than initially thought, a budget modification request should be submitted to <u>research@carilionclinic.org</u>. The Principal investigator may move line-item costs within the budget as long as these changes are justified fully. Note that this does not allow the PI to request new funds. It should be noted that any unused funds, whether from an original overestimate of costs or from denial of budget adjustments, will be returned to Research and Development upon completion of the project. Funds are not available to "roll-over" to another grant, nor can funds be used by the investigator for non-research purposes.

Extension Requests

RAP awards are not intended to provide ongoing, long-term support for a project. At the end of up to two years from the date of award notification or IRB approval, the PI should have completed the project and have sufficient data to submit for an extramural award. The Review Committee is aware that occasionally complications arise that require a project to be extended. If a PI has met most benchmarks and has submitted all reports to date, an extension request may be made to the committee. These extensions are for time only; **no additional funds will be awarded.** To request a project extension, the PI should contact the research office at research@carilionclinic.org.

Selection Criteria & Scoring

Submissions will be evaluated based on the criteria shown below. Only applications that follow the specified guidelines will be considered for award. The following criteria will be used to score the grant application. Each category will be scored with a number between 1 and 9. 1 is exceptional and 9 is poor. This is analogous to the NIH scoring system. An overall impact score

between 1-9 will also be given. The grant will be scored by no less than two reviewers with expertise in the subject area.

Scored Review Criteria

Reviewers will consider each of the four review criteria below in the determination of scientific and technical review and give a separate score for each.

1. <u>Significance</u>	Score (1-9)
Strengths	
•	
Weaknesses	
•	

2. Innovation	Score (1-9)
Strengths	
•	
Weaknesses	
•	

3. <u>Approach</u>	Score (1-9)
Strengths	
•	
Weaknesses	
•	

4. <u>Feasibility</u>	Score (1-9)
Strengths	
•	
Weaknesses	
•	

Overall Impact or Criterion Strength	Score	Descriptor
	1	Exceptional
HIGH	2	Outstanding
	3	Excellent
	4	Very Good

MEDIUM	5	Good
	6	Satisfactory
LOW	7	Fair
	8	Marginal
	9	Poor

Section Elaboration:

<u>Section 1 – Significance</u>

Specific aims of the proposed work are clearly stated and understandable to a non-specialist reader.

The research objectives would be a significant achievement and represent a meaningful advance in science and/or quality of care.

The research objectives are reasonable and attainable given the time period and requested support.

The application successfully demonstrates the potential impact of the project. The issues addressed are important and timely. The severity and prevalence of the issue make the proposal compelling.

The application is consistent with and would contribute to Carilion's care objectives and clearly describes how the proposed work may advance knowledge or practice in the field (i.e., the work addresses gaps in the literature, advances the state of scholarship, and/or adds value in some other way).

Demonstrates that this is an area of interest for extramural sponsors.

Section 2 – Innovation

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions?

Section 3 – Approach

The descriptive, analytical, and other proposed research methods are clearly articulated and sufficiently detailed so that a non-specialist reader understands how the applicant will conduct the proposed work.

The application persuades general readers that the proposed methods are reasonable, appropriate, and likely to result in the accomplishment of the research objectives.

The Principal Investigator and research team are capable of performing all research procedures and tasks.

The work plan states realistic benchmarks and proposed timeline for completing the tasks required to achieve the research objectives.

There are no immediately identifiable concerns regarding compliance, including IRB or biosafety committee approvals.

The application includes description of collaborative efforts within Carilion and/or with external partners.

The application contains information about the extent to which Carilion's infrastructure is capable of supporting the project.

Section 4 – Feasibility

The research project is feasible from a Human Resource standpoint (personnel).

The research project is feasible from a subject recruitment standpoint (have patient population in excess of recruitment goal).

The research project is feasible to be completed within the 24 month funding period.

The research project appears feasible according to the data acquisition and analytic plan.