**Application for Research Acceleration Program Funding**

**(Tier I and II)**

Carilion Clinic has designated funds for the Research Acceleration Program (RAP) to provide seed money for pilot research projects. This seed funding will enable Carilion faculty to conduct preliminary research in order to develop and enhance pilot projects into competitive candidates for external funding and publication opportunities.

Applications will be reviewed according to the following criteria:

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| * Significance
 | * Innovation
 |
| * Approach
 | * Dissemination
 |
| * Feasibility
 | * Relation to Applicant’s Work & Goals
 |

The RAP funding cycle is annual. The average project period will be one year, and funds must be spent within that one-year period. The deadline for submitting an application and all supporting documentation will be announced on the Department of Research & Development’s (R&D) webpage and via a general email announcement. The original signed and completed application packet must be delivered to R&D no later than 4:00pm on the due date.

**Applications must include the full protocol/abstract.** If your project involves any outside person or organization, if funded, your project will require a collaborative agreement, which will be negotiated by R&D and will need to be approved by the VP of Academic Affairs. Should you have any questions about the process, please contact R&D at 540-985-8510, (F) 540-985-9816, or research@carilionclinic.org.

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| 1. **General Project Information**

**NOTE: Once you enter the application process your project PI & Title MUST remain the same****\*\*PI cannot be a resident or medical student** |
| Carilion Principal Investigator/Program Director: |       |
| Department& Address:  |       |
|  | Telephone: |       |  Email: |       |
|  |
| Contact Person (if other than PI): |       |
|  | Telephone: |       | Email: |       |
|  |
| Project Title: |       |
| **II. Additional Funding Information** |
| Does your project have additional funding? | [ ]  Yes or pending [ ]  No (If no, skip to section III) |
| Project Sponsor: |       |
| Program Name: |       |
| Sponsor Due Date |       | [ ]  Receipt Date  |  |
| Sponsor Address: |       |
| Sponsor Contact: | Name: |       |
|  | Email: |       | Phone: |       |
| Sponsor Type: | [ ]  Federal [ ]  Fed Flow Thru [ ]  State [ ]  Foundation/Non Profit [ ]  Industry/Commercial |
| Check All That Apply:  | [ ] Research | [ ] Instruction  | [ ] Scholarship / Fellowship / Training [ ] Public Service |

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| **III. Personnel & Time and Monthly Effort on Project of Carilion Employees** |
| **Name** | **Role &Responsibility** | **Percent Effort**\* | **Signature** |
|       |       |       |        |
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| **\*Please enter the total monthly percentage of effort each individual will spend on the duration of the project. As an example, if a full-time investigator will work one day a week on the project, the percent effort would be 20%.** |

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| **IV. Non-Carilion Collaborator Contribution, including Students (see details below)** |
| **Name** | **Role &Responsibility** | **Institution** | **In-Kind Contribution** |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |
| If your project has any non-Carilion collaborator or team member, including students and faculty from other institutions such as VT (including VTCRI & VA-MD Vet Med), VTCSOM, VCOM, LTC/Nursing facilities, etc. Please include a Letter of Intent and a Statement of Work, which can be downloaded at [here.](http://insidecarilion.org/system/files/Statement_of_Work_SAMPLE.DOC) **NOTE:** Additional agreements may be required. |

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| **V. Required Attachments** |
| The following documents must be attached to this form in order for your application to be considered complete. |

1. **Research Acceleration Application**

Must be complete with all signatures.

1. **Biograhical Sketches of PI and all Key Personnel**Must be in NIH format, no more than 4 pages each.
The biosketch form is available on Inside Carilion Research RAP Info and Forms
2. **Completed Budget Request and Justification**

Complete the budget request in Section XI (page 6). Include a justification of each expense in the space provided in Section XII (page 7).

1. **Completed Project Narrative**

See Section XIII (page 8) for required outline

1. **Support Letters (if project involves outside collaborators or intuitions)**

If there is a collaborating institution (subcontractor), a letter from the institutions research office is required; see page 10 of the RAP Guidelines.

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| **VI. Additional Department Involvement**  |
| **\*\*If services from other areas are being requested please note that a Feasibility Meeting will be scheduled to work through the roles and responsibilities and possible charges to the project. Non-sponsored projects are required to undergo review by the Carilion Research Review Committee (CRRC).**Signatures from area leadership **must** be included if leadership from that department is not able to attend the feasibility meeting. Note that some of these services will incur a charge and you should plan your budget accordingly.  |
| [ ] Technology Services/  Health Analytics[ ] EPIC/EMR Optimizations[ ] MyChartReporting[ ]  Analytics  (Biostatisticians) [ ]  Reports/Extracts[ ]  EPIC Build or Set-up | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | [ ]  Basic Science  Laboratory[ ]  Biohazards[ ]  Hazardous  Chemicals/  Waste[ ]  Recombinant  DNA/RNA[ ]  Animals | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| [ ]  Pharmacy |  | [ ]  Emergency Dept. |  |
| [ ] Solstas Lab |  | [ ]  Psychiatry Dept. |  |
| [ ]  Nursing |  | [ ]  Surgery Dept. |  |
| [ ]  Medicine Dept. |  | [ ]  Jefferson College |  |
| [ ]  OB/GYN Dept. |  | [ ]  Human Resources |  |
| [ ]  Pediatrics Dept. |  | [ ]  Pathology |  |
| [ ]  Physical Therapy |  | [ ]  Radiology |  |
| [ ]  Respiratory |  | [ ]  Center for Simulation, Res &Pt Safety |  |
| [ ]  Other (Please Specify): |  |  |  |

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| **VII. Assurance & Compliance Information** |
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| **Yes** | **No** |  |
| [ ]  | [ ]  | Is this project a retrospective record review only? |
| [ ]  | [ ]  | Is it anticipated that this project will be a QA/QI project that will not require any support from other areas nor require access to any potentially identifiable patient information? |
| [ ]  | [ ]  | Does this project involve intervention or interaction with human subjects (including physical procedures, communication, subject data, or surveys)? If yes, CRRC review needed. |
| [ ]  | [ ]  | Does the project involve more than minimal risk (greater than those encountered in daily life or during routine examinations)? |
| [ ]  | [ ]  | Does this project involve a commitment to cost sharing or matching? |
|  |  | If **Yes**, complete and attach [Cost Share Approval form](http://insidecarilion.org/system/files/Cost%20Share%20Approval%20Form.xls). |
| [ ]  | [ ]  | Intellectual Property (IP): – contact baharber@carilionclinic.org for additional information:[ ] Ideas [ ] proprietary data [ ] computer software [ ] inventions [ ] patents  |
| [ ]  | [ ]  | Check if there is any Carilion IP involved or potential commercial IP to be developed. If **Yes**, you will be provided a more detailed form to complete. |
| [ ]  | [ ]  | Does this project need to be registered with ClinicalTrials.gov?\*Projects that involve a drug or device must be reported per Section 801 of the Food and Drug Administration Amendments Act (FDAAA801) by the Responsible Party. For FAQs relating to your responsibilities for registering on clinicaltrials.gov visit: <http://clinicaltrials.gov/ct2/manage-recs/faq#industryFDAAA> Please contact R&D to assist with your log in credentials. |

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| **VIII. PHI – Protected Health Information** |
| **Will your project access any Protected Health Information?** | **[ ]  Yes** **[ ]  No** |
| \*\*If you do need to access any PHI for your project then you will also need to submit the PHI Access Request form for research purposes to R&D. The form can be downloaded @ [http://insidecarilion.org/hubs/privacy-security/documents/privacy-and-information-security-clinical-research-questionnaire#](http://insidecarilion.org/hubs/privacy-security/documents/privacy-and-information-security-clinical-research-questionnaire). If you are not sure if you will be accessing PHI, please view the PHI Policy for clarification @ <http://insidecarilion.org/hubs/privacy-security>.  |

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| **IX. Recruitment Plan** |
| How many study subjects:  |       | What time line: |       to       |
| Where are participants coming from – referral source(s):  |       |       |       |
| How will you engage the referral source(s): |       |

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| **X. Signatures & Certification** |

**Your application will not be deemed complete without all appropriate department chair or designee signatures. Once you enter the application process your project PI & Title MUST remain the same.**

**By signing below, PI/PD certifies that:**

1. The information submitted within the application is true, complete and accurate to the best of the PI’s knowledge;
2. Any false, fictitious, or fraudulent statements or claims may subject the PI to criminal, civil, or administrative penalties;
3. The PI agrees to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of the application;
4. The proposal complies with federal regulations including standards for integrity of research, RFP/ Announcement requirements, and Carilion's Policies and Procedures;
5. The principal investigator, co-investigators, or anyone involved in the sponsored activity is not presently debarred, proposed for debarment, suspended, declared ineligible, or voluntarily excluded from transactions by the federal department, or agency; and are aware of no circumstance invalidating the legal certifications in the proposal to be made on behalf of the Carilion Clinic.

Principal Investigator/PD: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_

**By signing below, management certifies that:**

The following have reviewed and approved this application, and by signing, certify that:

1. The proposed activities are appropriate to the research, instruction or public service mission of Carilion;
2. It is believed that the project aligns with Carilion’s organizational values.
3. The necessary resources for the project, including percent of investigator(s) effort and space and/or facilities are committed and/or budgeted in the RAP grant application.

Chair/Vice President/Dean: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_

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| **XI. Requested Budget [not to exceed $40,000 (Tier I ) or $10,000 (Tier II)]** |
| Please fill out all applicable areas. Salary funds may be requested for support positions. These include students, Research Coordinators, Statisticians and other support staff. Note that the fringe benefit rate for Carilion staff varies by department; please contact R&D for rates. Additional areas of support include supplies, ancillary services, and subcontractors/consultants. As RAP funds are intended to underwrite research conducted by Carilion medical staff, overhead costs (F&A) will not be included. |
| **Other Personnel** |
| ***Name and/or Role*** | ***Percent Time***  | ***Salary Requested*** | ***Associated Fringe Benefits*** | ***Total Request*** |
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| **Other Personnel Total** |  |
| **Itemized Ancillary Services** |  |
| ImagingLab TestsPharmacyTechnology ServicesOther (please identify) |
| **Ancillary Services Total** |  |
| **Materials and Supplies** (Itemize below) |  |
|  |
| **Materials and Supplies Total** |  |
| **Consultant** |  |
|  |
| **Consultant Total** |  |
| **Subcontracting Institution**  |  |
|  |
| **Subcontracting Institution Total** |  |
| **Other Expenses** (itemize below) |  |
|  |
| **Other Expenses Total** |  |
|  |
| **TOTAL REQUEST** |  |

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| **XII. Budget Justification** |

On this page, justify each of the line items in the budget above. For support personnel, give a description of what their roles will be in the project.

**Personnel**

**Ancillary Services**

**Materials and Supplies**

**Consultants**

**Subcontracting Institution**

**Other Expenses (Travel, Equipment, etc)**

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| **XIII. Research Protocol/Abstract** |

**Applicants seeking IRB approval will require a clinical protocol.** The protocol must be submitted with your IRB application. If collaborating with any outside organization please include a [statement of work](http://insidecarilion.org/system/files/Statement_of_Work_SAMPLE.DOC) with your application.

Carilion Clinic Research Proposal/Protocol

**Carilion Clinic Protocol Template Version Date: September 2016**

**Study Abstract**

**{Provide a brief, non-technical summary of the study, including study purpose, methods, population(s) and expected outcomes. It should stand on its own and not refer to points elsewhere in the protocol.}**

**Background (Significance and Innovation)**

**{Summarize background information about the research question(s). Tell why the research is needed and include the relevance of the research to contribute to this field of study. Also, provide references to relevant articles in the literature. (If you have more than 10 references, please submit the list of references as a separate attachment. Otherwise, please insert them here.)**

**Objectives/Specific Aims**

**{State the research hypothesis or question(s) the research will answer. List the research objectives and expected outcomes. A primary outcome or objective must be identified. After the statement of the primary objective, secondary objectives may be listed. Objectives should be simple and specific.}**

**Study Design (Approach)**

**{Begin with a brief description of any preliminary studies. Give a description of the research design, including the use of placebo, randomization and an explanation of what is experimental. Include type of study: descriptive, retrospective, cross-sectional, longitudinal, prospective, observational, and experimental (controlled or non-controlled) or pilot.}**

 **Study Population**

**{Describe the subject population, including age, gender, ethnic characteristics and health status. State the inclusion/exclusion criteria along with how this was determined and by whom. Please state whether pregnant women, children, or other vulnerable groups will be included or excluded. Provide rationale for using or excluding special populations. Address the feasibility of your recruitment and retention strategies.}**

 **Methodology**

**{List all activities or procedures that will be performed (e.g. pre-treatment tests and medications, tests and medications used during therapy, diagnostic tests, X-rays, laboratory tests, questionnaires and other forms, interviews, focus groups, chart reviews, etc.) Describe how and where tests will be analyzed. Distinguish any standard processes from those that are research. Please describe activities/procedures in a step-by-step, chronological order.}**

 **Data Collection/Extraction**

**{List exactly what data is to be gathered during this research study. Include data collection methods and how data will be compiled for assessment. Attach a copy of your Data Collection tool to this application. Address the data extraction questions below and the feasibilityof obtaining the data within the RAP time frame}**

*Data extraction questions:*

*Over what time period will data be extracted?*

*How is the population defined (please provide detail on specific diagnosis codes, procedure codes or other elements)*

*What departments/locations should be included? Are there other exclusions like deceased or non-Carilion PCPs?*

*What data elements are you requesting on the report? Please be very specific for example specifying specific conditions or specific target medications or results? Keep in mind that you should have far fewer variables than patients.*

**Statistical Analysis**

**{State how qualitative and/or quantitative data will be analyzed. Other outcomes may be listed as secondary and descriptive.}**

**Research Dissemination**

**{Describe expected outcomes and how the findings will be used to inform future work. Indicate expected modes of dissemination of the study findings (publications, presentations, patents, etc). Provide specific extramural directions you will follow should your hypotheses be supported and the directions you will take should the hypotheses not be supported. As such, indicate how you plan on submitting for an external grant (Foundations, NIH, state agencies, etc) based upon your findings, including specific information about potential funding opportunities (RFPs) to which a proposal will be addressed. Finally, if the application is related to a Carilion care priority, describe methods that will be used to ensure the findings are implemented broadly across the system, if applicable.}**

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| **XIV. Privacy & Information Security Clinical Research Questionnaire** |

**Privacy and Information Security Clinical Research Questionnaire**

Please answer the questions below to describe the plan to protect the data from improper use and disclosure.

## General Information – Study title

## Which HIPAA identifiers will the study team collect?

**INSTRUCTIONS**: Select YES to any item that will be written down/kept/recorded in **any** way that relates to this study.

|  |  |  |
| --- | --- | --- |
| **YES** | **NO** | **HIPAA Identifier** |
|  |  | 1. Name |
|  |  | 2. Postal address information, other than town or city, state, and zip code |
|  |  | 3. Age or Date of Birth if over the age of 89 |
|  |  | 4. Telephone numbers |
|  |  | 5. Fax numbers |
|  |  | 6. Electronic mail addresses |
|  |  | 7. Social Security number |
|  |  | 8. Medical Record number |
|  |  | 9. Health plan beneficiary numbers |
|  |  | 10. Account numbers |
|  |  | 11. Certificate/license numbers |
|  |  | 12. Vehicle identifiers and serial numbers, including license plate numbers |
|  |  | 13. Device identifiers and serial numbers |
|  |  | 14. Web Universal Resource Locators (URLs) |
|  |  | 15. Internet Protocol (IP) address numbers |
|  |  | 16. Biometric identifiers, including finger and voice prints |
|  |  | 17. Full face photographic images and any comparable images |
|  |  | 18. Any other unique identifying number, characteristic, code that is derived from or related to information about the individual (e.g. initials, last 4 digits of Social Security #, mother’s maiden name, first 3 letters of last name.) |
|  |  | 19. Any other information that could be used alone or in combination with other information to identify an individual (*e.g. rare disease, study team or company has access to the health information and a HIPAA identifier or the key to the code*). |

## Will data be collected retrospectively, prospectively or both? If retrospective, what is the timeframe for the data review?

**INSTRUCTIONS:**  Retrospective means that all data has already been collected at the time this protocol is approved by the IRB (e.g. the information is already in medical records).

**Response:**

## How will you collect data?

**IMPORTANT NOTE**: You may **not** store data on a personal device or locally to your workstation. You **may** use a shared drive.

**INSTRUCTIONS:** Please select one of the options below

 (i) Record review

 (a) What system will be used for the record review?

 Epic

 Other – Please specify.

 (ii) Interviews

 (a) How will these interviews be conducted?

 In person

 Other – please provide details.

 (iii) Surveys

 (a) How will you conduct the surveys?

 Kiosk

 Application – Please provide name of the application.

 (iv) Surveillance

 Video

 Audio

## How will you store the data?

**IMPORTANT NOTE**:

- You may **not** store data on a personal device or locally to your workstation. You **may** use a shared drive instead.

- You may **not** store data in an unapproved cloud provider such as Dropbox, Google Drive, Google Docs, etc.

 (i) On a Carilion Clinic shared drive

 (ii) Storage managed by the sponsor or CRO in which the data will be sent and stored encrypted
 (a) Please provide the name of the sponsor or CRO:

 (iii) Cloud (please see above for unapproved cloud providers)

 (a) Please provide the name of the application:

 (iv) Paper

 (a) What will be stored?

 (b) Where will it be stored?

## Data Access

**IMPORTANT NOTE:**

1.You may **not** store HIPAA identifiers with de-identified data.

2. You may **not** store the data key on a personal device or locally to your workstation. You **may** use a shared drive instead.

**INSTRUCTIONS:** If you did not choose YES to any item in question 1 skip this question.

**Response:**

## Who will have access to the data?

**Response:**

## Who will have access to the data key if the data is de-identified?

**Response:**

## How long will you retain the data?

**Response:**

## Do you have a plan to delete the data at the end of the project? If so, please describe.

**Response:**

## How will you share data related to the study with individuals inside Carilion Clinic?

**Response:**

## How will you share data related to the study with individuals outside Carilion Clinic?

**Response:**