

Navigating the Research Process at Carilion

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Objectives:

- Participants will have clear understanding of research process at Carilion Clinic
- Participants will be aware of the resources available to support their research endeavors
- Participants will be aware of the different entities at Carilion that are responsible for research oversight



Agenda:

- Navigating the approval process
 - Research and Development
 - *Research Compliance: Conflict of Interest*
 - Institutional Review Board
- Research oversight at Carilion
- SOPs governing clinical research



Introduction:

- Carilion Clinic is an Academic Medical Center with over 400 active, human subjects research studies
- As we continue to grow our research footprint, our goal is to educate our current and future researchers to ensure that their research endeavors are successful



Research Approval Process at Carilion:

- Research projects at Carilion require specific approvals before project initiation
 - Research and Development (R&D)
 - *Research Compliance: Conflict of Interest (COI)*
 - Institutional Review Board (IRB)
- Additionally, research training is required by R&D, Organizational Integrity and Compliance (OIC), and the IRB (CITI Modules)



Required Training

- Human subjects research requires CITI training (www.citiprogram.org)
 - Basic Biomedical and Good Clinical Practice module
 - *GCP is required for FDA regulated research and NIH funded research*
 - *Conflict of Interest for externally supported projects*
- R&D Research Training
 - Essentials of Grant Proposal Development for grant-funded study teams
 - Essentials of Research Administration for all funded study teams
 - Individual research training is available by request from R&D representatives
 - Contact research@carilionclinic.org to request training.
 - Optional modules include: Clinical Trial Billing Compliance and Clinical Research Coordination



R&D Application

- When seeking approval for a new research project, the first step is to complete the Research and Development application. This is also known as the “Department Level Review” and requires a signature from the investigator’s department chair/leader.
- **This application is available online at:**
 - https://is.gd/Research_Application
 - REDCap enabled application
 - 10-15 minutes to complete
 - eSignature
 - Automatic Routing for Approvals
- The R&D application provides department level approval for study personnel assignments and also serves as a trigger point for R&D to schedule a feasibility review meeting and begin contracting/budgeting, if needed.



R&D Application Step by Step

The screenshot shows a web browser window with the URL `redcapweb.carilionclinic.org/redcap/surveys/index.php?s=EE7LAYHFD`. The page features the Carilion Clinic logo and the text "Research and Development". A paragraph of instructions is displayed, followed by a "Contact information" section with several input fields. The Windows taskbar at the bottom shows the date as 3/13/2020 and the time as 5:55 PM.

CARILION CLINIC
Research and Development

Please complete and receive the department approval **prior to IRB PRISM application**. If you have any questions, please contact research@carilionclinic.org. If you need Epic data extract, biostatistics support, data management (REDCap), Epic research builds, Epic research access, or feasibility volume, please contact HART@carilionclinic.org.

Contact information

Carilion Clinic Principal Investigator Name	
* must provide value	
Position at Carilion	
* must provide value	
Email	
* must provide value	
Phone number	
* must provide value	
Estimated percent effort expended on project from the Principal Investigator. For an investigator, 1-2 percent is typical.	
* must provide value	
Contact Person (if other than PI)	



R&D Application Step by Step

The screenshot shows a web browser window with the URL `redcapweb.carilionclinic.org/redcap/surveys/index.php?s=EE7LAYHFDF`. The browser's address bar and tabs are visible at the top. The main content area displays a research application form with the following sections:

- Contact Information:** Includes fields for "Contact Person (if other than PI)", "Contact Email", and "Contact Phone Number". Each field has a red asterisk and the text "* must provide value" above it.
- Submission Type:** A question "Is this submission a Primary Research Domain Project to fulfill a VTCsOM medical student graduation requirement?" with radio button options for "Yes" and "No". A red asterisk and the text "* must provide value" are above the options. A "reset" link is located to the right of the "No" option.
- Project information:** A section header in a dark blue bar.
- Project Title:** A large text input field with a red asterisk and the text "* must provide value" above it. An "Expand" link is located to the right of the field.
- Primary Research Type:** A section with radio button options: "Basic Research (in vitro/tissue culture/cell biology)", "Clinical Trial (e.g., prospective patient enrollment)", "Clinical Research (e.g., retrospective chart review)", "Instructional", and "Other (e.g., community outreach)". A "reset" link is located to the right of the "Other" option.

The Windows taskbar is visible at the bottom of the screen, showing various application icons and the system clock indicating 5:57 PM on 3/13/2020.



R&D Application Step by Step

The screenshot displays a web browser window with the URL `redcapweb.carilionclinic.org/redcap/surveys/index.php?s=EE7LAYHDFD`. The browser's address bar and tabs are visible at the top. The main content area shows a research application form with two sections: "Funding Source" and "Personnel information".

Funding Source

- ☐ Industry
- ☐ Federal or Federal Flow Through
- ☐ Foundation / Non-profit
- ☐ Other University / Institution
- ☐ Investigator Self-Funded (e.g., discretionary; start-up funds)
- ☐ Internally Funded (e.g., RAP grant)
- ☐ I do not yet have this information available
- ☐ Other

reset

Personnel information

Department: (Chair/Officer/Dean)

* must provide value

- ☐ Emergency Medicine (Dr. Burton)
- ☐ Family and Community Medicine (Dr. Jeremiah)
- ☐ Jefferson College of Health Sciences (Dr. Allison-Jones)
- ☐ Medicine (Dr. Skolnik)
- ☐ Nursing (Ms. Scheaffel, RN)
- ☐ Obstetrics/Gynecology (Dr. Valea)
- ☐ Orthopaedic Surgery (Dr. Moskal)
- ☐ Pediatrics (Dr. Dunsmore)
- ☐ Surgery (Dr. Nussbaum)
- ☐ Radiology (Dr. Karolyi)
- ☐ Psychiatry (Dr. Trestman)
- ☐ Other

reset

Additional Carilion Clinic Research Team Member? ☐ Yes ☐ No

reset

The bottom of the browser window shows the Windows taskbar with various application icons and the system clock indicating 5:58 PM on 3/13/2020.



R&D Application Step by Step

Carilion Clinic Research Application

redcapweb.carilionclinic.org/redcap/surveys/index.php?s=EE7LAYHFDF

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Non-Carilion Clinic Research Team Member ☒ Yes ☐ No [reset](#)

Non-Carilion Clinic Research Team Member Name

Role and Responsibility

External Institution

Non-Carilion Clinic Research Team Member ☐ Yes ☐ No [reset](#)

Additional services

Additional Services: Check all that are requested

- ☐ Health Analytics data extraction
- ☐ Health Analytics statistics support
- ☐ Carilion REDCap
- ☒ EPIC research access for chart review
- ☐ EPIC research study build (e.g., research drug build, BPA, ordersets)
- ☐ Pharmacy
- ☐ Clinical laboratories
- ☐ Basic science laboratory support
- ☐ Pathology
- ☒ Simulation laboratory
- ☐ Imaging
- ☐ Other service (Please note - any service that will be required for research purposes outside of your home department should be listed. i.e., ECGs, Pulmonary functions tests, etc.)

Upload protocol below or describe your study with sufficient detail to gain approval from your department chair, officer, vice president or dean before IRB submission/review.

Start

6:10 PM 3/13/2020



R&D Application Step by Step

Carilion Clinic Research Application

redcapweb.carilionclinic.org/redcap/surveys/index.php?s=EE7LAYHFDF

home department should be listed. i.e., ECGs, Pulmonary functions tests, etc.)

Upload protocol below or describe your study with sufficient detail to gain approval from your department chair, officer, vice president or dean before IRB submission/review.

Include specific aim(s), scope, time frame, number of subjects/population, methodology, or type in "attached" if uploaded.
* must provide value

See attached protocol and budget

Expand

Protocol: Please upload a protocol in this link if appropriate [Upload file](#)

Budget: Please upload a budget in this link if appropriate [Upload file](#)

If you are the PI, sign below and submit. If you are submitting on behalf of the PI, click submit. Use your mouse to sign.

Principal Investigator [Add signature](#)

Clinical section chief (not required of all departments/functional areas) [Add signature](#)

Authorized department chair/ officer/ dean or vice president (Required per Carilion Clinic policy) [Add signature](#)

Second clinical section chief (not required of all departments/functional areas) [Add signature](#)

6:12 PM 3/13/2020



R&D Application Step by Step

Carilion Clinic Research Application | x +

redcapweb.carilionclinic.org/redcap/surveys/index.php?s=EE7LAYHFDF

Apps | Bookmarks | Biochemistry | The Chiral Axis | Pageburst® | New Tab - Bookmarks | Home | Jchs | Bucks County Herald... | Citrix XenApp - Logon | Palmerton | Intrexon - Current Jo... | Other bookmarks

Protocol: Please upload a protocol in this link if appropriate [Upload file](#)

Budget: Please upload a budget in this link if appropriate [Upload file](#)

If you are the PI, sign below and submit. If you are submitting on behalf of the PI, click submit. Use your mouse to sign.

Principal Investigator [Add signature](#)

Clinical section chief (not required of all departments/functional areas) [Add signature](#)

Authorized department chair/ officer/ dean or vice president (Required per Carilion Clinic policy) [Add signature](#)

Second clinical section chief (not required of all departments/functional areas) [Add signature](#)

Second Authorized department chair/ officer/ dean or vice president (Required per Carilion Clinic policy) [Add signature](#)

Powered by REDCap

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R&D Approval

- R&D will provide feedback within 5 business days for studies that require revisions
- Industry funded studies are reviewed by Director of Clinical Trials
- Grant funded studies are reviewed by Grants Administrator
- Once study is deemed satisfactory by R&D, Director of Clinical Trials, Grants Administrator, or Senior Director of R&D provides approval letter.
- **The IRB will not approve a project without R&D letter of approval. This should be uploaded to your IRB application prior to submission.**



Conflict of Interest (COI)

- Non-externally supported studies do not require COI disclosure or training
 - Studies with a Carilion Clinic Physician utilizing internal research funds do not require a COI disclosure
 - If VTCSOM student research funds are the only external support, please note in applications but select “N/A” for completing COI process
- Externally supported studies require COI disclosure and training
 - Research COIs should be disclosed in your annual COI disclosure to Carilion.
 - For investigators and study team members with a conflict, OIC will work with you to create a management plan. If a plan cannot be created, the study may not be able to be completed.
 - The CITI Program COI training should be completed initially and then renewed every 4 years or if the COI process changes significantly
 - Contact Carilion OIC’s Research Compliance for further assistance (researchcompliance@carilionclinic.org)
- **RECENT CHANGE to COI Process**
 - Only Carilion Clinic personnel and affiliates must complete the CC COI process
 - Transactional questionnaires are no longer required for individual protocols
 - All Research COIs should be disclosed on annual COI disclosure. If new potential conflicts arise, annual COI must be updated within 30 days to reflect changes
 - OIC will review annual disclosures and CITI COI training at the time of IRB submission to verify completion; however, COI disclosure and training can occur earlier in the research application process.
 - Updated CITI COI training will be available soon! Details to come
- **The IRB will not approve an externally supported study without COI clearance.**



IRB Approval

- Following R&D approval and COI clearance (externally supported studies only), the study team can submit to the IRB for the final step in the approval process.
- Carilion Clinic's IRB reviews all human subjects research and can provide QA/QI determinations for projects that do not meet criteria for HSR.
- Industry-funded clinical trials are reviewed by Carilion Clinic IRB for personnel and local safety issues but rely on Western IRB as the IRB of record.
- Other commercial IRBs may be considered for industry-sponsored trials on a per-project basis.



IRB Approval, Continued

- The Carilion Clinic IRB uses an online review system PRI3SM
 - <https://carilionclinic.imedris.net>
- The IRB will review your submission and provide feedback
- The study may meet criteria for expedited review and can be reviewed without convening the IRB full board review committee
- If the study meets criteria for full board review, it will be brought before the IRB review committee for discussion with the investigator and study team
 - Please visit the IRB's website for additional details regarding exempt, expedited, and full board criteria
 - <https://www.carilionclinic.org/irb>
- Once the review is completed and the application is determined to be acceptable, approval will be granted
- **Any changes to your study protocol, personnel, or study materials, such as the Informed Consent Form, require additional approval from the IRB!**



What is the difference between IRB approval and R&D approval? Why are both necessary?

- The IRB is responsible for protecting the rights and welfare of human subjects research participants.
- R&D is responsible for operational aspects of research such as billing compliance, contracting/budgeting, feasibility analysis, and personnel assignments.



In Summary

- IRB approves studies if they are safe and ethical.
- R&D approves studies if they are feasible for the organization and processes the necessary agreements for you to proceed
 - Ex) Research Collaborative Agreements, CTAs, CDAs, DUAs, MTAs, etc.



Which studies require a feasibility meeting?

- Any study that prospectively enrolls patients and involves an intervention.
 - I.e., a drug, device, or research procedure is being studied
- Survey studies, observational studies, and retrospective studies **do not** require feasibility meetings.



What is discussed at a feasibility meeting and why is that important?

- Approval from ancillary departments
- *Coverage analysis*
- *Budget development and review*
- *Contract review*
- Logistical flow of study schedule of events
- Appropriate patient population – TriNetX
- Any glaring issues that would keep you from being successful?



Grant Startup Process

- Please notify R&D as soon as you plan on submitting an extramural application.
- Grant Administrator works with study team to prepare budget, gather documentation (such as biosketches, institutional forms, etc), and determine requirements for submission.
- If external collaborators (sub-investigators) are involved, letter of commitment must be received to confirm participation.
- R&D Application must be completed and approved by Dept Chair prior to submitting application package



Grant Startup Process, Cont.

- Grants that involve prospective patient enrollment with research intervention will require feasibility meetings prior to submission.
- Depending on grant type, IRB approval also may be required for interventional studies prior to submission/award.
- If grant is awarded, the agreement/contract will be negotiated and study will be submitted to IRB, if not already done in pre-award.



Grant Submission Deadlines

- The PI/PD must submit the budget and budget justification for review and approval no later than **10 business days** prior to the sponsor submission deadline.
- All collaborative/subaward materials (letters of commitment, budget and budget justification, biosketches, statement of work, etc.) must be received at least **5 business days** prior to the sponsor submission deadline.
- With at least **3 business days** lead time prior to the sponsor submission deadline, R&D will perform a complete final proposal review.
- R&D will submit with no less than **1 business day** prior to the application deadline.



Contracts

- Carilion Clinic does not permit investigators to sign contracts on behalf of the organization.
- All contracts must be reviewed centrally by R&D and signed by our institutional official (Dr. Daniel Harrington)



Resources for Research

- Central Clinical Research Coordinator support
- Central budgeting for grants and clinical trials
- Central regulatory management for industry-funded clinical trials
- Central post-award financial management for grants and industry-funded clinical trials
- Central contracting – CDAs, CTAs, Grant Agreements, Non-funded agreements (DUAs, MTAs, RCAs, etc)
- Assistance with project development and protocol development
- Feasibility review



Research Oversight at Carilion

- R&D
 - Organizational Integrity and Compliance (OIC)
 - IRB
-
- R&D, OIC, and the IRB are all responsible for research oversight at Carilion.
 - Each of these departments can conduct quality reviews and/or study audits to ensure that researchers are following organizational policies/SOPs and federal regulations.
 - Additional education will be provided as needed to study teams.
 - When in doubt, reach out to these departments for guidance. It is better to ask questions than to make assumptions that can lead to mistakes.



Clinical Research SOPs

- Standard Operating Procedures provide specific guidance to our investigators for conducting clinical research at Carilion Clinic.
- Standardized procedures increase compliance, reduce errors, and allow new investigators to learn the proper way to conduct clinical research.
- Our SOPs are based on federal regulations, FDA guidance, and local best practices.
- https://www.insidecarilion.org/system/files/2018-11/Clinical%20Trial%20SOPs_2018.pdf



Questions

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