Carilion Research Submission and Approval Process

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Carilion Clinic

VTC | Virginia Tech Carilion School of Medicine

Research Approval Process at Carilion:

- R&D application/approval
  (https://redcapweb.carilionclinic.org/redcap/surveys/index.php?s=EE7LAYHFDF)

- IRB approval
  - PRIS3M. Investigator Initiated studies build protocol into IRB application.
  - Routed for COI approval before IRB receives initial submission

- HART establishes research services
  - Grants access after work order agreement received from R&D (if working with VT collaborators)
  - Depending on protocol: REDCap built, data extracted, etc

Plan, Plan, Plan

- The key to a successful investigator-initiated project is one that thoroughly plans the protocol before beginning any official paperwork
- You will need background and specific aims for your IRB application
  - Do a thorough lit review! Look for survey tools! What data will you need to collect via chart review?
- You'll need statistical methods for IRB applications

Prospective Helpful Tips

- Be aware of “standard of care” for your cohort
  - When are patients presenting to clinic for initial evaluation or follow up care?
  - Does your research intervention piggyback with standard of care, or will there be charges associated?
    - If charges associated, you’ll need funding!
- Creative Designs – Health Systems Science
- Recruitment processes
  - Who is making the initial contact with participants?
  - Don’t build a recruitment protocol around clinic staff assisting with research unless you have departmental approval

Prospective Helpful Tips

- Recruitment Continued:
  - Paper versus E-Consent
    - Coordinators love REDCap E-Consent for compliance reasons.
  - Develop a multi-faceted recruitment approach so that you have several avenues to introduce the study to eligible participants
    - Phone calls – work! Approaching in person – works!
      - Write both into your IRB application up front to give your team flexibility.
    - Create flyers!
    - Are you collecting survey data and will not require chart review? May be able to work with HART team for distribution methods via email addresses in EPIC until My Chart recruitment is rolled out.

Prospective Helpful Tips

- Data Collection
  - What are the participants' responsibilities?
  - Submit survey tools during initial review
    - Are you using a validated tool?
  - Data collection tools – needed for IRB submission
    - List data points that you will collect from the medical record including demographic information
    - You'll want to avoid using "text fields" in REDCap for a simplified analysis process
  - A well-designed REDCap up front, will allow for a smooth data collection process
    - Will participants have to complete several surveys in a longitudinal study? Use REDCap!

Retrospective Helpful Tips

- Retrospective studies rely heavily on EPIC. Is the information you need actually recorded?
- Consult in advance with HART team about what “can be extracted” and what will need to be manually collected via chart review
- Create a data collection tool – you may only collect IRB approved variables in REDCap.

TriNetX

- Unsure about your patient cohort, go to TriNetX!
- https://www.carilionclinic.org/health-analytics-research-team#trinetx

- TriNetX is a useful tool for retrospective AND prospective studies
  - This is where the design phase should start

- The tools search criteria related to demographics, diagnostic codes, procedures, laboratory results, medications and vitals.

- An approximate number of patients matching the search criteria is returned, but does not include any patient identifiers or other clinical data.

Required Training

- Carilion Physicians – must affiliate with Carilion Clinic
- Human subjects research requires CITI training (www.citiprogram.org)
  - Biomedical Researcher and Good Clinical Practice module
  - *GCP is required for FDA regulated research and NIH funded research*
  - *Conflict of Interest for externally supported projects*

- VTCSOM students/VT Collaborators – must affiliate with Virginia Tech
  - This is done Sem 1 of research domain class
  - Basic Biomedical Research
  - CITI Good Clinical Practice for NIH funded clinical trials
  - Will receive a COI email from VT IRB

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  - Once all post-approval paperwork is received (ACA on file)
  - Check email and feel free to follow up

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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.

R&D Application

- When all your planning is complete -

- **This application is available online at:**
  - https://redcapweb.carilionclinic.org/redcap/surveys/index.php?s=EE7LAYHFDF REDCap enabled application
  - 10-15 minutes to complete
  - eSignature
  - Melissa Mercure at Carilion R&D Routes for Approvals

- The R&D application provides department level approval for study personnel assignments and serves as a trigger point for R&D to schedule a feasibility review meeting and begin contracting/budgeting, if needed.

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 (Mohr)
  - Grant funded studies are reviewed by Grants Administrator (Vera Hollen)
- 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.**
- You can work in PRIS3M on your IRB app while you await R&D approval. But you cannot submit your IRB app without the R&D approval letter.
  - You should save a copy of your R&D application for your regulatory files.

IRB MUSTS pre-submission

- Informed consent form
- Survey tools
- Recruitment scripts
- Flyers
- Data collection tool ** key!!
- Very clear methods!
  - When are patients recruited
  - When do patients complete data collection timepoints
  - What is standard of care? What is for research only?
- Templates available: https://www.carilionclinic.org/IRB/Consent#consent-templates

IRB Approval

- The Carilion Clinic IRB uses an online review system called PRIS3M
  - 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
  - VTCSOM medical student projects are rarely exempt but do frequently qualify for expedited review
- 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
  - Full board review studies have certain deadlines that have to be met in order to be put on the agenda for a full board meeting
  - Please visit the IRB's website for additional details regarding exempt, expedited, and full board criteria
  - https://www.carilionclinic.org/irb/meetings#irb-2024-meeting-schedule
- Be "on call" after the IRB app is initially submitted! When the IRB sends back stipulations, address them as quickly as possible to ensure a smooth approval process

COI – happens after IRB submission and before approval

- Once a study is submitted in PRIS3M and signed by the PI, the study will be routed to the Department Chair or Unit Director for signature. Once that signoff is complete, the study will be routed to and reviewed by Research Compliance in OIC for a COI check and privacy review.

- VT students / VT Personnel COI and CITI training is verified by VT IRB. You must check your email and reply quickly!

AFTER IRB APPROVAL – you do not get to immediately start research

- Things that study team can control:
- Do you need to apply for Certificate of Confidentiality or register on CT.gov??
  - Check your IRB approval letter for more details

Behind the scenes processes that must happen

- Work Order Agreement** if you have external collaborators
  - Executed on behalf of R&D. Contract in place between VT and Carilion
    - HART will not give students access to research services until work order agreement is received
    - Melissa Mercure will provide work order agreement to all necessary parties when she receives it from VT.

- Remember, this presentation is from a Carilion partnering with VT POV only. If you are working with multiple institutions, the work order agreement and IRB approvals will have additional steps.

Please remember how important regulatory processes are

- A challenging area in clinical research revolves around the documentation required. Clinical care and research processes are not always equal!
  - Plan for this in the design phase
- Read your IRB approval letter
- Read your IRB protocol – do amendments when necessary!
- Be aware of what safeguards need to be in place for your data