Carilion Research Navigation

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MyProjectPath Virtual Assistant

- Every project is different. Follow your own path.
- https://redcap.link/MyProjectPath
- Provides asynchronous, self-service resources and information how to get live help!
- Support by HART, but provides information and links to resources across research, including Research and Development, HRPO/IRB, iTHRIV and more!

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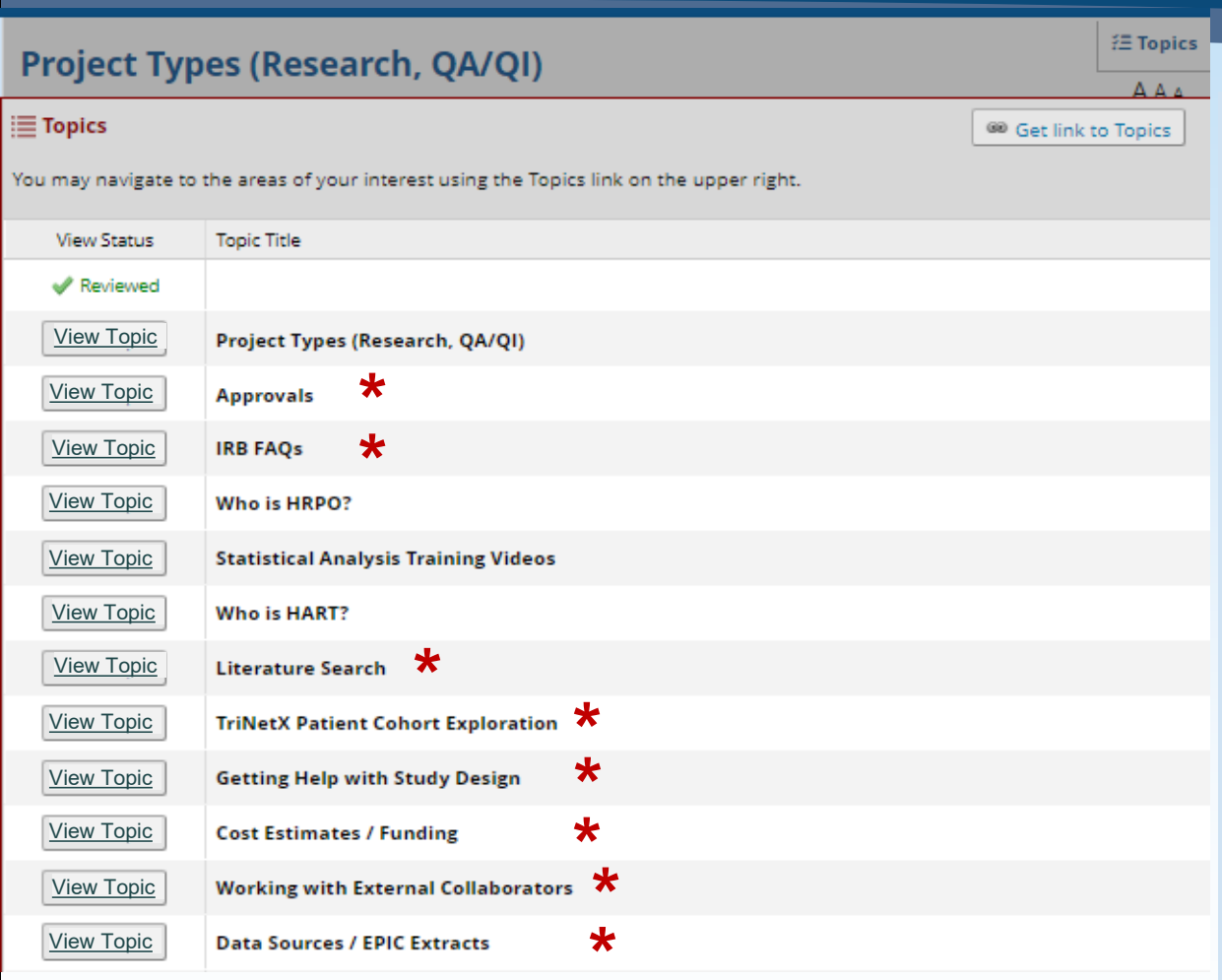
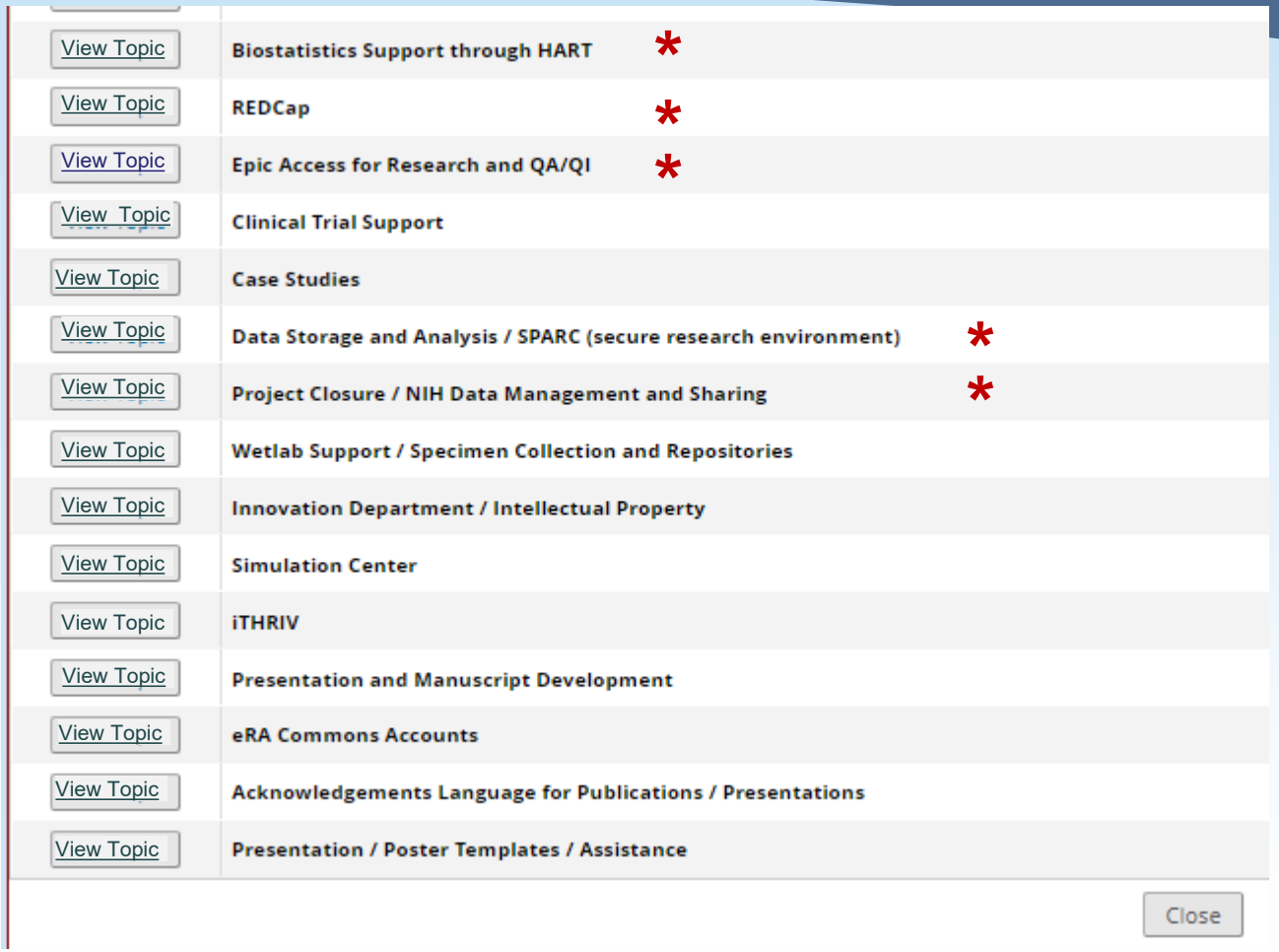
Topics: https://redcap.link/MyProjectPath





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MyProjectPath is your Virtual Assistant to navigate Research and QA/QI Processes and Resources at Carilion Clinic.

Instructions: On the Next Page, you may use the Topics Menu in the upper right to proceed sequentially, or go directly to the areas of interest.

Presented by HART

(Health Analytics Research Team)

This tool provides several options to display information, depending on your familiarity of the process and needs. You can choose:

- ○ Interactive PDF: Provides overall process with links to some resources, with no tracking.
- ○ Full Version: A comprehensive version presenting you with all resources to explore. Great for new investigators and experienced investigators interested in learning about new offerings.

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Continue to Topics

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Project Types (Research, QA/QI)

Topics

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Research vs QA/QI Determination

QA/QI activities are simply to assure known quality. QA activities present no risk to participants. They are typically observational and unobtrusive, and involve the collection and analysis of data to which the investigators have legitimate access through their institutional roles. They do not prevent or hinder standard practices and they do not impose additional risks or burdens on participants. They do not infringe on privacy or breach confidentiality. **QI activities determine quality and improve services or clinical care.** They are usually applied within a defined institutional setting, often a single department or division. **Their intent is to evaluate and alter processes constituting the delivery of care in the near future, with the expectation that the population of patients usually served in that location will benefit.**

QA/QI projects involve data that the project team is exposed to as a part of their job.

Therefore, QA/QI projects cannot have external collaborators (non-Carilion). The exception is VTCSOM, who due to their special status with us, are considered an extension of the Carilion workforce for QA/QI projects. However, work orders/agreements need to be in place when QA/QI projects involve VTCSOM students.

The Office of Human Research Protections (OHRP) defines research as a systematic investigation, including research development, testing and evaluation, that leads to generalizable knowledge.

A human subject is a living individual from whom an investigator obtains information or biospecimens through intervention or interaction with the individual and uses, studies or analyzes the information or biospecimens; or obtains, uses, studies, analyzes or generates identifiable private information or identifiable biospecimens.

The IRB assigns each application to an appropriate level of review:

- **Not Human Subjects Research**
- **Quality Improvement/Quality Assurance**
- **Exempt**
- **Expedited**
- **Full Board**

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Approvals

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The type of project you are doing will determine the approvals needed.

All **Research** Projects must be submitted to Research and Development and HRPO/IRB for Approval.

Some departments require **QA/QI projects** to also be submitted to Research and Development in order to route for Chair / Department Leader approval. QA/QI projects do not need to be submitted to the IRB, unless the Department requires it and/or a determination of exemption is desired.

ALL Projects with External Collaborators (including VTCSOM) require approval and contracts/agreements from Research and Development.

To submit to Research and Development, click on the link below.

https://is.gd/Research_Application

R&D is responsible for operational aspects of research, such as billing compliance, contracting/budgeting, feasibility, analysis, and personnel assignments.

To submit your IRB Research Application via the PRIS3M submission system, click the link below.

https://carilionclinic.imedris.net/

HRPO (IRB) is responsible for protecting the rights and welfare of human subjects research participants. HRPO will then determine what type of review is required. All application types should be submitted through PRIS3M including research submissions, QA/QI, case reports, and determination of human subjects applications. You must attach your Research and Development Approval letter.

EXTERNAL COLLABORATORS:

If your project involves **external collaborators**, be sure to include them on your Research and Development application, including what roles they play in the project and what access they will need. This will help facilitate the necessary agreements and access.

Contact research@carilionclinic.org with questions.

KEY STAKEHOLDERS:

It is important to involve the departments and individuals who will be impacted by your project. For example, if you plan to do a survey on employees or enroll patients from a particular clinical department, you will need their approval.

If you are submitting an IRB application, their approval is required.

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HRPO / IRB FAQs

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The Carilion Clinic Human Research Protections Office oversees human research conducted at Carilion Clinic to ensure that research is being conducted ethically and complies with federal, state, and institutional requirements.

The Institutional Official (IO) is the individual authorized to act for the institution and obligates the institution to the terms of the Federalwide Assurance. Robert L. Trestman, PhD, M.D., is the Medical Chair of the Carilion Mental Health Department and serves as the Institutional Official with oversight authority of the activities of the Human Research Protections Office (HRPO) and all research activities at Carilion.

Explore FAQs

If your project is designated as Research, you and your team will need to complete CITI training.

Click here to launch CITI

If your project involves external collaborators, be sure to include them on your IRB protocol, including what roles they play in the project and what access they will need.

You may not be able to look them up, as you would with a Carilion employee, but can add them in the section following.

To submit to the IRB PRISM software, click here.

https://carilionclinic.imedris.net/

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Topics

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Who is HRPO?

HRPO = Carilion Clinic Human Research Protections Office

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Before research can be conducted by Carilion employees or at Carilion facilities, it must first be reviewed by the Research and Development office and then approved by the Institutional Review Board (IRB). Carilion Clinic has established three IRB committees composed of members from a variety of medical and scientific backgrounds, including community members.

IRB members are appointed by the vice president for Academic Affairs. The work of the IRB committees is supported and administered by the Human Research Protections Office (HRPO).

Meet the Team!

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Statistical Analysis Training Videos

Topics

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HART has produced these training videos on various topics of interest.

Contact us at HART@carilionclinic.org with questions or suggestions for future topics!

Select the training video you would like to watch.

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Who is HART?

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HART = Carilion Clinic Health Analytics Research Team

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MISSION

To improve future patient care, further development and retention of top-notch clinicians, and enhance Carilion's national and regional reputation through Research, Quality Improvement Projects, and Data Science.

We will do this by supporting Carilion with innovative processes, research informatics solutions, data management, biostatistics and data science to further research, QA/QI, grants and decision support.

VISION

To grow research at Carilion Clinic and with our partners by developing collaborative relationships and by leveraging technology and tools to provide service excellence for our research community.

- 19 team members providing end to end support
- Mix of grant funded / institution supported
- 250+ combined years in healthcare/research
- 165+ combined years at Carilion
- Full support for Research Informatics, Biostatistics, Data Science, Epidemiology, Research Design, data extraction, Epic Research Build and Research Navigation Services
- Carilion component of NIH CTSA iTHRIV iBERDI group
- Innovation Department support (app development)

Meet the Team!

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Literature Search

Topics

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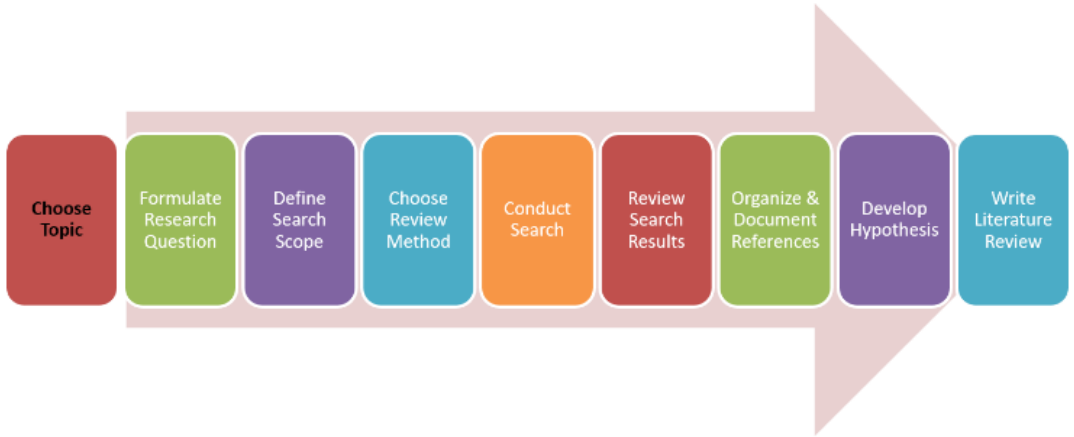
Literature review is a process that helps you:

- **Learn about what is known.**
- **See what is missing or what needs to be investigated.**
- **Build your opinion.**
- **Ask a research question to contribute to the advancement of knowledge about a topic.**
- **Discuss the implications of your findings.**



Open the attached powerpoint presentation to learn more about how to perform an effective literature search.

Attachment: Literature Review v 12.19.19.pptx (0.77 MB)

Save the attached Literature Search Template Tool and use it in your Lit Search process.

Attachment: Literature Review Table-Template.xlsx (14.9 kB)

Carilion Library Services (library@carilionclinic.org) can provide excellent support for your literature search.

In addition, check out the attached file for a great template.

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TriNetX Patient Cohort Exploration

Topics

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TriNetX at Carilion allows you to explore patient cohorts to better understand volumes, co-morbidities, outcomes, treatment paths, and other attributes, in a safe, de-identified manner prior to IRB approval. TriNetX also has large comparative cohorts with 180M+ patients, in addition to Carilion's 1.3+million patients.

TriNetX provides easy to use tools to search criteria from electronic medical records related to demographics, diagnostic codes, procedures, laboratory results, medications, vitals, oncology, and claims. An approximate number of patients matching the search criteria is returned and does not include any patient identifiers or other clinical data. Investigators can explore the feasibility of patient cohorts and then request assistance from HART@carilionclinic.org to obtain appropriate approvals and subsequently receive detailed clinical data for research, grant and QA/QI purposes.

In addition, the TriNetX Analytics and Collaborative Networks allow Real World Data research on massive cohorts, which have resulted in publications.

If you are interested in gaining access, complete the user agreement at this link:

***** LINK BELOW *****

Carilion TriNetx User Agreement

Once you sign the agreement electronically, it will be sent to leadership for signature, and to the HART team Director for final approval.

If the above link does not work, please copy and paste the following link to your browser:

https://redcap.link/g04t7xub

If you would like to download and review a PDF version of the user agreement, please click below.

Attachment: CCTriNetX User Agreement.pdf (84.3 kB)

If you plan to use TriNetX, you can copy and paste the relevant language below into your IRB protocol.

If using a volume of patients generated by TriNetX:
A feasibility query run through TriNetX with available inclusion and exclusion criteria generated an approximate volume of __ patients of ____ time period.

If you plan to re-identify these patients in order to do chart review or patient outreach:

The TriNetX cohort will be re-identified by the Health Analytics Research Team, and a list of MPIs (with or without other relevant data points) will be generated. The list may be used to generate Epic extracts and/or imported to REDCap for further chart review.

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Getting Help with Study Design

Topics

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Do you need advice about your study design, what data you can collect, how you will analyze the data, and/or if you have enough subjects to do the project? Contact HART@carilionclinic.org for a consultation about your project.

We have **expert biostatisticians and research data engineers** who can help you **design your project** including determining how to **acquire, manage and analyze your data.** We can also assist with **survey design, secure data collection tools, and defining patient cohorts.**

Our Carilion Clinic Health Analytics Research Team has the **expertise and access to Epic data**, in addition to other Carilion data sources. Because it is part of our job responsibilities, HART does not need to be included on your protocol, unless the HART member significantly contributed to study design. **No additional agreements, contracts or statements of work are required.**

All HART members have completed CITI training in case they do need to be included on your protocol. In addition, HART members have access to project shared drives and SPARC folders in order to facilitate the analysis of your datasets.

Click here to visit our website and explore our end-to-end support of your project!

https://carilionclinic.org/health-analytics-research-team

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Cost Estimates / Funding

Topics

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Please note that these are just estimates, and your costs may be significantly more or less, or even $0, depending on the circumstances of your project and funding status.

Even if you do not have funding, understanding the costs related to your project will assist you in determining the benefit and value.

If there is external funding for a project, a Conflict of Interest disclosure may need to be completed. Contact researchcompliance@carilionclinic.org with any questions.

If you want to search for **funding opportunities**, visit portal.iTHRIV.org to find internal and external funding opportunities that may apply to your project. Login with your Carilion credentials. The Events tab frequently has upcoming funding opportunities and deadlines, or you can navigate to Propose, Funding Resources to browse various grants.

How many years will your project take?
This is used to calculate any annual costs

* must provide value

How "big" and "complicated" is the **data extract**? Estimate based on number of fields that can be extracted from Epic (discrete values, not notes), variety of types of data to be collected, and complexity of data collection (which lab values if multiple, complexity of comorbidities, etc). If you don't know how to estimate, contact HART@carilionclinic.org for a consult.

* must provide value

○ Small ○ Medium ○ Large ○ Extra Large ○ No data extract

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Will you use REDCap?

Go to the REDCap page for more information.

* must provide value

○ Yes ○ No

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Will you use the secure research environment SPARC?

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Working with External Collaborators

Topics

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Projects with external collaborators will require a contract or an agreement to be put in place. The external collaborator will not be able to take part in the project until all agreements are in place. Please contact research@carilionclinic.org for more information.

In addition, if the external collaborator(s) needs access to Carilion systems, prior to receiving access, they will need to:

- sign an Access Confidentiality Agreement
- provide a copy of their driver's license or government issued ID
- provide the last 4 digits of their SSN and mmdd of DOB
- may be subject to a background check prior to receiving access.
- may need to undergo an OIG check

It is important to note that Carilion employees undergo background checks and provide ID, SSN and DOB at the time of hire. In addition, Carilion employees sign the Code of Conduct at hire and annually, which incorporates the Access Confidentiality Agreement. Therefore, requirements are not different for external collaborators, but the timing is.

The background check is required if the external collaborators institution has not performed a background check as part of employment. **VT, Radford and UVA perform background checks on their employees and the VTCSOM students, but NOT on the non VTCSOM students (undergrads, grads).**

Students (other than VTCSOM) **are onboarded to participate in Carilion Research through Visiting Student Affairs** (krproctor@carilionclinic.org).

There may be additional software licensing costs associated with external collaborators.

QA/QI projects should not have non-Carilion collaborators. VTCSOM students are an exception as it may be part of their education to participate in QA/QI at Carilion, but an agreement/SOW needs to be put in place.

Why? Data for QA/QI must be data that is part of the person's normal job. Carilion PHI would not be part of a non-Carilion, non-VTCSOM person's normal job.

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Data Sources / EPIC Extracts

Topics

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Understanding what data are available and limitations is critical to the success of your project, whether your project is Research or QA/QI, Retrospective or Prospective, and regardless of Data Source.

If you would like to learn more about what data are available, data extracts, chart review and data management, please review the attached Powerpoint.

Attachment: DataManagementOverview2024.pptx (242.7 kB)

Epic is Carilion's vendor for the patient electronic medical record. **www.epic.com**

We have almost all of Epic's modules except the ones in RED.

We are not an insurance company, so we do not have Tapestry.

We use Quest labs, so we do not have Beaker. Lab results are fed into Epic via a real time interface.

Epic Applications and Modules

Core Clinicals	ASAP EpicCare Ambulatory Clin Doc Orders	Ancillary Clinicals	Anesthesia Beacon Clinical Case Management Cupid Home Health Infection Control OpTime Phoenix Radiant Research Stork Willow Ambulatory Willow Inpatient Beaker (Lab system)
Access	Grand Central Cadence Prelude Health Information Management Identity		
Revenue	Hospital Billing Professional Billing Claims Tapestry (insurance payor)		

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Biostatistics Support through HART

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- **Career biostatisticians** (Masters, Ph.D, MD)
- **Ready to assist with all your statistical needs**, including design, data collection and management, analysis, interpretation, visualization, manuscripts and presentations.
- **Full Access to data**, including fully identified data, to support the project without any further agreements.
- **Certified by Epic** to extract electronic medical record data.
- **Carilion employees**, so they can clean fully identified information without protocol amendments.
- Work closely with Research and Development, the Health Research Protections Office (Carilion Clinic IRB) and the Office of Integrity and Compliance.
- Follow all contracting, agreements, data protection plans and protocols to safeguard you from protocol breaches and unnecessary risk of privacy or data loss.
- Services may be Free or Low Cost
- Support all size projects
- Our Services Have Led to Over 1000+ Publications
- Our Services Have Helped Secure NIH, RAP, Pharma, iTHRIV, VDH, State and Numerous Other Grants

GET EXPERT CONSULTATION, contact HART@carilionclinic.org

REDCap

Topics

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(When you are done, you may close this window or use the Topics menu to open another window on another topic)

If you are collecting patient information or doing a survey, you will need to use Carilion's REDCap environment to keep it secure and safe. Data can be entered directly to REDCap forms from chart review, imported from data extracts, or collected through surveys. Standard exporting formats are available for interaction with analytic software.

REDCap is a tool for data gathering and storage, but not for statistical analysis. The HART team will consult with you and then design and build your REDCap project to meet your needs. **REDCap data is stored securely on Carilion hosted servers behind the network firewall.**

If you would like to learn more about REDCap, please review the attached Powerpoint.

Attachment: REDCapOverview.pptx (1.32 MB)

Use the following language in your IRB protocol if you will be using Carilion's REDCap for data storage or surveys.

Carilion Clinic's REDCap software will be used as the central location for data collection. REDCap (research electronic data capture) provides a secure, web-based application designed to support data management and collection for research/QA/QI studies. Carilion's REDCap servers are securely housed on site in a limited access data center, and all data are stored on Carilion's firewall protected network. The Health Analytics Research Team supports the proper development of projects and surveys in REDCap, observing appropriate change control and enforcing appropriate security controls. Data collection projects are built with a study-specific data dictionary, enforcing intuitive, accurate, consistent and complete data entry. REDCap also provides a survey tool for building and managing online surveys. Health Analytics Research team restricts user access to the IRB-approved project research team utilizing the approved processes and standards of TSG. REDCap is HIPAA compliant and provides audit trails. Data can be easily exported in several formats to a secure network directory for combination with extracted data, if appropriate, and analysis with common statistical packages.

Use the following language in your manuscripts and presentations if you will be using Carilion's REDCap for data storage or surveys.

Study data were collected and managed using REDCap electronic data capture tools hosted at Carilion Clinic. REDCap (Research Electronic Data Capture) is a secure, web-based software platform designed to support data capture for research studies, providing 1) an intuitive interface for validated data capture; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for data integration and interoperability with external sources.

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Epic Access for Research and QA/QI

Topics

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If your project is research, you may need access to Epic to perform chart reviews, screen and/or enroll patients and/or document research visits. Even if you already have clinical access, you may need Epic Research Access to differentiate the patient charts that you are viewing with whom you have no clinical relationship. The type of research access you need will depend on the project, and whether it is chart review only or a prospective trial that may include billing, followup encounters, medications and/or ordersets.

If your project is QA/QI, you do not need special research access, because the data you see in Epic should fall under your normal job responsibilities with Carilion.

Epic Access is managed through Epic Contexts:

Epic Research: Read only Screening or chart review

Research Coordinator: Write access for enrolling and documentation in Epic

Standard Epic Access: Specific to your regular job. For QA/QI projects

You should always use the correct Context to ensure that chart access for approved Research projects is properly captured, avoiding questions regarding why you access a patient chart with whom you have no care relationship.

QA/QI projects should involve data and patients that you already have access to as a normal part of your job/position.

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Clinical Trial Support

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Consider who will be screening, consenting, and enrolling the patients. Will Epic need to be set up for this project, for tracking of the patient on the research project through Epic, visibility into enrollment to other providers, or for research billing purposes?

These processes require specific training, documentation, and access to specific software.

For clinical trials, the HART team frequently needs to build and coordinate items to facilitate:

1. The research record so that enrolled patients can be marked in Epic as part of the research project.
2. Ordersets specific to the research project
3. Medication build specific to the research project
4. Billing grids to ensure research activities are not inappropriately billed to the patient or their insurance

and more....!

Contact Andrea Mohr, Director of Clinical Trials almohr@carilionclinic.org to discuss the process and available resources.

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Case Studies

Topics

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(When you are done, you may Continue to proceed sequentially, Save and Return later, or use the Topics menu to open another window on another topic)

If you wish to conduct a patient case study, please review the documents provided below.

- "Reviews Requiring Special Consideration ..." should help you determine if your project is a case study or human subjects research.
- "Patient Authorization to Use PHI for Education/Academic Purposes Form" is a downloadable PDF to use for consenting patients.
- "Writing a Case Study Report" is a template that can be used to assist in preparing your report.

According to policy, only students who are approved for a formal rotation at Carilion Clinic are permitted to access patient medical records for educational purposes (which includes case studies). Allowable accesses include if the student was in a direct care relationship with the patient(s) OR if the student was formally assigned an educational/academic task which requires direct access to patient charts.

Please ensure the MRN/CSN/or EMPI # is listed on the bottom right hand corner of the PHI Authorization Form under "patient identification" on each page. Please ensure the signed form is scanned into the medical record. You can interoffice mail the form to Patterson Pope - Document Imaging Center for processing.

Please note that if you need an IRB letter for a journal, the data collection should not have already been completed as the IRB does not issue retroactive approval. Also, the PRISM application to the IRB will need to be completed by a Carilion individual involved in the case reporting.

Reviews Requiring Special Consideration: Not Human Subjects Research and QA/QI Submissions

Attachment: 7.6 Reviews Requiring Special Consideration Not Human Subjects Research and QAQI Submissions AUG 2023.doc (89.1 kB)

Writing a Case Study Report

Attachment: Writing a Case Report_Carilion Clinic_7_19_2023.docx (32.6 kB)

Patient Authorization to Use PHI Form

Attachment: PHI Auth Education Academic Purposes.pdf (67 kB)

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Data Storage and Analysis / SPARC (secure research environment)

Topics

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Retaining your data in a secure location for **analysis and retention** is critical, both for privacy and security reasons, but also to prevent data loss. **Data should never been transferred off of Carilion's network until and unless the exact dataset(s) are specified and approved in the IRB protocol, and all appropriate agreements are in place with Research and Development.**

If you have external collaborators who will need access to data to analyze, Carilion offers a secure research environment **SPARC (Storage and Programs Accelerating Research Collaborations)**. Powerful analytic tools are available within the environment, where your data will reside (SAS, R and R-Studio, Python, QSR NVIVO, MATLAB, GIS solutions).

If your project is entirely internal (no external collaborators), you may use a Carilion shared drive which is set up specifically for your project. You may also choose to use SPARC to leverage the analytics tools.

QA/QI is not required to use network folders or SPARC, but may choose to leverage these options.

Some sponsored trials do not require the retention of local data in an electronic format, so a secure Carilion location may not be necessary.

Any Carilion dataset used for research purposes that is NOT fully de-identified will be stored on a secure Carilion environment. This access will be set up for you after IRB approval.

Use the following language in your IRB protocol if you will be using Carilion's SPARC environment for data storage and analysis.

Carilion Clinic's SPARC secure research environment will be used to store and analyze datasets for analysis. SPARC (Storage and Programs Accelerating Research Collaborations) is Carilion's web-based, secure research environment, that provides accessible storage of research project files in addition to advanced analytics programs to apply to those files for analysis. Current product offerings are SAS Viya and Statistics, integrated with R and Python, in addition to Microsoft Excel, Powerpoint and Word. AWS offerings may be possible to implement, depending on the needs of the project. Once access is authorized through an IRB approved protocol and a signed end user agreement, the clients utilize their institution's credentials to sign in. Data are prevented from download from the environment, without appropriate permissions and managed by the Health Analytics Research Team (HART). Folders are set up specifically for each approved project, with access limited to the research team, as specified on the protocol. This mitigates most of the minimal risk of privacy breach.

Use the following language in your IRB protocol if you will be using Carilion's SPARC environment for long term data storage post project conclusion:

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Project Closure: NIH Data Management, Sharing, and Cold Storage

Topics

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NIH data management and sharing requirements are summarized in the **NIH Data Management and Sharing Policy document, downloadable below.** A template is also provided to help you build and document a compliant DMS policy for your projects with Carilion Clinic.

The DMS policy document covers the following key points:

- NIH DMS plan submission requirements
- Data generation and management
- Findable, Accessible, Interoperable, Reusable Principals (FAIR)
- Consent requirements
- Data repository options
- Allowable costs
- Investigator resposibilities
- Links to additional helpful resources

Once a project reaches conclusion, SPARC will be used for "cold storage". Zipped project data will be uploaded by HART team SPARC Administrators to archive folders. These folders are date stamped with the future final deletion date as specified in each research protocol. SPARC archive folders are unavailable to the public or internal investigators. This helps investigators comply with their protocol requirements for retention of research data for a required time period, while simultaneously no longer having access to identifiers.

This cold storage may also be used to retain a copy of project data as a backup to an NIH approved repository, see below. Data would be stored in the SPARC secure research environment. If one of the external repositories used by Carilion investigators becomes unavailable, SPARC would provide the source to reload to an alternative repository.

Here is language that can be used in your protocol to designate Sparc as the cold storage retention option for your protocol:
Carilion HART will utilize the SPARC system for secure long-term storage for this concluded project. This process provides a new long-term storage solution with appropriate automated deletion of data/records at the protocol-specific required timeframe. HART will transfer data and/or documents related to the IRB approved project to SPARC in a secure folder for cold storage to comply with the retention and deletion requirements according to the IRB approved protocol. An expiration date will be set on the files to allow for appropriate tracking of the time for deletion. The automatic process will prevent "orphaning" of data/documents in other folders/directories in the event that no research team members remain at Carilion at the time data deletion is required. Access to the data/documents will not be available without specific IRB approval to do so, in which case, the file(s) will be recovered as stipulated in the new IRB approved submission.

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Wetlab Support / Specimen Collection and Repositories

Topics

AAA

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Carilion's Research Laboratory, located at Carilion Roanoke Community Hospital (CRCH), is equipped with advanced scientific equipment and software applicable to a wide variety of research pursuits.

Contact satolliver@carilionclinic (Susan Tolliver) for more information.

Visit our website by clicking here: https://www.carilionclinic.org/research/lab#research-lab

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Innovation Department / Intellectual Property

Topics

A A A

(When you are done, you may close this window or use the Topics menu to open another window on another topic)

Carilion physicians, nurses, and staff make unique discoveries through their research and continuous improvements to the care they provide our community. A set of these discoveries are innovations with commercial potential -- where not only our patients will benefit, but when brought to market by an Industry partner or spun out as a startup, patients across the country and globe could benefit.

Carilion Innovation is a catalytic agent and resource for our innovators.

When to engage Carilion Innovation:

- You have an *invention that you believe has commercial potential.
- Industry would like to license your invention/intellectual property (IP).
- Industry would like you to create or co-create a new product/service that they will then bring to market.

Capabilities and resources for our innovators:

- Assisting development of inventions
  - Connecting innovators to resources for further development (e.g., engineers, 3D printers, local universities like Virginia Tech, accelerators) and external funding opportunities.
- In-house development and acceleration capabilities

INNOVANCE
An Affiliate of Carilion Clinic

  - Best for inventions in low-fidelity prototype form with validated commercial interest. Innovance provides $20,000 to $30,000 in milestone-based funding to build a high-fidelity prototype and further (in)validate.

THE WORKSHOP
An Affiliate of Carilion Clinic

  - Focuses on concept refinement and building a low-fidelity prototype to establish technical and commercialization feasibility. The Workshop provides rapid prototype development resources and funding up to $5,000
  - CCI's Makerspace
    - located in the Center for Simulation, Research and Patient Safety, Makerspace houses a suite of resources for rapid prototyping and testing. The resources include two Prusa 3D printers, two medical-grade Formlabs 3D printers, an on-site innovation engineer and a 3D-printing technology specialist.
- Commercial Opportunities and Deal Management

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Simulation Center

Topics

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(When you are done, you may Continue to proceed sequentially, Save and Return later, or use the Topics menu to open another window on another topic)

Human factors is a science that explores human capabilities and limitations, and designs work processes that make it easy to do the right thing and hard to do the wrong thing. Our human factors team works closely with clinicians and patients to improve patient safety and quality of care for all of our patients and staff.

Visit the SIMI web page by clicking here.

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iTHRIV

Topics

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(When you are done, you may close this window or use the Topics menu to open another window on another topic)

If you have specific project needs beyond what is covered here, visit portal.iTHRIV.org to find internal and external resources that may apply to your project.

Login with your Carilion credentials. Navigate to Conduct, to browse various resources.

A good source for general learning about resources available and educational opportunities related to research is the iTHRIV portal.

Login with your Carilion credentials. Navigate to the Learn Section to browse various topics.

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Presentation and Manuscript Development

Topics

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1) **Select the video you would like to watch.**

Writing Numerical Data in Manuscripts
(right click on the video and select Open in New Tab to watch it in Full Screen)

(22:05 minutes)

View media

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eRA Commons Accounts

Topics

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eRA Commons Accounts

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eRA Commons (https://public.era.nih.gov/commons) is an online interface where grant applicants, recipients, and federal staff at NIH and grantor agencies can access and share administrative information relating to research grants. All Senior/Key Personnel and Other Significant Contributors listed on an application are required to have active eRA Commons usernames (Commons IDs).

Note: A single Commons account can be affiliated with multiple organizations. It does not matter which organization initially establishes the account.

Carilion's Grants Management Director holds the institutional eRA Commons account and can create new eRA Commons IDs for Carilion-affiliated staff. In addition, if a Carilion staff member has an existing account created by another institution, the Grants Management Director can add the Carilion affiliation.

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Acknowledgements Language for Publications / Presentations

Topics

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If you used iTHRIV support (including Carilion Clinic REDCap), include the following citation in your presentations/manuscripts:

This content was supported, in part, by the National Center For Advancing Translational Sciences of the National Institutes of Health under Award Numbers UL1TR003015 and KL2TR003016. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

If you used TriNetX, TriNetX should be mentioned in the methods section.

A suggested adequate general description would read like:

If a TriNetX platform with browser-based real-time analytical features was used:
"....We used TriNetX, a global federated health research network providing access to electronic medical records (diagnoses, procedures, medications, laboratory values, genomic information) from approximately xy Million patients in yz large Healthcare Organizations. The TriNetX platform only uses aggregated counts and statistical summaries of de-identified information. No Protected Health Information (PHI) or Personal Data is made available to the users of the platform..."

If a dataset, downloaded from TriNetX, was used:
"....TriNetX, a global health research network provided a de-identified dataset of electronic medical records (diagnoses, procedures, medications, laboratory values, genomic information) from xy patients with [cohort definition]. The data is de-identified based on standard defined in Section §164.514(a) of the HIPAA Privacy Rule. The process by which Data Sets are de-identified is attested to through a formal determination by a qualified expert as defined in Section §164.514(b)(1) of the HIPAA Privacy Rule. Protected Health Information (PHI) or Personal Data is made available to the users of the platform..."

This general description should be followed by a description of the actual methods used including the date of the data download or when the analytics were performed.

If you used REDCap, use the following language in your manuscripts and presentations.

Study data were collected and managed using REDCap electronic data capture tools hosted at Carilion Clinic. REDCap (Research Electronic Data Capture) is a secure, web-based software platform designed to support data capture for research studies, providing 1) an intuitive interface for validated data capture; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for data integration and interoperability with external sources.

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Presentation / Poster Templates / Assistance

Topics

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For poster and presentation templates, Carilion employees can access them here.

https://www.insidecarilion.org/hub/communications-marketing-and-planning/resources

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