Carilion IRB Application (Version 1.5)

1.0 General Information

*Please enter the full title of your study (#[%irb_number%]):		
Insert Study Title Here		
*Please enter an abbreviated study title or key words you would like to use to reference the study:		
Please enter the abbreviated study or key words here		

2.0 Add departments

2.1 Add the departments of all Key Study Personnel that will be involved with the design, conduct, or reporting on this project:

Is Primary?	Department Name
◉	Please select your correct primary department and any departments that will be involved.

3.0 ■ Assign key study personnel(KSP) access to the study

3.1 * Please add a Principal Investigator for the study:

Name	Role	Training Record
Please select the PI	**Principal Investigator**	View Training Record

3.2 Please add the Research Staff, if applicable:

A) Additional Investigators

Name	Role	Training Record
Please add any additional investigators		

B) Research Support Staff

Name	Role	Training Record
Please add any additional research support staff		

3.3 *Please add a Study Contact:

Name	Role	Training Record

Please add any study contacts	Study Contact	View Training Record

The Study Contact(s) will receive all important system notifications along with the Principal Investigator. (e.g. The project contact(s) are typically either the Study Coordinator or the Principal Investigator themselves).

4.0 Key Study Personnel (KSP) Info

4.1 Provide the following information below for each Carilion Clinic research team member: You will be asked to provide information about members of the research team that are outside Carilion at a later time.

Click "add another entry" to respond to this item.

****CITI Training in Human Subjects Research Biomedical Researchers and GCP (for FDA-regulated and NIH-funded) will be verified for each team member before the application will be reviewed by the IRB. Detailed instructions for Carilion's CITI training requirements can be found at https://www.carilionclinic.org/irb/education . Please ask all team members to ensure their Carilion email address is added to their CITI account profile so that their CITI training is pulled into this system. This feed occurs on a nightly basis.***

Entry 1

Research team member name:	Please enter an entry for each research team member
Degree:	
Status:	Carilion Staff/Employee **If other, specify:**
Email address:	irb@carilionclinic.org
Phone number:	540-224-5882
Alternate phone number (optional):	
Affiliation:	Carilion Clinic **If other, specify:**
Research Duties (check all that apply):	☐ PI: Ultimately responsible for the study including conduct by all study team members ☐ Identification of potential subjects ☐ Contacting potential subjects ☐ Screening of subjects, including assessing eligibility criteria ☐ Obtain Informed Consent ☐ Randomization ☐ Conduct of study procedures that result in research data ☐ Prepare or dispense study drug/device ☐ Research specimen collection/shipping ☐ Adverse Event documenting and reporting ☐ Data entry ☐ Data Analysis - Identifiable ☐ Data Analysis - De-identified

- [ ] Regulatory document maintenance
- [ ] Other (specify):

5.0 Application Type

IRB-19-344

5.2 Select the application type:

- ○ Human Subject Research Study
- ◉ Determination of Human Subjects Research (including QA/QI Determination)
- ○ Establishing a prospective Data or Specimens Research Repository
- ○ Humanitarian Use Device (non-research use)
- ○ Expanded Access or Compassionate Use
- ○ Single Patient Emergency Use
- ○ Preparatory to Research Application
- ○ IRB Grant Review ONLY for preliminary approval if required by funder
- ○ Requesting Carilion Clinic RELY on another IRB of Record (WIRB, CIRB, VT, UVA, Advarra etc.)
- ○ Conversion of a paper application due for Continuing Review or Annual Check-In

6.0 Funding Information and Outside Services

6.1 Select the applicable funding source(s).

- [ ] None (no money, equipment, supplies, and/or services will be provided by external source)
- [ ] No monetary funding BUT equipment, supplies, and/or services will be provided
- [ ] Federal Government
- [ ] Foundation or Non-profit
- [ ] Industry/Commercial Sponsor
- [ ] State or Local Government
- [ ] Investigator or Departmental/Unit Funds
- [ ] Carilion RAP Grant
- [ ] Other

Please specify:

Select all the Federal funding sources that apply:

- [ ] National Institutes of Health (NIH)
- [ ] National Science Foundation (NSF)
- [ ] Department of Agriculture
- [ ] Department of Commerce
- [ ] Department of Defense
- [ ] Department of Education
- [ ] Department of Energy
- [ ] Department of Energy, Office of Science, STTR
- [ ] Department of Energy, Office of Science, SBIR
- [ ] Department of Health and Human Services
- [ ] Department of the Interior

- [ ] Department of Justice
- [ ] Department of Transportation
- [ ] Environmental Protection Agency
- [ ] National Institutes of Standards and Technology
- [ ] U.S. Air Force Office of Scientific Research (AFOSR)
- [ ] U.S. Army Research Office
- [ ] U.S. Navy Office of Naval Research
- [ ] Other

Please specify:

Example Text

Please provide more detailed information about the funder, as applicable, including funder name or department (including name of NIH institute, center, or offices, name of NSF directorate, etc.).

Example Text

Award / Contract Status:

Example Text

Grant Title, if applicable:

Example Text

6.2 Select services from all areas outside of the Research Team members' affiliations that are necessary to conduct the work.

Research and Development (R&D) will contact you to arrange a Feasibility Meeting based on your responses below. This will ensure roles, responsibilities, and costs associated with this project are understood by all parties. Final sign-off from leadership in the additional service areas, as well as contracts, may be required.

- [ ] Animals
- [ ] Basic Science Laboratory Services
- [ ] Center for Simulation, Research & Patient Safety (CSRPS)
- [ ] Department of Medicine
- [ ] Department of Pediatrics
- [ ] Department of Psychiatry
- [ ] Department of Surgery
- [ ] Emergency Department
- [ ] Hazardous Materials
- [ ] Health Analytics Research Team (HART), including Epic Data Extraction, Statistics Services, Carilion RedCap, Epic Research Access
- [ ] Human Resources
- [ ] Jefferson College
- [ ] Nuclear Medicine
- [ ] Nursing
- [ ] Pathology
- [ ] Pharmacy
- [ ] Physical Therapy
- [ ] Radiology
- [ ] Recombinant DNA/RNA
- [ ] Respiratory
- [ ] Solstas Lab
- [ ] Technology Services Group (TSG)
- [ ] Other
- [ ] None

6.3

You have selected that HART services are needed for this research. Specify the resources needed.

- ☐ Epic Data Extract
- ☐ Statistics Support (biostatisticians)
- ☐ Carilion REDCap (Data management)
- ☐ Epic Research Access for Chart Review
- ☐ TriNetX Identifiable Patient List/Data Set
- ☐ SPARC Carilion Secure Research Environment

Note: If you have not yet discussed this project with the HART team, please contact them at HART@carilionclinic.org before proceeding any further with this application. This will ensure that your request for this project is feasible.

7.0 Determination of Human Subjects Research Drugs under FDA Jurisdiction

7.1 Will activities involve the use of a drug in one or more persons?

○ Yes ○ No

8.0 Determination of Human Subjects Research Devices under FDA Jurisdiction

8.1 Will the activities evaluate the safety and effectiveness of a device in a person?

○ Yes ○ No

8.2 Will any of the data regarding the use of a device on human specimens (identified or de-identified) be submitted or held for inspection by the FDA as part of an application for a research or marketing permit?

○ Yes ○ No

9.0 Determination of Human Subjects Research Description and NHSR Categories

9.1 Describe the role(s) of any Carilion staff or students in the design and/or conduct of the proposed activity and if this work is within the scope of their normal job activities.

Example Text

9.2 Briefly describe your project, including the purpose and aims of the work. Please include the current state of knowledge about your project topic by summarizing and synthesizing the available research (including published data) to provide justification for the proposed project. Include a reference list of literature cited to support your response. Include a description of the population targeted by the project and the benefit that this project may provide.

Example Text

9.3 Describe how you will utilize the data (ex: internal to Carilion use only, or dissemination beyond Carilion including presenting and/or publishing) and who will have access to the results.

Example Text

9.4 Describe the proposed methods and procedures that will take place over the course of this project. Reference assessment measures as appropriate and upload copies of them with the submission packet at the end of this application.

Example Text

9.5 Describe how data collection will occur and the type of information to be collected. If you will be working with existing data or specimens, explain where they will come from and the reason for which they were originally collected.

Attach a copy of your data collection tool or spreadsheet listing exactly what data is to be gathered during this project.

Example Text

9.6 Indicate whether data and/or specimens will be:

- ☐ De-Identified (i.e., not linked to individual identifiers)
- ☐ Identifiable
- ☐ Coded

9.7 Will the code will be accessible to the investigators?

○ Yes ○ No

9.8 Please describe the specific identifiers that will be accessed, reviewed, recorded, or created for this work.

Example Text

9.9 Will this work involve collaboration with anyone outside of Carilion?

○ Yes ○ No

9.10 Please be specific about the information, including specific identifiers or specimens, that will be sent outside of Carilion. Provide the name of the collaborator, their title, institutional affiliation, and any information about the status of their institution's IRB review.

Example Text

9.11 There are certain types of work that are common and do not meet the definition of Human Subjects Research (NHSR) requiring IRB review. If the below categories describe your ENTIRE project, please check next to the category(ies) and ensure all requirements under that category are met for your project. Depending on the category selected, you may be required to provide some additional information. If your ENTIRE project is not captured in the categories below, select the applicable category as well as the last category.

☐ NHSR 1. Health Care Delivery Improvement, including Quality Improvement, Process Improvement, or Performance Improvement

In order for NHSR 1 to apply, all the following criteria must be applicable:

- The activity is intended to improve the process/ or delivery of care while decreasing inefficiencies within a specific setting
- The activity is intended to evaluate current practice and/or implement practices and interventions within Carilion that are consensus-based or evidence-based
- The activity is conducted by individuals who are responsible for the practice change in the institutions where the activity will take place
- The methods for the activity are flexible and include approaches to evaluate rapid and incremental changes
- The activity will involve a sample of the population (patients/participants) ordinarily seen in the institution where the activity will take place
- Future patients or employees at the institution where the planned activity will be implemented will potentially benefit from the project
- There is no additional risk to patients/participants and participating in the activity is acceptable and expected in order to implement practice changes within a healthcare environment
- The activity could be considered part of the usual care and therefore will not require additional consent from participants

- **If this work is to be published, you must place the following statement in your methods section:** ***"This project was undertaken as a Health Care Delivery Improvement Project, and as such was not reviewed as Human Subjects Research."***

☐ NHSR 2. Establishment of a database for clinical care or quality assurance/quality improvement ONLY. A subsequent decision to extract data for research will require submission of a regular IRB application.

In order for NHSR 2 to apply, all the following must be applicable:

- The primary reason for establishing this database is for clinical purposes or future improvement projects (e.g. Health Care Delivery Improvement, including Quality Improvement, Process Improvement, or Performance Improvement)
- Only those involved with the care of the patient will have access to the data and this data must be stored in a secure location
- A subsequent decision to extract data for research will require submission of a regular IRB application and IRB approval. Contact the IRB Office if you have questions.

☐ NHSR 3. Evidence-based Medical Practice

For NHSR 3 to apply, all the following must be applicable:

- The primary reason for this work is to integrate the best available research-based evidence with clinical expertise and patient values to improve outcomes
- The process involves asking a relevant clinical question, finding the best evidence to answer it, applying the evidence to practice, and evaluating the evidence based on clinical outcomes
- **IRB approval of a protocol IS required if you wish to do research contributing to generalizable knowledge. Contact the IRB office if you have questions.**

☐ NHSR 4. Use of Public Data Sets

In order for NHSR 4 to apply, all the following must be applicable:

- Research will NOT involve merging any of the data sets in such a way that individuals might be identified
- Researcher will NOT enhance the public data set with identifiable, or potentially identifiable data
- Researcher will NOT use data from the NIH GWAS (Genome Wide Association Studies) data repository
- The data host does not require the researcher or the researcher's institution to sign a Data Use Agreement.

What is the name of the public data set you intend to use?

☐ NHSR 5. Research using Coded Data/Specimens

In order for NHSR 5 to apply, data or specimens will not be submitted to the FDA and all the following must be applicable:

- The data/specimens being accessed by or provided to the Carilion researchers will not contain any of the 18 HIPAA identifiers
- The entity releasing the data/specimens will retain a code or link which may be used to re-identify the donor, however, the key to the code will not be shared with the Carilion researchers
- The data/specimens were collected for purposes other than this project
- The person providing the data/specimens to the researcher will not otherwise be involved in this project (such as interpretation or analysis of data or preparation of a manuscript)
- No data will be returned to the source of the specimens/data
- Specimens do not include newborn dried blood spots or fetal tissue
- A Material Transfer Agreement (MTA) will be obtained through the Office of Research and Development prior to receipt of data or specimens
- If anyone on the research team unexpectedly learns the identity of a living individual or wishes to identify the individual(s) from the coded data/specimens, the research will require further IRB review.

In order for NHSR 5 to apply, one of the following must be true and selected:

- ☐ A signed agreement will be executed between the person releasing the specimens/ data and the researcher receiving the specimens/data stipulating that the key to the code will never be released to any member of the research team
- ☐ Confirmation of the data/specimen provider's IRB approval of written policies and operating procedures for a repository or data management center that prohibit the release of the key to the researchers under any circumstances
- ☐ There are other legal requirements prohibiting the release of the key to the investigators, until the individuals are deceased.

Will this study involve genomic sharing?

○ Yes ○ No

☐ NHSR 6. Research using De-identified Data/Specimens

In order for NHSR 6 to apply, all the following must be applicable:

- The data/specimens were collected for purposes other than this project.
- The data/specimens will be provided to the researcher without any HIPAA identifiers or other personally identifiable information.
- **No codes or links of any sort exist with either the researcher or by the person releasing the data /specimens.**
- Specimens do not include newborn dried blood spots or fetal tissue.
- A Material Transfer Agreement will be obtained through the Office of Research and Development prior to receipt of data or specimens.

☐ NHSR 7. A case series involving no more than three Carilion patients

In order for NHSR 7 to apply, all must be applicable:

- Any health information in the case series must be de-identified per HIPAA regulations
- For all case reports and case series, a signed HIPAA authorization should be obtained from the patients or their legally authorized representatives for the use and disclosure of their Protected Health Information. The only exception to the requirement for obtaining authorization is if the author of a case report or case series believes that the information is not identifiable; in this case, the author must consult with the HIPAA Privacy Officer to seek an expert opinion about the magnitude of the risk of identifying an individual.

☐ NHSR 8. Decedent research (all potential subjects are deceased)

In order for NHSR 8 to apply, all must be applicable:

- If the work will entail reviewing medical records of former patients, you must first consult with the Carilion Privacy Officer at (540) 981-7000 or **privacy@carilionclinic.org.**
- Any published health information must be de-identified per HIPAA regulations.
- If using specimens, the specimen is NOT fetal tissue.

☐ NHSR 9. Contributing data/specimens for research outside of Carilion

In order for NHSR 9 to apply, all the following criteria must be met:

- Individuals releasing the data/specimens are NOT working in collaboration with the recipients on the research project (ie: have not been involved in the design of the research and will not be involved with the conduct beyond providing data, analysis or publication of the research). The data/specimen, in its entirety, was collected for purposes other than the research project to be done by those with whom you are sharing the data/specimens.
- If the original data/ specimens were collected for research purposes, the study team confirms the secondary use does not disagree with language in the consent under which the data/specimens were obtained.
- Data/ samples must meet the HIPAA criteria of Limited Data Set or completely de-identified data at the time of release, unless you are contracting with the recipients outside of Carilion to de-identify the data or partially de-identify it to create a Limited Data Set. If so, contact the Carilion Compliance Office in order to execute a HIPAA Business Associate Agreement (BAA) with the recipient for this purpose.

- Study team must obtain a Material Transfer Agreement with the Research & Development Office prior to sending Limited Data Set or completely de-identified data/specimens.
- If the data/specimens meet the criteria of a Limited Data Set, Research & Development will incorporate a HIPAA Data Use Agreement into the Material Transfer Agreement.

☐ NHSR 10: Public Health Practice

In order for NHSR 10 to apply, all the following must be applicable:

- Intent is to prevent or control a disease or injury and improve health or to improve a public health program or service through such activities as disease surveillance, program evaluation, and outbreak investigation
- Focused on improving the health of a specific population or group
- There is a specific legal authorization for conducting the activity or governmental duty to perform the activity to protect the public's health and there may be direct performance or oversight of the activity by a governmental public health authority (or authorized partner) accountable to the public

☐ None of the above, or unsure if the project meets the above criteria

Based on your answers, your research project does not appear to fall within the scope of the Common Rule and therefore IRB review is likely not required. However, you are highly encouraged to submit this application for a final and formal determination by the IRB that this work is not Human Subjects Research. You may also save and print this application for your files.

Please be aware that if you wish to publish or present this work, the journal or conference may require documentation that the IRB made an official determination as to whether your work required IRB review. They may choose not to accept your submission for publication or presentation without the IRB's formal determination.

Failure to submit a project to the IRB that does meet the definition of Human Subjects Research before starting the work may be serious noncompliance with Carilion Clinic's policy and could result in corrective actions and inability to use the data. The IRB cannot make a determination once the project is started.

9.12 If you will be submitting to the IRB for a final determination regarding whether your project requires IRB review, please provide additional information regarding your work under NHSR 1 (Health Care Delivery Improvement, including Quality Initiatives, Quality Assurance, Quality Improvement, Process Improvement, Performance Improvement).

Please explicitly describe HOW the change will potentially improve the process, quality or delivery of care at Carilion. Provide references of the recommendation to change the process or practice and upload those references in the submission packet at the end of this application.

Example Text

Has the Carilion Quality Improvement Committee or your clinical practice unit (hospital, clinic, division, or care group) discussed the project and agreed that this is a QI/QA project that will be implemented to improve the process or delivery of care?

○ Yes ○ No

9.13 If you will be submitting to the IRB for a final determination regarding whether your project requires IRB review, please provide more information regarding your selection of NHSR 9 (Contributing data/specimens for research outside of Carilion).

Please describe Carilion's involvement in this work, the purpose of sharing the data, what identifiers will be shared, and how the data will be used by the recipient. Please also provide the name of the collaborator, their title, and institution. If the recipient will utilize this data for their research project, please provide the name of the project and attach their IRB approval letter, protocol, and IRB-approved consent form in the submissio packet.

Example Text

10.0 Application Questions Complete

10.1 You have now completed the IRB Application. Please click Save & Continue to proceed to the Initial Submission Packet.

Date Completing Form:

Please enter the date completing the form.

The Initial Submission Packet is a short form filled out after the IRB application has been completed and is where you will attach protocol-related documents, such as consent forms and recruitment materials. You will also be able to conduct a final review of the IRB application.

The PI will be required to sign off on the final Initial Submission Packet. The study may then proceed to the Department Signoff, if necessary based on the application type selected, and may require COI review before proceeding to the IRB.

You can view the Submission History of the study at any time to determine the status.