Carilion IRB Application (Version 1.0)

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:	Other: **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-23-1788

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

Please ensure the PI has completed and submitted the R&D Application Department Level Review Form (eCRAF), and that the PI's Department Chair or signatory has signed off on the R&D Department Level Review eCRAF Form BEFORE you proceed any further with this IRB application. Please read the below bullet points carefully and acknowledge your understanding.

- **The R&D Application Department Level Review eCRAF Form must be submitted by the PI and signed off by Department Chair or signatory through RedCap BEFORE you may proceed with this IRB application.**
- **The R&D Application Department Level Review eCRAF Form serves a major function for section and department level review and may result in this study not being permitted due to resources, scientific validity, or other reasons.**
- **You must submit a copy of the signed R&D Application Department Level Review eCRAF Form with this IRB application in the supplemental document section.**
- **Failure to complete the steps in the above order will result in a significant delay in the IRB's review of this study.**

◉ Acknowledged

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

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 Regulatory Compliance

7.1 How many studies is the PI currently responsible for?

Please enter the # of studies

7.2 Does the PI have protected or dedicated time available to conduct this research?

○ Yes ○ No

7.3 Has any member of the research team ever received a FDA 483, "Warning Letter", Notice of Disqualification, or other warning or disciplinary action from an agency or licensing authority?

○ Yes ○ No

7.4 Has this study been disapproved or terminated by another IRB?

○ Yes ○ No

8.0 Conflict of Interest

8.1 A Conflict of Interest, per the Carilion Clinic Organizational Policy, is a situation in which an Investigator's and/or their Family Member's financial, professional, or other personal consideration may directly or indirectly affect, or reasonably appear to affect, the Investigator's professional judgement in performing their Institutional Responsibilities. A Conflict of Interest may be actual, apparent, or potential. Any research team member listed on the IRB application is considered to be an Investigator. It is the Principal Investigator'

s responsibility to query all Carilion research team members on this study to ensure they have honestly completed their Annual COI Disclosure and that it is current. The Principal Investigator should be notified by the study team member if the study team member has disclosed any related interests. Carilion Clinic's Conflicts of Interest in Research Policy can be found here.

If this study has any external funding or support, have all Carilion research team members filed an Annual COI Disclosure through Carilion Clinic's Office of Organizational Integrity and Compliance via the COI-Smart online disclosure system?

- ○ Yes
- ○ No
- ○ N/A - this study does not have any external funding or support

Do any Carilion research team members or their family members have a Conflict of Interest or related outside interest with the sponsor/funding agency of this study?

○ Yes ◉ No

It is the Principal Investigator and conflicted employee's responsibilities to ensure the conflict or any changes that result in a potential conflict are disclosed to the Office of Integrity and Compliance who will refer it to the Carilion Clinic's Research Conflict of Interest Commitee for appropriate management when necessary. Disclosure and management must occur before the conflicted employee is permitted to engage in any research activities. Any employee who violates the Conflict of Interest policy is subject to disciplinary actions, up to and including termination.

9.0 Specimen and/or Data Repository

9.1 Select the type of repository.

Please click on the Help bubble to the right to learn more about when you should use this repository application.

- ○ Specimens
- ○ Data

9.2 Were or will the data/samples be collected through a separate human subjects research study requiring IRB approval?

○ Yes ○ No

IRB #:

PI:

Study Title:

Describe the purposes for which the data/samples were initially collected. Describe the consent process by which the data/samples were or will be obtained:

Please provide the IRB-approved informed consent document for the initial study in the Initial Submission Packet.

9.3 Describe the general purpose and objectives of the repository.

9.4 Provide background information that led to the development of this research repository.

9.5 Describe from how and where the data or specimens will be collected. State whether the data/specimens to be utilized in the repository are already in existence (retrospective) or if the data will be generated in the future (prospective).

- **"Retrospective data" is data that is already in existence at the time of application receipt by the IRB. Retrospective is in reference to the date the data was GENERATED, not the date the data is COLLECTED. If all data is retrospective, please provide the start date from which data will be collected and the end date, and note that ALL data must be in existence at time of submission of this application.**
  - **Example: This IRB application is being submitted on 12/1/21 and is collecting data on a standard of care surgery and looking at patient outcomes. All surgeries for this retrospective studies will be completed between 11/31/2018 and 11/31 /2021 (the day before the study is submitted to the IRB). This study will likely qualify for a waiver of consent.**
- **"Prospective data" includes any data (including data from the medical record) that are not currently in existence at the time of receipt of the application by the IRB, even if the data is being collected solely for Standard of Care. Prospective data collection typically requires informed consent from the participant to be able to use their clinical data or specimens for research purposes. If all data is propective, please state date range from which data will be generated.**
  - **Example: This IRB application is being submitted on 12/1/21 and is collecting data on a standard of care surgery and looking at patient outcomes. All surgeries for this prospective studies will be completed between 1/1/2022 and 1/1/2025. This study will require informed consent UNLESS a waiver of consent is requested and justified.**

9.6 Describe who is involved in the management of the repository/database.

9.7 Describe the location of the repository.

9.8 Where will the repository data be stored?

Please check all that apply:

- ☐ Hardcopy data in a locked office in a locked cabinet
- ☐ Electronic data on a password protected, encrypted Carilion laptop
- ☐ Electronic data on a password protected, secure drive on a Carilion server

Select the software to be used:

- ☐ Excel
- ☐ SoftMed
- ☐ RedCap
- ☐ Other

No other storage options are permitted, including the use of personal laptops, flash drives or other portable devices. Data must not be placed in a cloud or other hosted environment. Any exceptions must be approved by the Carilion Privacy and Information Security Officer and documentation provided to the IRB.

9.9 Describe how specimens/data will be received and stored by the repository.

9.10 Will the data/specimens maintained by the repository be directly identifiable or will they be coded or de-identified?

- ☐ Identifiable (includes any of the 18 HIPAA direct identifiers or information such that subject identities could be ascertained)
- ☐ Coded or linked (identifying information, including any of the 18 HIPAA identifiers, that would enable the investigator or collaborator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol, etc., and a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens)

☐ De-identified or unlinked (specimens/data cannot be linked to specific individuals by the investigator, either directly or indirectly through coding systems)

9.11 What identifiers will be maintained?

9.12 Who will have access to identifiers?

9.13 How will you limit access to the identifiers?

9.14 When and how will the identifiers be destroyed?

9.15 Please indicate which of the following identifiers will be maintained within or linked to the repository/database.

- ☐ name
- ☐ a geographic subdivision smaller than state except for the first three digits of the zip code
- ☐ an element of a date, except year, for dates related to an individual, including birth date, admission date, discharge date and date of death; and all ages over 89 and all elements of such ages may be aggregated into a category of age 90 or older
- ☐ telephone numbers
- ☐ fax numbers
- ☐ electronic mail address
- ☐ social security number
- ☐ medical record number
- ☐ health plan beneficiary numbers
- ☐ account numbers
- ☐ certificate / license numbers
- ☐ vehicle identifiers, including license plate number
- ☐ device identifiers and serial numbers
- ☐ Web Universal Resource Locators (URLs)
- ☐ Internet Protocol (IP) address numbers
- ☐ biometric identifiers, including finger and voice prints
- ☐ full face photographic images and any comparable image
- ☐ any other unique identifying number, characteristic, code

9.16 Please describe how participants can withdraw their consent and request their data/specimens be removed from the repository.

9.17 Will repository data include information that subjects or others might reasonably consider to be sensitive in nature (e.g., genetic test results, communicable disease status, substance abuse, mental health information, illegal behaviors, etc.)?

○ Yes ○ No

9.18 Who may request or use data/specimens from the repository for research and the conditions under which specimens/data will be shared with other researchers for future research?

9.19 Describe any restrictions on the types of research or testing that may be performed using data/specimens from the repository (e.g., cardiovascular research only, no whole genomic sequencing).

9.20 Describe the review process and documentation that will be used for each request by investigators to obtain specimens/data from the repository and the process to verify that any proposed uses of data/specimens are consistent with the IRB-approval for the repository.

9.21 Describe the process to verify that the proposed research has been IRB-approved or determined exempt or "not human subjects research".

9.22 Describe the process to verify consent and authorization, or waiver of the requirements, for the proposed research.

9.23 Describe how repository data/specimens will be distributed to recipient investigators and the provisions to protect confidentiality.

9.24 Explain how the repository will receive assurances that data/specimens will be used/managed in accordance with repository requirements, including any restrictions on re-identification (e.g., terms of use, data use agreement, confidentiality agreement, materials transfer agreement).

9.25 Will the data/specimens distributed by the repository be identifiable or will it be coded or de-identified?

- ○ Identifiable (includes direct identifiers or information such that subject identities could be ascertained)
- ○ Coded (direct identifiers are replaced by a unique code)
- ○ De-identified (all identifying elements have been removed or replaced, including dates, and the remaining information cannot readily be used to re-identify subjects)
- ○ Combination of the above or determined on a pre-protocol basis

Please note if individuals external to Carilion Clinic will have access to PHI, additional confidentiality requirements may be necessary.

9.26 Who will own the specimens/data once they are shared?

10.0 Collaboration

10.1 Is this research project a collaboration between Carilion Clinic and another institution (including, but not limited to Fralin Biomedical Research Institute at VTC, VTCSOM, VT, UVA)?

- ◉ Yes ○ No

10.2 Please provide the name(s) of the collaborating institution(s) and the name(s) and contact information of the lead PI(s) at that institution.

10.3 Is Carilion acting as one site of a multicenter study?

- ○ Yes ○ No

10.7 Are any members of the research team listed on this IRB application under the jurisdiction of another institution's IRB?

○ Yes ○ No

10.8 Are you requesting that Carilion Clinic serve as the IRB of record for the other participating institutions or organizations?

For more information on IRB reliance requests, please visit the Carilion Clinic IRB website or contact the IRB Office.

○ Yes ○ No

10.11 Describe any plans for initial and ongoing training of the other sites on important aspects of the protocol.

10.12 Describe the plan to manage communication of information at the other sites that is relevant to the conduct of the research and the protection of human subjects, such as reporting of unexpected problems, protocol modifications, and interim results for all sites to the Carilion Clinic IRB.

For FDA-regulated clinical trials, the plan must include the plan for reporting serious adverse events or serious adverse device effects, significant new risk information, and any other reports mandated by regulation or policy.

10.13 Describe the Carilion Clinic investigator's plan for oversight of research activities at other sites including verification of Institutional approvals, data safety monitoring, and ensuring data quality and integrity.

For FDA-regulated clinical trials, the plan must include the use of trained and qualified monitors to oversee the progress of the research.

10.14 Will identifiable data or specimens be transferred, transmitted, or shared outside of Carilion?

For example, transfer of data or specimens from Carilion Clinic to an external collaborator (including VT, VTCRI, UVA, etc.).

○ Yes ○ No

10.15 Provide information about the types of specimens and/or data, including specific datapoints, that will be shared and the methods of storage of the data at the collaborating site. Include a description of the process for shipping the specimens and/or transmitting the data to the collaborator, including the method of encryption if sharing data electronically.

11.0 Applicable Regulations for ClinicalTrials.gov Registration

11.1 Is this study FDA-regulated?

○ Yes ○ No

11.2 Is this research funded wholly or in part by NIH?

○ Yes ○ No

11.3 Is this study a Clinical Trial, as defined by FDA or NIH, and therefore needing registration on ClinicalTrials.gov? Click the help button to the right to learn more about the definition of a clinical trial.

○ Yes ○ No

11.5 Is the clinical trial already registered in ClinicalTrials.gov?

○ Not yet, but clinical trial will be registered prior to enrolling any subjects
○ Yes
○ No, this clinical trial will not be registered

ClinicalTrials.gov #:

Note: The following statement must be included verbatim in the consent form for trials that are/will be registered on ClinicalTrials.gov:

"A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time."

11.6 Who is responsible for registering this trial in ClinicalTrials.gov and ensuring information is updated, as necessary? Please provide a name if the person is at Carilion or listed on the research team, or state the sponsor or lead site if the sponsor or lead site will register the trial.

The responsible party for an applicable clinical trial (ACT) must register the trial and submit results information. The responsible party is defined as:

- ***The sponsor of the clinical trial, as defined in 21 CFR 50.3; or***
- ***The principal investigator (PI) of such clinical trial if so designated by a sponsor, grantee, contractor, or awardee, so long as the PI is responsible for conducting the trial, has access to and control over the data from the clinical trial, has the right to publish the results of the trial, and has the ability to meet all of the requirements for the submission of clinical trial information***

The responsible party for an ACT must submit the required clinical trial information **no later than 21 days** after enrollment of the first participant, but registration is highly recommended before enrollment begins due to some journal requirements.

12.0 Study Procedures

12.1 Provide a step-by-step description of the research procedures and/or and interactions with human subjects.

Provide a study schedule and list all activities or procedures that will be performed and describe the frequency and duration of research procedures, diagnostic and research tests, questionnaires or surveys, specimen collection, and experiments, including screening, intervention, follow-up etc in step-by-step chronological order. State the length of time subjects will be in the study and the expected amount of time required for each study visit or activity. Describe how, when and where research activities will be administered and analyzed. If the research includes blinding, indicate whether researchers or subjects will be "unblinded" to study assignment and describe when and how this will be done.

You must attach surveys, instruments, interview questions, focus group questions, etc. in the Initial Submission Packet and label them clearly.

12.2 Specify which procedures, tests, visits, etc. described above are part of usual standard of care at Carilion Clinic and which are being performed solely for research purposes. If procedures, tests, visits are routinely performed for clinical care, but are providing data for this research study, state this as well.

12.3 Describe the data collection methods and how data be compiled and collected for assessment. State whether the data/specimens to be utilized in the repository are already in existence (retrospective) or if the data will be generated in the future (prospective).

- **"Retrospective data" is data that is already in existence at the time of application receipt by the IRB. Retrospective is in reference to the date the data was GENERATED, not the date the data is COLLECTED. If all data is retrospective, please provide the start date from which data will be collected and the end date, and note that ALL data must be in existence at time of submission of this application.**
  - **Example: This IRB application is being submitted on 12/1/21 and is collecting data on a standard of care surgery and looking at patient outcomes. All surgeries for this retrospective studies will be completed between 11/31/2018 and 11/31/2021 (the day before the study is submitted to the IRB). This study will likely qualify for a waiver of consent.**
- **"Prospective data" includes any data (including data from the medical record) that are not currently in existence at the time of receipt of the application by the IRB, even if the data is being collected solely for Standard of Care. Prospective data collection typically requires informed consent from the participant to be able to use their clinical data or specimens for research purposes. If all data is prospective, please state date range from which data will be generated.**
  - **Example: This IRB application is being submitted on 12/1/21 and the study is collecting data on a standard of care surgery and looking at patient outcomes. All surgeries for this prospective studies will be completed between 1/1/2022 and 1/1/2025. This study will require informed consent UNLESS a waiver of consent is requested and justified.**

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

12.4 Describe how long individual participants will be actively in the study. If there will be a period of time after the active component of the study where participants will still be in the study (ex: participants outcomes are being extracted from the medical record at 1 year, but the last research study visit was at 3 months), state this as well.

Example Text

12.5 Describe how long the entire study is expected to last, including data analysis.

Example Text

12.6 Describe the qualifications of study personnel conducting the research procedures. This could include medical training specific to conducting the interventional procedures in this research, phlebotomy training for those drawing blood, study protocol specific training to be provided by the sponsor, or any other training to demonstrate that the research personnel are appropriately quailified to conduct the study.

Example Text

12.7 Please describe appropriate alternatives to the study procedures or course of treatment.

(For example: not to participate, standard of care treatment, other research study, same treatment offered off study)

13.0 Research Involving Drugs or Biologics

13.1 Indicate the phase of drug trial.

- ☐ Phase I
- ☐ Phase II
- ☐ Phase III
- ☐ Phase IV
- ☐ None of the above

13.2 Trade Drug Name:

View Details	Drug Name	FDA Approved	A new drug or a new use of an already approved drug:	IND Number
Add Drugs Here				

13.3 Additional Information Needed for Drug Studies

Please upload the package insert for any drugs/biologics that are FDA-approved in the Initial Submission Packet.

If any of the drugs being used in this research are under an IND, documentation must be provided to validate the IND (e.g., a FDA letter, a Sponsor letter, a FDA-approved protocol with the IND number noted).

If any of the approved drugs proposed for use in this research are being used outside of the FDA-approved labeling and an IND has not been obtained, documentation supporting that an IND is not needed must be provided. This can be in the form of a FDA letter, Sponsor letter providing justification, or Investigator letter providing justification. You should consult the FDA website for more information on IND requirements and exemptions. You may also contact the IRB for guidance.

14.0 Incidental Findings

14.1 Does this study involve any imaging procedures (x-rays, CT, MRI, PET, ultrasound, etc.) specifically for research purposes?

○ Yes ○ No

14.2 Does the research include any of the following?

☐ Exams, blood tests, genetic tests or markers, or other tests or procedures that may generate incidental or secondary findings, including disease or conditions other than the one under study, or familial relationships including paternity and ancestry.

☐ Testing for communicable diseases

☐ None

14.3 Specify the imaging procedures, exams, tests, or other procedures being done for the research that may generate incidental findings, including whether they will be of clinical quality.

14.4 Describe the likelihood and nature of incidental or secondary findings and whether such findings could be clinically significant and if they may require additional interpretation (clinical imaging) or verification (e.g., certification by a CLIA lab).

14.5 Describe the plans for sharing such findings with subjects and their healthcare provider. If you will not be sharing findings with subjects, please provide your justification. The plans to share or not to share must be described in the Informed Consent document.

14.6 If the research includes testing for communicable diseases, indicate whether the findings will require verification (e.g., by a CLIA lab), any plans for sharing findings with subjects, and whether findings must be reported to a state or federal agency.

15.0 Identification/Recruitment of Subjects

15.1 How do you plan to identify potential subjects?

To "identify" a potential subject refers to procedures to determine which individuals may qualify to participate in the study in order to decide which individuals to contact about taking part.

Check all that apply:

☐	Existing Record Review, including Medical Chart Review, Clinic Schedule Review, or QA-QI Database Review.	Select all that apply: ☐ Patients' records reviewed will be those from research team's own patient population ☐ Patients' records will be those from other physicians or medical practices' patient population ** You must request Waiver of Informed Consent and, if any HIPAA identifiers are collected, a Waiver of HIPAA Authorization for recruitment purposes.*
	Researchers who ARE NOT treating clinicians of potential subjects will ask treating clinicians for referrals of eligible patients interested in the study.	Select all that apply: ☐ Treating clinicians will identify potentially eligible patients and obtain patient permission before providing researchers with patient contact information. ☐ Treating clinician will provide documentation of patient permission in a email/letter to researcher, and researcher must document permission in research record. **You must request a Waiver of Informed Consent/HIPAA Authorization for recruitment purposes.*
☐	Potential subjects will not be directly identified by the researchers from existing records. The potential subject will obtain IRB-approved information about the study from an advertisement, flyer, brochure, website, grand rounds presentation, department meeting, etc. In most cases, the potential subject will contact the researcher if interested.	Comments:

☐	Review of Registry/Database in which individuals have previously signed a consent giving their permission to be contacted for future studies.	Comments:
☐	Student Records	Comments:
☐	Other	Please specify other:

15.2 Please describe the identification process.

List all information you plan to collect and record during the identification process PRIOR to contacting potential subjects. This includes the inclusion/exclusion criteria and demographics to determine if a person qualifies for a study before contacting that person to be a potential subject.

15.3 Through what methods will potential subjects be contacted or recruited?

Check all that apply. To "recruit" a potential subject refers to the initial contact method you plan to use to convey information to a potential subject to determine if he or she would be interested in taking part in your study.

- ☐ Direct in-person contact
- ☐ Telephone call
- ☐ Letter
- ☐ E-mail
- ☐ Brochure
- ☐ Radio/Television script
- ☐ Newspaper Ad
- ☐ Online advertisement (including Facebook, Twitter, Craigslist, other websites, etc.)
- ☐ Flyer/Poster
- ☐ Snowball sampling
- ☐ Clinical trial website posting
- ☐ Other
- ☐ None (there will be no interaction or intervention with potential participants in this study)

Please specify:

15.4 Please provide any additional details about how potential subjects will initially be contacted, who will contact them, or how they will be introduced to the research.

- ***If recruitment material is being mailed, emailed, or otherwise distributed, describe where/how the distribution list will be obtained.***
- ***If potential subjects will be recruited by telephone, describe how many times the research team will attempt to call / leave a voice message.***
- ***When subjects respond to recruitment material, describe the information that will be provided to them about the study and the information that will be collected from subjects (e.g. name, telephone number, etc.). Describe also, how many times you will attempt to respond to call the subject back / leave a voice message.***

15.5 After potential subjects are identified, describe the pre-screening process that will take place prior to obtaining informed consent.

This could include asking questions to a potential subject to determine whether he or she meets eligibility criteria, for example: patients will answer questions about their medical history, be expected to come to the first screening visit after fasting, stop taking medications, change diet, etc. To comply with HIPAA regulations, only the minimum necessary protected health information may be collected at this time. This means only questions relating to the inclusion and exclusion criteria may be asked.

☐ No prescreening will take place

15.6 Indicate whether pre-screening information will be retained on persons who do not ultimately participate in the study and what specific information, including identifiers, will be retained.

Attach all recruitment materials, letters, phone scripts, flyers, etc. in the Supplemental Documents section after you complete the IRB application.

16.0 Risks and Risk Minimization and Benefits

16.1 List the possible risks, discomforts, or harms to subjects associated with the research.

If the risks differ based on group assignment, describe for each group. Estimate the (1) probability of occurrence, (2) the seriousness, and (3) the duration of each risk. If this information is captured in the protocol or investigators brochure (IB) or other materials, indicate the document and page numbers where the information can be located.

16.2 Define adverse events (AEs), serious adverse events (SAEs), and unanticipated problems (UAPs) for the study. Describe the protocol-specific reporting procedures, including who will be responsible for each step (e.g., PI), timeframes for reporting, how reports will be distributed, and follow-up that will occur.

Ensure that the reporting procedures meet the reporting requirements of Carilion Clinic IRB, the FDA, NIH, OHRP, sponsor, study leadership and any other regulatory body that applies to the study, as applicable. Please note that all Carilion Privacy breaches must also be reported to the Privacy office by the PI. Noncompliance must be reported to the IRB as well as Office of Integrity and Compliance.

16.3 Describe the actions that will be taken to minimize the risks associated with participation in this research.

If this research includes risks that might require immediate or prompt medical management, describe access to/availability of emergency medical equipment and trained personnel at each setting where procedures that impart physical/health risks will take place. If this information is available in the study protocol indicate the page numbers where the information can be located.

Example Text

16.4 For studies involving drugs, devices, biologics, or imaging, describe the type of pregnancy testing that will occur and how frequently it will be conducted on women of reproductive potential.

Include:

- ***If pregnancy testing will not be conducted, provide the reason.***
- ***State the types of birth control methods women of reproductive potential will be instructed to use.***

- ***If women will not be instructed about acceptable methods of birth control, provide the reasoning.***
- ***Describe the birth control methods men of reproductive potential will be instructed to use. If men will not be instructed about acceptable methods of birth control, provide the reasoning.***

Example Text

16.5 Does the research include screening tools, questionnaires, or procedures that may indicate the presence of serious depression and/or suicidal ideation?

○ Yes ○ No

16.6 Describe the Data Safety Monitoring Plan or Data Safety Monitoring Board, or indicate the page(s) of the protocol or name of the document where this information can be located. While a robust Data Safety Monitoring Plan is REQUIRED for greater than minimal risk studies, a plan should also be in place for studies that are minimal risk. Please click on the Help circle to the right for information on writing a DSM plan based in risk levels of the research.

Include:

- ***The data that will be reviewed, including safety data, untoward events, and efficacy data;***
- ***Who is responsible for reviewing the data;***
- ***How the safety information will be obtained and documented (e.g., case report forms, by telephone calls with participants, printouts of laboratory results, etc.);***
- ***The frequency or periodicity of review of cumulative data;***
- ***The statistical tests for analyzing the safety data to determine whether harm is occurring;***
- ***Any conditions that trigger an immediate suspension of the research or other action for the research.***

Example Text

16.7 Describe the plans and rationale for conducting an interim analysis.

○ Yes ○ No

16.8 Have stopping rules been established for the study, including for reasons of futility?

○ Yes ○ No

16.9 Are there defined criteria (ex: rates of adverse events) for when study interventions should be discontinued?

○ Yes ○ No

16.10 Are there exams or procedures that the subject will be asked to have done or follow to safely withdraw from the study?

○ Yes ○ No

16.11 Will subjects who withdraw from the interventional component of the study be asked for their permission to continue to gather information about them through follow up visits, phone calls, records review, or other methods?

○ Yes
○ No
○ N/A

16.12 Describe the potential benefits to science and/or society expected from this research.

16.13 Are individual subjects expected to directly benefit from participating in this research?

Note: Compensation is not considered a benefit.

○ Yes ○ No

17.0 Costs and Compensation

17.1 Will the subject, or the subject's insurance, be responsible for any medical costs incurred as a result of participation in the research?

Take into account medical costs associated with study procedures, drugs, or devices.

○ Yes ○ No

17.3 Will subjects be reimbursed for any expenses related to their research participation, including medical costs, travel, parking, or transportation?

○ Yes ○ No

17.4 Will subjects receive any monetary compensation (cash, check, or giftcard) or non-monetary gifts, incentives, or tokens of appreciation for participating in this research?

Note: Reimbursement for costs is not considered compensation. Use of raffles or lotteries are discouraged at Carilion Clinic since the compensation is not being equitably dispersed to participants. Raffles and lotteries may be permitted on a case-by-case basis with appropriate justification.

○ Yes ○ No

18.0 Application Questions Complete

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

Date Completing Form:

Date of 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.