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:	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-xx-xxxx

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

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)
- [ ] 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

An Annual COI disclosure must be completed for ALL Carilion research team members. Please contact the Carilion Clinic Office of Organizational Integrity & Compliance immediately at researchcompliance@carilionclinic.org in order to ensure you can submit a disclosure through COISmart.

If new Carilion study team members are added to this study in the future, you must contact researchcompliance@carilionclinic.org. If the new team member needs to submit an Annual COI disclosure, this must occur before the new team member is permitted to conduct any work on this research study.

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

Please email researchcompliance@carilionclinic.org and irb@carilionclinic.org immediately to ensure this Conflict of Interest or Outside Interest has been appropriately managed. Please note that the IRB may require additional management conditions for this study.

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 Request to Rely on an External IRB (WIRB/WCG IRB, CIRB, VT, UVA, Advarra, etc.)

9.1 Who will be the IRB of Record? Please click on the Help text to the right of this question to determine when Carilion may rely on another IRB.

ONLY SELECT WIRB/WCG AS THE IRB OF RECORD FOR MULTICENTER STUDIES WHERE WCG HAS BEEN SELECTED BY THE SPONSOR AS THE SINGLE IRB OF RECORD! OTHERWISE, ADVARRA IS THE PREFERRED IRB OF RECORD.

FOR INVESTIGATOR-INITIATED STUDIES REQUESTING RELIANCE ON A COMMERCIAL IRB, ADVARRA MUST BE UTILIZED AS THE IRB OF RECORD. CARILION'S CONTRACT WITH WCG NO LONGER PERMITS NEW STUDIES TO BE REVIEWED BY WCG FOR INVESTIGATOR-INITIATED STUDIES.

*****Please note that the decision to execute a Reliance Agreement is a discussion and decision that occurs between the two IRBs and institutions, so your Reliance Request may not be granted. Please contact the IRB at irb@carilionclinic.org if you will be requesting to use a commercial IRB not on this list.***

- ○ WIRB-Copernicus Group (WCG)
- ○ Virginia Tech
- ○ Advarra
- ○ NCI CIRB
- ○ Other

Please provide copies of the protocol, consent, and HIPAA Authorization, as well as the IRB approval letter (if the study is already approved by the requested reviewing IRB) in the Initial Submission Packet following completion of this form.

9.2 Please provide the Contact Information for the individual overseeing the Reliance process at the collaborating institution.

This information is not necessary for studies Requesting to Rely on WIRB or VT IRB.

External IRB Contact Name	Phone	Email
Please enter External IRB Contact Name, Phone, and Email		

9.3 Describe how the external Principal Investigator will train and supervise the research team members at Carilion.

Example Text here

Upload IRB reliance agreement in the Initial Submission Packet following this application.

9.4 Does the research include interaction with or observation of subjects?

○ Yes ○ No

9.5 Please describe the subject population to be included in this study.

Example Text here

9.7 How do you plan to identify potential subjects?

To "identify" a potential subject refers to steps you plan to take to determine which individuals may qualify to participate in your study so that you can decide which individuals to contact about taking part

Check all that apply:

- ☐ Medical Chart Review, Clinic Schedule Review, or QA-QI Database Review (own patient population) *Study team requests Waiver of Informed Consent and, if any HIPAA identifiers are collected, a Waiver of HIPAA Authorization for recruitment purposes.
- ☐ Medical Chart Review, Clinic Schedule Review, or QA-QI Database Review (other physicians /practices patient population) *Study team requests Waiver of Informed Consent/HIPAA Authorization for recruitment purposes.

- [ ] Potential subjects will not be directly identified by the researchers. The potential subject will obtain IRB-approved written information about the study from his or her health care provider /faculty or from an advertisement, flyer, brochure, website, etc. The potential subject would then contact the researcher if he or she is interested.
- [ ] Researchers who ARE NOT treating clinicians of potential subjects will ask treating clinicians for referrals of eligible patients interested in the study. Treating clinicians identify potentially eligible patients and provide researchers with patient contact information with patient permission documented (e.g. email/letter to researcher from treating clinician states patient permission given. Researcher documents permission in research record.)
- [ ] Contact information will be provided by a patient's Carilion health care provider without the patient's knowledge to the researchers AND this is a minimal risk study that does not involve investigative drugs, devices, biologics or medical or surgical procedures.
- [ ] Review of Registry/Database in which individuals have previously signed a consent giving their permission to be contacted for future studies.
- [ ] Other

9.8 Describe the identification process.

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

Example Text here

9.9 Who will conduct the identification process?

- [ ] Principal Investigator
- [ ] Other investigator
- [ ] Research coordinator
- [ ] Other research team member

9.13 Describe the screening process for your study.

To "screen" a potential subject refers to additional information that will be collected or activities that will take place after he or she has been identified and contacted and prior to obtaining informed consent for the study. This could include asking questions to a potential subject to determine whether he or she meets eligibility criteria. Note: 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.

Please include whether you plan to ask potential subjects to do anything or answer questions prior to signing an informed consent document. (Ex: patients will come to the first visit fasting, stop taking medications, change diet, etc.)

- [ ] N/A

Example Text here

9.14 Who will conduct the screening?

- [ ] Principal investigator
- [ ] Other investigator
- [ ] Research coordinator
- [ ] Other research team member

9.15 Do you plan to collect or record individually identifiable health information about subjects from a healthcare record at any other non-Carilion healthcare provider, health plan (e.g. insurer), employer, or healthcare clearinghouse (e.g. billing service) at any point in the project?

○ Yes ○ No

9.16 Select the data points that will be reviewed, collected, recorded, or created for research purposes, including screening or recruitment.

Check all that apply:

- ☐ name
- ☐ all geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census
- ☐ 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/ master patient index (MPI)
- ☐ health plan beneficiary numbers
- ☐ account numbers
- ☐ hospital account receivable (HAR)/contact serial number (CSN)
- ☐ 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
- ☐ None of the above

9.17 Is the private information being requested the minimum necessary to meet the research goals?

○ Yes ○ No

9.18 Under the Privacy Rule, when accessing or using PHI, a HIPAA Authorization of the subject must be obtained, or the IRB must grant a waiver.

Indicate which of the following apply:

- ☐ The HIPAA Authorization is embedded in the research consent document.
- ☐ A partial waiver of the requirement for HIPAA Authorization is requested (e.g., for screening or for some subjects, such as a retrospective cohort)
- ☐ A full waiver of the requirement for HIPAA Authorization is requested
- ☐ The HIPAA Authorization will be sought but one or more required elements will be eliminated or altered
- ☐ The PHI accessed or used for this research is a Limited Data Set (LDS) and a Data Use Agreement (DUA) is or will be in place prior to accessing or obtaining the LDS.
- ☐ HIPAA Authorization will be obtained as a separate document (only permitted if required by sponsor)
- ☐ Other

9.19 Describe the provisions to protect the privacy interests of subjects.

Include a description of the following:

1. *the settings where subjects will be interviewed, examined, or observed for the purposes of the research;*
2. *the settings where interventional components of the research and research procedures will take place,*
3. *any provisions being taken to maximize privacy.*

Example Text here

9.20 Please describe where the data will be stored, how it will be transmitted (if applicable), and if it will contain identifiers. Please describe how long research records, data, and specimens will be retained following completion of the study.

Example Text here

9.21 Please provide any additional necessary information regarding your Request to Rely on another IRB.

Example Text here

10.0 Applicable Regulations for ClinicalTrials.gov Registration

10.1 Is this study FDA-regulated?

○ Yes ○ No

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

○ Yes ○ No

10.3 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

10.5 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."

10.6 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.

Example Text here

11.0 Application Questions Complete

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

Date Completing Form:

Enter the date here

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.