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

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)
- [ ] 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

Explain how the PI will have adequate availability to conduct and/or supervise the research:

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

Include a copy of the notice or report and related correspondence in the Initial Submission Packet.

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

- ○ Yes
- ○ No

Provide the basis for the disapproval or termination:

Please upload a copy of the IRB letter, if available, and any other relevant documentation in the Initial Submission Packet.

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

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 Collaboration

9.1 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

9.2 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.

Example Text

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

◉ Yes ○ No

9.4 Will the multicenter protocol be followed as written or are there components or aspects of the research that this site will not participate in or that will be modified?

(E.x:, local site will not recruit into one of the cohorts or into a sub-study; the age range will be narrowed, a specific procedure or test isn't available locally so another will be performed, etc.)

○ The protocol will be followed as written.
◉ The protocol will be modified locally.

Please explain:

Example Text

9.5 Is Carilion acting as the coordinating center for the multi-center study?

◉ Yes ○ No

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

◉ Yes ○ No

Please state specifically which external personnel are under the jurisdiction of another IRB, their role on this research study and the type of interaction they will have with the subjects, the name of the institution's IRB(s), and an explanation as to why they are listed on this IRB application.

Example Text

9.8 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

List all the team members on the study at the collaborating site(s) and describe their role in the research, including if they will have access to identifiable data. Please also ensure all external team members have met the training requirements for their home institution. Failure to do so will delay the execution of the IRB Reliance.

9.9 If this study has any external funding or support, do the external collaborators' institutions possess a PHS-Compliant FCOI policy?

☐ Yes
☐ No
☐ N/A - study does not have external funding or support

9.10 Have the external collaborator research team members filed a COI Disclosure through Carilion Clinic's Office for Organizational Integrity and Compliance via the COI-Smart online disclosure system?

○ Yes ○ No

A COI Disclosure will need to be completed for ALL external research team members whose institution does not already possess a PHS-compliant FCOI policy. Please contact the Carilion Clinic Office of Organizational Integrity and Compliance

immediately at researchcompliance@carilionclinic.org in order to ensure those team members can submit a disclosure through COI-Smart.

If new external study team members are added to this study in the future, you must contact researchcompliance@carilionclinic.org. If the new external team member(s) needs to complete and submit a COI Disclosure, this must occur before the new team member is permitted to conduct any work on this research study.

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

Example Text

9.12 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.

Example Text

9.13 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.

Example Text

9.14 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

9.15 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.

Example Text

10.0 Human Subjects Research Description

10.1 In the opinion of the Principal Investigator, does this research impart minimal risk or greater than minimal risk to subjects?

As defined by regulation, minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Please note that the IRB makes the final determination of risk level and may ask you to change this based on their decision.

If this is a Conversion of a Paper Application, select the risk level that has been determined already by the IRB at most recent review per the most recent approval letter (expedited review = minimal risk, full board review = greater than minimal risk).

○ Minimal Risk

- ○ Greater than minimal

10.3 Select ALL the types of research activities that will be involved in your human subject research subject, or select None.

- ☐ Drugs, biologics or other FDA-regulated products (other than devices)
- ☐ Medical devices
- ☐ Review of data/records (i.e. prospective clinical data collection from medical records, reviewing previously collected data)
- ☐ Biospecimen collection (i.e. blood, tissue, urine, saliva)
- ☐ Analysis of existing specimens from patients and/or bank or repository
- ☐ Human genetic analysis or Recombinant DNA, or Gene Therapy
- ☐ Invasive medical procedures (i.e. lumbar puncture, biopsy, endoscopy, surgery, etc.)
- ☐ Non-invasive medical procedures routinely employed in medical practice (i.e., physical measurements, EKG, EEG, moderate exercise, etc.)
- ☐ Imaging (i.e., x-ray, CT, DEXA, MRI, ultrasound, etc.), Use of Therapeutic or Diagnostic Radiation, Radioactive Drugs
- ☐ Task-based activities or games, or Psychometric Testing
- ☐ Surveys, questionnaires, focus groups, or interviews
- ☐ Examination of educational practices, instructional techniques, curricula or classroom management
- ☐ Observations of public behavior
- ☐ Interventions or procedures involving deception
- ☐ Use of Internet
- ☐ Audio or Video recording
- ☐ International Research
- ☐ NONE OF THE ABOVE

10.4 Briefly describe the proposed research in language that can be understood by a non-scientist.

This description should summarize the objectives of the research and the procedures to be used, with an emphasis on what will happen to the subjects. If this is an application for the establishment of a research repository, summarize the objectives of the repository and how data/specimens will be used in the future.

Example Text

10.5 Provide background information about the research question(s.) Explain why the research is needed and include the relevance of this research to the contribution of this field of study.

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 study. Include a reference list of literature cited to support the protocol statement, either in your response below or as a supplemental document as part of the application packet.

Example Text

10.6 State the research hypothesis or the question that the research will answer.

List the research objectives and expected outcomes. A primary outcome or objective must be identified. After the statement of the primary objective, secondary objectives may be listed. Objectives should be simple and specific.

Example Text

10.7 State how qualitative and/or quantitative data will be analyzed in order to answer the research questions.

Include an analysis from a statistician (or someone familiar with statistical methods) that either indicates the power calculation for the sample size necessary to meet the primary study outcome or objective OR a

statement from the statistician indicating reasons why a power calculation is waived or not necessary for this study. Also include the statistical test(s) that will be used to analyze your primary study objective (t-test, chi-square, etc.). Secondary outcomes may be listed as descriptive.

If this is a proof of concept or feasibility study that includes limited efficacy testing, please provide a description on how your design will determine if an intervention should be recommended for broader efficacy testing. If a study is meant to be solely descriptive, then the primary outcome or objective must be limited in scope. As such, the study results apply only to the sample being studied, and conclusions cannot be drawn about the larger population.

This is required for ALL studies, as this section helps the IRB confirm the data being collected are relevant to the study aims and planned analysis.

Example Text

10.8 Statistical Review

Name of statistician or person who prepared the statistical plan:	Department/Institution:	Date statistical review was conducted:

**Note: The statistician or individual that prepared the statistical plan must also be included on the study team if they meet the definition of key research personnel (ex: significantly involved in the study design, conduct, or reporting of the research).*

If a statistical review has not been submitted, explain why:

Example Text

10.9 Do you want to view the minimal risk exempt categories to determine if your research may qualify for exemption before completing the full application? Please note that determination of exemptions must be made by the IRB.

Your research may be Exempt from future IRB oversight if it only involves retrospective review of data (including Limited Data Sets), non-sensitive interviews or surveys, or falls into other minimal risk categories. If the research is determined to be exempt by the IRB, you will not be required to complete a full IRB application. If you complete the Exempt application and the IRB determines your research is not exempt, you will be required to complete the full IRB application.

○ Yes ○ No

11.0 Request for Exempt Determination

11.1 Basic Criteria for Eligibility for Exemption:

Are prisoners being targeted for inclusion or anticipated as a likely population in this research?

○ Yes ○ No

Is the research subject to FDA regulations (i.e., clinical investigation of drugs, devices, biologics, and other FDA-regulated products)?

○ Yes ○ No

11.2 Please select the exempt category(ies) that apply to your research under the Revised Common Rule, effective January 21, 2019.

☐ 1- Education: Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction.

Category 1 Additional Information Needed: Please select the correct statement pertaining to children in this research:

- ○ There WILL be subjects in this research younger than 18 years of age
- ○ There WILL NOT be subjects in this research younger than 18 years of age

☐ 2- Interactions: Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording)

Category 2 Additional Information Needed: Please select one regarding the identifiability of data being reviewed, collected, or stored:

- ○ Information obtained is recorded in such a manner that the identity of human subjects CAN NOT be identified, directly or through identifiers linked to the subjects
- ○ Information obtained is recorded in such a manner that human subjects CAN be identified, directly or through identifiers linked to the subjects

Category 2 Additional Information Needed: : Could any disclosure of the human subjects' responses outside the research reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement or reputation?

○ Yes ○ No

The IRB must conduct a detailed review of privacy and confidentiality protections to determine whether adequate protections are in place for the research to fall under this category. You are encouraged to select "NO" to the below question asking if all proposed research activities are encompassed within an exempt category since this study may not meet this exempt category. You will then proceed through the full Human Subjects Research application.

Category 2 Additional Information Needed: Please select the correct statement pertaining to children in this research:

- ○ There WILL be subjects in this research younger than 18 years of age
- ○ There WILL NOT be subjects in this research younger than 18 years of age

Category 2 Additional Information Needed: Please select the correct statement pertaining to children in this research.

- ○ The researchers WILL have interaction with the children (surveys, interviews)
- ○ The research is limited to educational tests and observation of public behavior where the investigator(s) will NOT participate in the activities being observed

Research under Revised Exempt Category 2 may not place minors at the above stated risks. Due to your selection, please select "NO" to the below question asking if all proposed research activities are encompassed within an exempt category. You will then proceed through the full Human Subjects Research application.

Research under Revised Exempt Category 2 may not involve researchers interaction with children or researchers participation in the activities being observed. Due to your selection, please select "NO" to the below question asking if all proposed research activities are encompassed within an exempt category. You will then proceed through the full Human Subjects Research application.

☐ 3- Behavioral Interventions: Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording

Category 3 Additional Information Needed: Will there be subjects in this research that are younger than 18 years of age?

○ Yes ○ No

Category 3 Additional Information Needed: Please select one regarding the identifiability of data being reviewed, collected, or stored:

○ Information obtained is recorded in such a manner that human subjects CAN be identified, directly or through identifiers linked to the subjects

○ Information obtained is recorded in such a manner that human subjects CAN NOT be identified, directly or through identifiers linked to the subjects

Category 3 Additional Information Needed: Could any disclosure of the human subjects' responses outside the research reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement or reputation?

○ Yes ○ No

The IRB must conduct a detailed review of privacy and confidentiality protections to determine whether adequate protections are in place for the research to fall under this category. You are encouraged to select "NO" to the below question asking if all proposed research activities are encompassed within an exempt category since this study may not meet this exempt category. If you do so, you will then proceed through the full Human Subjects Research application.

Category 3 Additional Information Needed: Will all subjects be able to and will prospectively agree to the intervention and information collection for this research?

○ Yes ○ No

Category 3 Additional Information Needed:

Please also see **Help** bubble/question mark to right for more information, including examples of studies that do and do not meet this criteria.

a. Will any and all behavioral interventions be brief in duration?

- **The term *behavioral intervention* is used in the language of the regulations to define research procedures that are employed in the study of psychological states and processes, cognition, ideas and attitudes, or behavior, and DO NOT include physical (bodily) tasks or physical manipulations (e.g., range of motion activities, physical exercise).**
- **To meet the requirement of brief in duration, the benign behavioral intervention should last a few minutes to a few hours. While it does not have to occur in a single session, the entire time for the intervention should occur on a single day and not exceed a few hours in its entirety.**

b. Will any and all behavioral interventions be harmless, painless, not physically invasive, and not likely to have a significant adverse lasting impact on the subjects?

- **The term *benign* describes an intervention that is not expected to cause physical or emotional harm, persistent discomfort, be experienced by the subject as embarrassing, or be offensive. Ordinary, mild, transient forms of discomfort,**

such as the stress associated with completing a timed cognitive task, anxiety about performance, and boredom, are consistent with the intent of the exemption.

- **Behavioral interventions are not physically invasive when they do not involve the introduction or administration of instruments, substances or energy onto or into the body.**

If "yes" to both questions a and b, be sure to explain how the research meets each of these criteria when describing the study procedures.

If the answer to either "a" or "b" above is "no", then the research does not meet this exempt category.

○ Yes ○ No

Category 3 Additional Information Needed: Does the investigator(s) have any reason to think or believe that the subjects will find the interventions offensive or embarrassing?

○ Yes ○ No

Research under Exempt Category 3 must meet certain regulatory requirements that your research does not meet. Due to your selection, please select "NO" to the below question asking if all proposed research activities are encompassed within an exempt category. You will then proceed through the full Human Subjects Research application.

☐ 4- Secondary Research Without Consent: Secondary research uses of identifiable private information or identifiable biospecimens

Category 4 Additional Information Needed: Please select at least one of the following.

☐ 4(i) -The identifiable private information or identifiable biospecimens are publicly available

☐ 4(ii) - Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects

☐ 4(iii) - The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b)

☐ 4(iv) - The research is conducted by or on behalf of a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated, ect

☐ None of the above

Category 4(iii) Additional Information Needed:

You have selected Exempt Category 4(iii). This category only applies if Carilion's patients' Protected Health Information (PHI) **will not** be shared outside of Carilion and **will not** be reviewed by external collaborators. This includes Virginia Tech, so if VT researchers, including VTCSOM medical students, are collaborating on this study and will have access to patients' PHI for any purposes, this category CANNNOT apply and you therefore must select "Yes" to this question. Does this study involve sharing PHI with external collaborators or allowing external collaborators to have access to Carilion's patients' PHI?

○ Yes ○ No

Research under Exempt Category 4 must meet certain regulatory requirements that your research does not meet. Due to your selection, please select "NO" to the below question asking if all

proposed research activities are encompassed within an exempt category. You will then proceed through the full Human Subjects Research application.

- [ ] 5- Federal Demonstration Projects: Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs

- [ ] 6- Taste and Food: The research involves taste and food quality evaluation and consumer acceptance studies where wholesome foods without additives are consumed, or food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S.D.A.

- [ ] None of the above categories apply

11.3 Do all of the proposed research activities appear to be encompassed within the above selected exempt categories and meet the required criteria in order to be encompassed in that category?

Select "NO" if you were informed that your research does not meet the criteria for exemption under any single category above.

○ Yes ○ No

Please answer the abbreviated exempt application questions below.

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

Provide a study schedule or describe the frequency and duration of research procedures, tests, specimen collection, and experiments, including screening, intervention, follow-up etc. If the research includes blinding, indicate whether 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.

Example Text

11.5 Describe the possible risks and likelihood of these risks to subjects, as well as minimization of the risks.

Please note that all research studies have some risk. Examples of risk may include: possible loss of confidentiality; emotional discomfort when providing personal information in surveys or interviews, etc.

Example Text

11.6 Describe the anticipated benefits of this research to the subject or for society.

Example Text

11.7 Will potential subjects be asked to provide informed consent?

Although the regulations do not require signed consent for exempt research, researchers have an ethical obligation under the Belmont Report to ensure that subjects are properly informed and voluntarily agree to participate in research whenever possible (e.g., the research involves interactions with subjects in person or through surveys or interviews). Please click on the Help bubble to the right for information about what should be included.

- [ ] Yes
- [ ] No, as there will be no interaction or intervention with the subjects

Describe the consent process, including whether the consent form will be signed by the participant, and include with the submission any materials that will be used to explain the research and/or document consent:

Example Text

11.8 Describe any measures that will be taken to ensure that subjects do not feel obligated or pressured to participate in the research.

Example Text

11.9 Describe any provisions that will be taken to protect the privacy of potential and actual subjects during the process of obtaining consent and other study activities.

Consider the settings where recruitment, observation, interaction, procedures, and/or interventions will occur. If subjects will be audio or video recorded, provide information about the recording.

Example Text

11.10 Describe compensation or non-monetary gifts that will be provide to subjects for their participation, or state none.

Example Text

11.11 Describe how subjects will be identified and recruited to participate in the research. If this is a chart review, describe how you will determine the appropriate patient charts to access and how you will extract the necessary information. Please provide the start and end dates of the charts that will be reviewed (e.g. procedures or encounters occurring between x and y). Please include the age range of the subject population and if the population includes any vulnerable populations.

Upload any materials that will be used to recruit subjects in the Initial Submission Packet.

Example Text

11.12 State the inclusion and exclusion criteria.

Example Text

11.13 Please select the data points that will be reviewed, collected, recorded, or created for research purposes, including screening or recruitment:

- ☐ 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/ 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

Will any of the above selected data points be reviewed, collected, recorded, or created from the subject's medical record (or other healthcare record)?

○ Yes ○ No

Provide justification for needing the above identifiers in order to conduct the research.

Example Text

11.14 Please state the specific identifiers from those selected above that will be recorded/documented within the research record.

Example Text

11.15 Could any data points that will be reviewed, collected, recorded, or created for research purposes be considered sensitive, including but not limited to:

- **Information about sexual attitudes, preferences, practices;**
- **Information about the use of alcohol, drugs, or other addictive products;**
- **Information that could damage an individual's financial standing, employability, or reputation within the community;**
- **Information in a subject's medical record that could lead to social stigmatization or discrimination; and/or**
- **Information about a subject's psychological well-being or mental health.**

○ Yes ○ No

11.16 Describe the sources of the identifiable data or PHI, including whether PHI is being obtained from any non-Carilion Clinic sources.

Example Text

11.17 If the sources of the PHI include any external (non-Carilion Clinic) entities, explain the steps you are taking to ensure compliance with the entities' HIPAA and data use requirements.

☐ N/A

Example Text

11.18 Describe the provisions that will be taken to protect the confidentiality of subjects' information and research data in order to protect it from improper use and disclosure.

In your description, be sure to include:

- *describe where this information will be stored and the security controls in place, including physical safeguards for paper records and technical safeguards for electronic records*
- *state whether the data will be shared outside of Carilion, and if so, methods for secure sharing and transfer of data outside of Carilion*
- *describe whether data will be aggregated/summarized in publications and presentations, or whether individual results will be communicated*

Example Text

11.19 Describe your plan to destroy identifiers at the earliest opportunity consistent with the conduct of the research (unless there is a health or research justification for retaining them or a legal requirement to do so).

Please note that any data involving PHI must be maintained for a minimum of 6 years, and data that does not contain PHI must be maintained for a minimum of 3 years. In many cases, identifiers will need to be retained after the research is completed (e.g., for publication or data verification purposes or because of contractual requirements or grant terms).

Example Text

11.20 Will you obtain written HIPAA authorization from subjects for use of their data or are you requesting a waiver of HIPAA authorization?

The requirement to obtain authorization, or a waiver of authorization, does not apply if your only use or exposure to PHI will be a Limited Data Set.

- ☐ N/A - Limited Data Set
- ☐ HIPAA authorization will be obtained from all subjects
- ☐ HIPAA authorization will be obtained from some subjects (e.g., prospective subjects

Please explain:

Example Text

- ☐ Waiver of Authorization: All subjects
- ☐ Waiver of Authorization: Some subjects (e.g., historical control)

Please explain:

Example Text

11.21 Describe why the research could not practicably be conducted without the waiver.

Example Text

11.22 Describe why the research could not practicably be conducted without access to and use of the PHI.

Example Text

12.0 Sharing of Research Data/Specimens

12.1 Describe the data or specimens to be transferred, transmitted, or shared and the purpose of sharing.

Example Text

12.2 Describe procedures for verifying that proposed use is consistent with the informed consent under which materials were collected.

Example Text

12.3 Categorize the identifiability of the data/specimens that will be shared.

- ○ Identifiable (data/specimens includes direct identifiers such as name, identifying elements of PHI, or that the type or nature of the information is such that the identify of individual subjects may readily be ascertained)
- ○ Linked/coded (a link exists from the specimen to the identifiable information)
- ○ De-Identified (The specimens/data CANNOT be linked back to the identifiable information or medical record by anyone)

12.4 Describe the information to be shared in detail, including which of the 18 HIPAA identifiers or other sensitive information will be shared, and justify the need to share identifiable data.

Describe who will maintain the link, if applicable.

Example Text

12.5 Who will data or specimens be sent to or shared with, including their name, title, and role on research?

Example Text

12.6 Describe how the data or specimens will be transferred, transmitted, or shared and how it will be protected in the new location.

Example Text

12.7 Who will be responsible for supervision of non- Carilion Clinic personnel to ensure the appropriate storage and security of the data/specimens, and that future proposed research has undergone IRB review?

Example Text

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

Please submit any signed agreements in the Initial Submission Packet.

Example Text

12.9 If the specimens being shared will be retained in a repository for possible future research, provide the protocol for the repository and the external investigator's IRB approval letter for the repository in the Initial Submission Packet.

Example Text

13.0 Applicable Regulations for ClinicalTrials.gov Registration

13.1 Is this study FDA-regulated?

○ Yes ○ No

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

○ Yes ○ No

13.3 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

13.5 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."

13.6 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.

14.0 Application Questions Complete

14.1 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.