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-23-1794

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

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:

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 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.

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.

Example Text

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

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

10.2 Does the research offer the prospect of direct benefits to the individual subjects?

○ Yes ○ No

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

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.

☐ 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)

☐ 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

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

☐ 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

Your research does not qualify for exemption. 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.

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

Since your research does not meet the criteria for exempt research, you will now be taken through the full IRB application.

If you still believe your research is exempt, you can contact the IRB to discuss, and the IRB will make a recommendation on how to proceed.

12.0 Subject Population

12.1 Please select the population(s) being targeted, or likely to be included in this research study. (select all that apply)

- ☐ Medical Chart Review of patients only (no in-person contact)
- ☐ Normal Adults/Healthy Volunteers
- ☐ In-Patient Population
- ☐ Out-Patient Population
- ☐ Patients in emergency situations
- ☐ Terminally ill patients
- ☐ Employees/Staff
- ☐ Students

Note: An investigator, research coordinator, or other member of the research team that does not have direct authority over the students or employees should obtain informed consent.

Describe the type of students: Example Text

- ☐ Children/Minors (anyone younger than 18 years of age in the state of Virginia. For research conducted outside of the state of Virginia, age of majority is dependent on state/local law)
- ☐ Prisoners
- ☐ Pregnant Women
- ☐ Fetuses
- ☐ Neonates of uncertain viability and/or nonviable neonates
- ☐ Adults with Impaired Decision-Making Capacity
- ☐ Persons with Limited-English proficiency (LEP) or Non-English Speakers
- ☐ Individuals of Childbearing Potential

Please contact the IRB immediately to discuss this research, as a Prisoner Representative must be involved in the review of this study.

12.2 Please indicate the total number of subjects anticipated to be enrolled at this site/by this investigator.

For the purposes of the IRB, a subject is enrolled once they have provided consent to participate, or for studies approved with a waiver of consent, once data has been collected on the subject.

Example Text

12.3 If the research involves multiple subject groups or cohorts at this site, provide the anticipated number of subjects in each of group or cohort (e.g., control/experimental, adults/children, etc.).

Example Text

12.4 Provide the age range for the proposed subject population (e.g., 0-5 years old):

Example Text

12.5 Specify the inclusion criteria for each of the subject groups to be included in the research.

If there are multiple different groups being recruited with different eligibility criteria, instead add an Eligibility Criteria checklist for each group as a supplemental document after you complete this application. Please make note of this in the Inclusion Criteria below.

Order	

Number	Criteria
	Enter Criteria Here

12.6 Specify the exclusion criteria for each of the subject groups to be included in the research.

If there are multiple different groups being recruited with different eligibility criteria, instead add an Eligibility Criteria checklist for each group as a supplemental document after you complete this application. Please make note of this in the Exclusion Criteria below.

Order Number	Criteria
	Enter Criteria Here

12.7 Is information being obtained about individuals other than the "target subjects" (such as a family member or colleague of the subject), making the other individuals "secondary subjects"?

○ Yes ○ No

12.8 What languages do you expect the subjects with Limited English Proficiency will be fluent in?

12.9 How will you ensure that subjects with Limited English Proficiency will understand the information provided to them and will be able to ask questions and communicate with the researchers during recruitment, the consent process, and throughout participation (i.e., plan for interpretation).

12.10 Will consent forms and other subject materials be translated?

NOTE: Cost alone is typically insufficient justification for not translating materials when recruitment of persons with LEP is anticipated.

○ Yes
○ Some, but not all materials
○ No

13.0 Research Involving Children as Subjects

13.1 What is the age range of the children in this research?

Enter Age Range Here

Note: Please click the question mark to the right for better understanding of Virginia's definition of minors and applicable legal requirements.

13.2 Do you anticipate enrolling any children who may be wards of the state (including foster children) or any other agency, institution, or entity?

Wards may not be enrolled without specific IRB approval.

○ Yes ○ No

13.3 Select the regulatory category(ies) that best represents the degree of risk and benefit to which the children in this study will be exposed.

☐	**Category 1: Research not involving greater than minimal risk. (46.404/50.51)** **Note: Permission from one parent is sufficient for research that falls under this category.**	Provide rationale for your assessment that this research is minimal risk: Example Text
☐	**Category 2: Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects. (46.405/50.52)** **Note: Permission from one parent is sufficient for research that falls under this category.**	Provide rationale for why/how: (a) The risk is justified by the anticipated benefit to the subjects: Example Text (b) The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches: Example Text
☐	**Category 3: Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition. (46.406/50.53)** **Note: Permission is required from both parents/legal guardians, unless one parent is deceased, unknown, incompetent, not reasonably available, or does not have legal responsibility for the custody of the child.**	Which intervention(s) or procedure(s) present more than minimal risk without offering the prospect of direct benefit to individual subjects: Example Text Provide rationale for why/how: (a) The risk of the intervention (s) or procedure(s) represents a minor increase over minimal risk: Example Text (b) The intervention(s) or procedure(s) presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations: Example Text (c) The intervention(s) or procedure(s) is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition: Example Text

☐	**Category 4: Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. (46.407/50. 54)** **Note: Parental permission is required from both parents/legal guardians, unless one parent is deceased, unknown, incompetent, not reasonably available, or does not have legal responsibility for the custody of the child.**	Provide justification for why this research should be approved: Example Text

If you selected more than one category above, such as when a protocol involves both an experimental and a control group, please specify which category you believe applies to which subject group, or state N/A.

13.4 How will you obtain parental permission from parents/legal guardians of child participants? Check all that apply.

Please note that parental permission cannot be waiver or altered for FDA-regulated research.

- ☐ Written consent document with signature(s) of parent(s)
- ☐ Waiver of documentation of parental permission (parental permission will be obtained through verbal confirmation from the parent(s) rather than through a signed document)
- ☐ Requesting waiver of parental permission, including when there is no intervention or interaction with children or their parents (ex: chart review only)
- ☐ Alteration of some of the elements of informed consent (such as in research involving deception)

13.7 Please indicate whether the children you intend to include in the research are generally capable of providing assent, taking into account the ages, maturity and psychological state of the children proposed to be involved.

The default age for if a child is capable of providing assent at Carilion is age 7 so if all subjects will be younger than 7 years, then the requirement for assent may be waived.

- ☐ All are capable
- ☐ None are capable
- ☐ Some are capable
- ☐ Requesting a Waiver of Assent as there is no intervention or interaction with children (ex: chart review only)

14.0 Research Involving Prisoners as Subjects

14.1 The individuals in the study include:

Please provide the name of the facility in the "Explain" box and contact information for the facility. A letter of permission from the facility must be uploaded as part of the Initial Submission Packet at the end of this application.

☐	Individuals involuntarily confined or detained in a penal institution.	Explain: Example Text
☐	Individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution.	Explain: Example Text
☐	Individuals detained pending arraignment, trial, or sentencing.	Explain: Example Text
☐	Other individuals involuntarily detained under a criminal or civil statute.	Explain: Example Text

14.2 Allowable Categories (46.305(a)(1))

Check the category below that best represents the nature of the research and the degree of risk and benefit to which the prisoners in this study will be exposed.

NOTE: The definition of minimal risk for prisoners is slightly different than the definition for other subjects. The definition of minimal risk for research involving prisoners is given in 46.303(d), is as follows:

Minimal risk is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

☐	Category 1 (46.306(a)(2)(i)): The study of the possible causes, effects, and processes of incarceration, and of criminal behavior, where the study presents no more than minimal risk and no more than inconvenience to the subjects.	Explain: Example Text
☐	Category 2 (46.306(a)(2)(ii)): The study of prisons as institutional structures or of prisoners as incarcerated persons, where the study presents no more than minimal risk and no more than inconvenience to the subjects.	Explain: Example Text

☐	Category 4 (46.306(a)(2)(iv)): The study of practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject.	Explain: Example Text Does the study in Category 4 involve a control group which will not receive a benefit from being in the study? ○ Yes. Additional procedures required for approval. Contact the Carilion Clinic IRB. ○ No
☐	Category 5 (46.305(a): The DHHS Secretarial waiver for certain epidemiological research conducted or supported by DHHS functions as a fifth **category of permissible research** [68 FR 36929]. The criteria for this category are that the research must have as its sole purpose (i) to describe the prevalence or incidence of a disease by identifying all cases, or (ii) to study potential risk factor associations for a disease.	○ Yes. If yes, the organization still must review the research under subpart C and certify to OHRP that an appropriately constituted IRB has reviewed the proposal and made all other required findings under DHHS regulations at 45 CFR 46.305(a) and receive OHRP authorization prior to initiating any research involving prisoners. All of the other requirements of subpart C apply to research in this category. ○ No

14.3 Additional Criteria

46.305(a)(2) - Are there any possible advantages accruing to the prisoner through his or her participation in the research that when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired?

○ Yes ○ No

46.305(a)(3) - Are the risks involved in the research commensurate with risks that would be accepted by non-prisoner volunteers?

○ Yes ○ No

46.305(a)(4) - Are the procedures for the selection of subjects within the prison fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners?

○ Yes ○ No

46.305(a)(5) - Is the information presented in language which is understandable to the subject population?

○ Yes ○ No

46.305(a)(6) - Does adequate assurance exist that the Parole Board will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole?

○ Yes ○ No

Explain: Example Text

46.305(a)(7) - If there may be a need for follow-up examination or care of subjects after the end of their participation, has adequate provision been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing subjects of this fact?

○ Yes
○ No
○ N/A

15.0 Research Involving Subjects with Impaired Decision Making or Otherwise Unable to Consent for Themselves

15.1 There are conditions that limit the use of Legally Authorized Representatives (LAR) in Virginia. By submitting this application with the request to obtain consent from LARs, the research team is acknowledging reading and understanding of the requirements described below.

Conditions limiting the use of LARs in Virginia:

- *A legally authorized representative may not consent or give permission unless the IRB has approved the use of a legally authorized representative. If written consent is required for the study, written consent must be obtained from the LAR.*
- *When obtaining consent from a legally authorized representative, the signature shall be witnessed.*
- *A legally authorized representative may not consent or give permission unless the subject has been determined to be incompetent to provide consent for themselves.*
- *A legally authorized representative may not consent or give permission to non-therapeutic research unless it is determined by the human research committee (IRB) that such non-therapeutic research will present no more than a minor increase over minimal risk to the human subject and*
    - *(i) the intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations; and*
    - *(ii) the intervention or procedure is likely to yield generalizable knowledge about the subject's disorder or condition, which is of vital importance for the understanding or amelioration of the subject's disorder or condition.*
- *A legally authorized representative may not consent or give permission to participation in human research on behalf of a prospective subject if the legally authorized representative knows, or upon reasonable inquiry ought to know, that any aspect of the human research study is contrary to the religious beliefs or basic values of the prospective subject, whether expressed orally or in writing.*
- *A legally authorized representative may not consent or give permission to participation in human research involving non-therapeutic sterilization, abortion, psychosurgery or admission for research purposes to a facility or hospital as defined by the Code of Virginia at § 37.1-1.*
- *If participation in the research is protested by the prospective subject. In the case of persons suffering from organic brain diseases causing progressive deterioration of cognition for which there is no known cure or medically accepted treatment, the implementation of experimental courses of therapeutic treatment to which a legally authorized representative has given informed consent shall not constitute the use of force.*
- *If two or more persons who qualify as legally authorized representatives and have equal decision-making priority under this chapter inform the principal investigator or attending physician that they disagree as to participation of the prospective subject in human research, the subject shall not be enrolled in the human research that is the subject of the consent.*
- *The Principal Investigator or designee shall certify in writing upon personal examination of the patient that the patient is incapable of making an informed decision regarding health care and shall obtain written certification from a capacity reviewer that, based upon a personal examination of the patient, the patient is incapable of making an informed decision. However, certification by a capacity reviewer shall not be required if the patient is unconscious or experiencing a profound impairment of consciousness due to trauma, stroke, or other acute physiological condition. The capacity reviewer providing*

written certification that a patient is incapable of making an informed decision, if required, shall not be otherwise currently involved in the treatment of the person assessed, unless an independent capacity reviewer is not reasonably available.

Please review HRP-021 Policy: Legally Authorized Representatives, Children, and Guardians.

- (•) The researchers acknowledge reading and understanding of the above information.

15.2 Describe the root causes or conditions that led to subjects having impaired capacity to provide informed consent for participation in this research (e.g., Alzheimer's, stroke, chemically induced, physical injury, etc.).

Example Text

15.3 Indicate the expected nature/duration of incapacity.

- ( ) Temporary
- ( ) Permanent
- ( ) Diminishing
- ( ) Fluctuating
- ( ) Other

15.4 Explain why this research could not be accomplished without including subjects with impaired decision-making capacity.

Example Text

15.5 Describe the procedures to be used to determine the individual subject's capacity to provide consent. Include the following:

- **Which research roles will conduct the capacity assessment;**
- **The method by which prospective subjects' decisional capacity will be evaluated. If a standardized decisional capacity instrument is to be used, submit a copy of the instrument tailored to the specific protocol;**
- **The criteria or cut-off score for identifying incapable subjects.**

Unless obvious (ex: person is unconscious), the decision-making capacity of individual subjects should not be assumed because of a condition or diagnosis. When at risk for impaired decision-making capacity or when capacity is in question, the capacity of individual subjects to provide consent for research should be determined through the use of a well-validated and standardized measure or evaluation by a qualified professional.

Example Text

15.6 When it has been determined that a subject lacks the capacity to provide consent, describe how it will be determined who may provide surrogate consent and how the surrogate's qualification to do so will be determined (i.e., who may serve as Legally Authorized Representative (LAR))?

Please review the Help text under the Help bubble to the right to learn more about the Commonwealth of Virginia's priority order for LARs. You may also review HRP-021 Policy: Legally Authorized Representatives, Children, and Guardians.

Example Text

15.7 Describe how the LAR's role and responsibilities as surrogate decision-maker will be explained.

For example:

- ***They will be asked to make the decision that they believe the subject would want***
- ***They or the participant have the ability to withdraw from the research at any time***
- ***They must understand the procedures and the investigator may evaluate their understanding and ability to fulfill their role.***

Example Text

15.8 If capacity may fluctuate or diminish over the course of the research, describe any plans and procedures to re-evaluate capacity.

Please include if the capacity of the participant will be assessed at each research visit, at established intervals, or when certain signs or symptoms emerge, etc.

Example Text

15.9 If capacity may be regained over the course of the research, describe any plans or procedures to explain the research and to obtain consent for ongoing participation.

Example Text

15.10 Will subjects with impaired decision-making capacity be asked to provide assent to participate if they have been determined to be unable to consent for themselves?

Please see help text within Help bubble to right for additional information about when assent should be obtained.

○ Yes ○ No

15.12 Describe any plans and procedures to obtain ongoing assent.

Ex: Will assent be established at each research visit of procedure, at established intervals, etc.

Example Text

16.0 Pregnant Individuals, Individuals of Childbearing Potential, Breastfeeding Infants, Fetuses, or Neonates

16.2 Are there any additional risks to pregnant individuals by participating in this study?

If your research involves fetuses or neonates, please contact the IRB prior to submission.

○ Yes ○ No

16.3 Are there any additional risks to individuals of childbearing potential, individuals who become pregnant, breastfeeding infant, or fetus or neonate by participating in this study?

☐ Yes ○ No

16.4 Describe the additional risks.

Example Text

16.5 Provide justification for including this population.

Example Text

16.6 Please provide the following information, as applicable:

- **For individuals of childbearing potential: How participants will be asked their current pregnancy status.**
- **For individuals of childbearing potential: The type and timing of pregnancy testing to be used.**
- **For individuals of childbearing potential: How participants will be informed that they should prevent pregnancy including use of adequate methods of birth control.**
- **For individuals of childbearing potential: Investigator's evaluation of the participant's willingness to, and reliability to practice effective birth control.**
- **For individuals of childbearing potential: Instructions for the participant if they suspect they may have become pregnant**
- **For individuals of childbearing potential: Plan in case a participant suspects pregnancy, or becomes pregnant (pregnancy testing, termination from the study, assistance with obstetrical follow up).**
- **For breastfeeding infant, fetus, or neonate if individual does become pregnant: Plan to monitor and minimize risk.**

Please address the following points if applicable:

- *In research where individuals of childbearing potential will have one or more MRI (magnetic resonance imaging) scan conducted solely for research purposes, special protections include informing the individual that they should not have the MRI scan unless they are certain they are not pregnant.*
- *In research on drugs where there is a concern about the female partners of male subjects receiving the drugs, special protections include provisions for informing males of the precautions they should take to prevent pregnancy in the individuals of childbearing potential.*

Example Text

16.7 Please provide the following information for pregnant individuals, as applicable:

- **How participants will be asked if they are pregnant, and how this will be confirmed, if applicable**
- **How participants will be informed of additional risks**
- **Plan to monitor and minimize risk.**
- **For breastfeeding infant, fetus, or neonate: Plan to monitor and minimize risk.**

Example Text

17.0 Informed Consent for Adult Subjects

17.1 How do you plan to obtain consent from ADULT subjects or their Legally Authorized Representative?

Check all that apply:

- ☐ Written consent document with signature (ie: obtaining signature from subject or Legally Authorized Representative)
- ☐ Waiver of written documentation of consent (ie: consent will be obtained through verbal confirmation from the subject or Legally Authorized Representative rather than through a signed document)
- ☐ Waiver of informed consent for minimal risk research (ie: typically appropriate only when the study does not involve any interaction or intervention with subjects)
- ☐ Waiver or alteration of the elements of informed consent (ie: research involving deception)
- ☐ Waiver of the informed consent document and process for PLANNED EMERGENCY RESEARCH. Contact the IRB before submission.
- ☐ No adults are being enrolled; this study is only enrolling children. (You will answer questions about the assent and parental permission process later.)

You must attach all consent forms, consent scripts, and information sheets in the Initial Submission Packet.

17.2 Is it expected that surrogate consent will need to be obtained from Legally Authorized Representatives (LARs) for some or all adult subjects?

○ Yes ○ No

17.3 If the research includes more than one subject group or you have selected multiple responses above due to the inclusion of multiple subject groups, please specify the requested consent method for each group, or state N/A.

Example Text

17.4 How will written consent be documented?

Click the Help bubble to the right for more information about requirements for eConsent before selecting this option.

Traditional signed written consent form on paper document

- [ ] eConsent: signed via an REDCap or other electronic or web-based form
- [ ] Short Form Method (for non-English speaking subjects only)
- [ ] Other

17.5 Describe the process of obtaining consent and documenting the process, including the following:

- **Circumstances under which consent will be obtained, including how the potential participant will first be approached;**
- **Where the consent process will take place (ex: in person in a private clinic room, over the phone, through WebEx, etc.);**
- **When the consent process will take place and how long participants will be given to decide;**
- **If eConsent is being utilized, describe how you will first contact the potential participants and provide the consent form to them to review;**
- **Steps that will be taken to ensure voluntary participant and to minimize the possibility of coercion or undue influence;**
- **Any cultural considerations (ex: tribal or group permission requirements, age of majority, technological implications, etc.);**
- **If any participants do not speak English, whether a translator with witness will be used, whether translated materials will be used, whether the consent process changes based on the language;**
- **If multiple participant groups or consent procedures are to be included, these need to be clearly delineated;**
- **how participants will be provided with a copy of their signed consent;**
- **Describe the method you will use to document the consent PROCESS within each participants' research record /medical record (state which). This should include a process note or checklist that will document all the components listed above, the start and end time of the discussion, and is in addition to the signed and dated consent form (if applicable).**

For example, describe it consent will take place in the research office, in a private conference room, in the doctor's office, in a group setting, over the phone, etc.

Example Text

17.6 How will you ensure that subjects or LARs have sufficient opportunity to consider whether or not to participate?

Check all that apply:

- [ ] Subjects will be provided the consent form to take home for consideration prior to signing.
- [ ] Subjects will be allowed a waiting period to consider their decision.
- [ ] Other

17.7 How will the subjects' or LARs understanding of the consent information presented be assessed?

Check all that apply:

- [ ] Subjects will be asked to "Teach-Back" the study to the researchers
- [ ] Subjects will be asked open-ended questions about the research (purpose, procedures, risks, alternatives, voluntary nature)
- [ ] A tool or post-consent assessment will be used
- [ ] Other

17.8 Utilizing eConsent has additional requirements. Please describe the following:

- **The method to verify the identity of the individual providing consent;**
- **How participants will sign the eConsent (ex: type their name, use stylus or finger to sign);**
- **If potential participants will sign the consent while having a virtual conversation or if they will have additional time to consider their participation;**
- **If use of LAR is being requested, how you will ensure this individual is an appropropriate LAR per Virginia requirements and verify their identity.**

Example Text

17.9 If the enrollment of subjects who cannot read the consent form, due to visual impairment, literacy, or other issues, is anticipated, how will consent be obtained and documented?

Refer to 45 CFR 46.117(b)(2) or 21 CFR 50.27(b)(2) for information regarding when the use of a short form is appropriate. A witness to the consent process is needed.

- ☐ N/A
- ☐ Short form
- ☐ Other mechanism
- ☐ Consent form read to participant with witness present

17.10 How will you ensure research participants remain informed about the study and continue to agree to participate in the research study after their initial informed consent has been obtained?

- ☐ N/A

18.0 Request for Waiver, Alteration, or Waiver of Documentation of Consent for Adult Participants

18.1 Select the type of Waiver of Informed Consent or Alteration of Informed Consent being requested.

- ○ Full Waiver – Informed Consent will not be sought from any subjects or for any research activities
- ○ Partial Waiver – Informed Consent will not be sought for some subjects (such as a historical cohort) or for some activities (such as for recruitment or screening)

18.2 General (46.116(d))
In order to waive the requirement for informed consent, the research must not be FDA-regulated and ALL of the following criteria must be met. If the waiver is only for recruitment or screening, justify the criteria for the waiver usage you are requesting.

☐	The research involves no more than minimal risk*. *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 explain: Example Text
☐	The waiver or alteration will not adversely affect the rights and welfare of the subjects.	Please explain: Example Text
☐	The research could not practicably be carried out without the requested waiver. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format.	Please explain: Example Text

☐	Whenever appropriate, the subjects will be provided with additional pertinent information after participation.	Please explain: Example Text

18.3 Explain which element(s) of consent you wish to alter or exclude and why.

Note: ***A listing of the required elements of consent is available in the help button.***

Example Text

18.4 In order for an IRB to grant an alteration of consent, ALL of the following criteria must be met:

☐	The research involves no more than minimal risk.	Please explain: Example Text
☐	The alteration will not adversely affect the rights and welfare of the subjects.	Please explain: Example Text
☐	The research could not be carried out without the requested alteration. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format.	Please explain: Example Text
☐	Whenever appropriate, the subjects will be provided with additional pertinent information after participation.	Please explain: Example Text

18.5 Select the type of Waiver of Written Informed Consent being requested.

- ○ Full Waiver of Written Consent; Verbal consent process is being requested for all subjects and for all research activities
- ○ Partial Waiver of Written Consent; Verbal consent process is being requested for only some subjects and/or for some research procedures (such as certain pre-study screening activities)

18.6 In order for the IRB to grant a Waiver of Documentation of Consent, one of the the following regulatory categories must apply:

Please select all applicable:

- ☐ The research presents no more than minimal risk AND involves only procedures that do not require written consent outside of the research context.
- ☐ The only record linking the subject and the research would be the consent document AND the principal risk would be potential harm resulting from a breach of confidentiality. Please note that each subject must be asked whether they want documentation linking them with the

research, and the their wishes will govern. This could be a signed consent document or a written notation in the research record by the investigator. (note: FDA regulated research does not meet this category)

☐ Subjects are members of a distinct cultural group or community in which signing forms is not the norm, the research involves no more than minimal risk, and there is an alternative method for documenting that consent was obtained

18.7 A written statement that embodies the elements of informed consent must be provided to the IRB for review. Please select how the subject will receive this written statement:

○ Subjects will be provided with a written statement describing the research

○ Subjects will not be provided with a written statement, but the investigator will read the written statement to the subject

○ Subjects will decide whether they want to receive the written statement or if the statement is read to them

NOTE: ***Copies of scripts, information sheets, survey introductions, videos, and other materials or aides should be included with your submission in the Initial Submission Packet. If your script, survey introduction, information sheet or other mechanism will not include all required elements of consent (see checklist at the end of this form), you also will need to request an alteration of consent (see question above, "Request for an Alteration of Consent").***

19.0 Privacy and Confidentiality

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

◉ Yes ○ No

19.3 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

19.4 Will any of the above data points be reviewed, collected, recorded, or created from the medical record (or other healthcare records)?

○ Yes ○ No

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

○ Yes ○ No

19.7 Will educational records protected under the Family Educational Rights and Privacy Act (FERPA) be accessed or used for the research?

○ Yes ○ No

19.8 Does the research involve the administration or use of surveys, interviews, or other evaluations or examinations protected under the Protection of Pupil Rights Amendment (PPRA)?

○ Yes ○ No

19.9 Will the research records (other than the consent form) and/or specimens contain data that is identifiable, coded, or de-identified?

☐ Identifiable (includes direct identifiers or information such that subject identities could be ascertained)

☐ Coded or linked (identifying information 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 anyone, including the Carilion investigator, either directly or indirectly through coding systems)

19.10 Where will research data be stored during the period the research is active? Describe the security controls in place, including physical safeguards for paper records and technical safeguards for electronic records

Storage options other than those listed below are NOT currently permitted, including the use of Carilion provided or personal laptops, flash drives or other portable devices, non-Carilion cloud or other hosted environment. Any exceptions to the list above must be approved by the Carilion Privacy and Information Security Officer and documentation provided to the IRB.

☐ Hardcopy data in a locked office in a locked cabinet

☐ Electronic data on a password protected, secure drive on a Carilion server (contact mmtenzer@carilionclinic.org to set up a shared drive)

☐ REDCap (contact mmtenzer@carilionclinic.org to discuss use of REDCap)

Sponsor's electronic data capture system

☐ SPARC Carilion Secure Research Environment (contact mmtenzer@carilionclinic.org to discuss)

Specify the software to be used:

Example Text

19.11 Provide any additional information pertaining to the storage and management of the research data.

Best research pratice is to have data management plan which will help you manage and protect your data, meet funder requirements, and help others use and protect your data, if shared. A well structured project can help protect the confidentiality of patient and participant data. Carefully planned data management also allows for a

better use of your time and resources. For guidance on data management pratices, please review the Harvard Catalyst document and upload your data management plan into the Supplemental documents.

Example Text

19.12 How long will research records, data, and specimens be retained following completion of the study? Where will study records will be retained when the study has been closed (long-term storage)?

Describe when and how the identifiers, if applicable, will be destroyed. If specimens will be retained, describe where.

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).

Please click the Help bubble to the right for more information on minimum storage requirements.

Example Text

19.13 Describe the structure of the code (e.g., randomly generated number, sequential number plus initials, etc.) and indicate whether a linking file (key) will be created and, if so, how it will be protected.

Example Text

19.14 Please state the specific identifiers that will be recorded/documented within the research records, including on specimens, and why they are needed.

Example Text

19.15 Who will have access to identifiers?

Example Text

19.16 How will access to the identifiers be protected?

Example Text

19.17 Describe whether data will be aggregated/summarized in publications or presentation, or whether individual participant results will be published/presented.

Example Text

19.18 Will research records include information that subjects or others might consider to be sensitive in nature?

E.g.,communicable disease status, substance abuse, mental health information, illegal behaviors, etc.

○ Yes ○ No

20.0 Sharing of Research Data/Specimens

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

Example Text

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

Example Text

20.3 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)

21.0 Research Settings/Performance Sites

21.1 Indicate the sites where research activities will occur, or from which subject data or specimens will be obtained, and a brief summary of the activities that will occur at each.

☐ N/A (Select this option if this research is a Medical/Chart Review ONLY)

	Site	Summary
☐	CRMH	
☐	CRCH	
☐	CNRVMC	
☐	CFMH	
☐	JCHS	
☐	CRMH Rehab	
☐	Riverside	
☐	Crystal Spring Medical Office Building	
☐	Other Carilion Clinic Physician's Office	
☐	Blue Ridge Cancer Care (BRCC) / US Oncology	
☐	Fralin Biomedical Research Institute at VTC	
☐	VT Blacksburg Campus	
☐	Assisted Living Facility or Nursing home	

☐	Other Locations (specify):	

21.2 Where is the international research to be conducted?

Describe the cultural norms in this setting with respect to research, individual autonomy, consent, age of majority, etc. Example Text Here

21.3 What are the investigator's qualifications to conduct research in this setting?

Will the investigator be collaborating with locals from the international setting (e.g., researchers, universities, community leaders, etc.)?

○ Yes ○ No

Will this research be reviewed by a local IRB or ethics committee?

○ Yes ○ No

22.0 Applicable Regulations for ClinicalTrials.gov Registration

22.1 Is this study FDA-regulated?

○ Yes ○ No

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

○ Yes ○ No

22.3 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

22.5 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."

22.6 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.

23.0 Study Procedures

23.1 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.
Example Text

23.2 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.

Example Text

23.3 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.

Example Text

23.4 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

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

Example Text

23.6 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

23.7 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)

Example Text

24.0 Research Involving Drugs or Biologics

24.1 Indicate the phase of drug trial.

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

24.2 Trade Drug Name:

View Details	Drug Name	FDA Approved	A new drug or a new use of an already approved drug:	IND Number
No drugs have been added to this Study				

24.3 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.

Example Text

25.0 Research Involving Device(s)

25.1 Device Name:

View Details	Device Name	Is the Device FDA Approved
No devices have been added to this Study		

25.2 Describe any credentialing procedures and training in the use of the device that will occur prior to use.

Example Text

25.3 Who will assume primary responsibility for the storage of the device used in this study?

Name:

Example Text

25.4 Describe storage and control of the device, including precautions being taken to minimize the chances of device use by health care providers not listed on this application.

(Ex: special ordering requirements, labeling, separate stocking, etc.).

Attach the PMA or cleared (510k) by FDA if used in accordance with labeling, or for investigational devices, attach sponsor/FDA risk assessment documentation if available in the Initial Submission Packet. Attach sponsor device manual of operations if available.

Example Text

26.0 Research Review of Data/Records

26.1 What types of records will be reviewed for this research study?

- ☐ Medical record/medical chart
- ☐ Films/x-rays
- ☐ Data in a database
- ☐ Hospital administrative/billing records
- ☐ Quality improvement records
- ☐ Publically available database
- ☐ Other

Provide a detailed description about your selection above, including if the records are already in existence at the time of this submission or if you will be accessing future records, and special permissions that may be needed to access the data/records:

Example Text

26.2 What is the original purpose of the data being reviewed?

- ☐ Clinical Care
- ☐ Collected as part of routine business activities
- ☐ Research Study
- ☐ Collected under Repository Protocol
- ☐ Other

26.3 If collected as part of a previous research study or repository protocol, enter the IRB number for the study.

Example Text

26.4 Is the data identifiable private information or Protected Health Information (PHI)?

○ Yes ○ No

27.0 Biospecimens Collection

27.1 Select type of biospecimen(s) to be collected.

- ☐ Blood
- ☐ Tissue
- ☐ Urine
- ☐ Stool
- ☐ Saliva
- ☐ Other

Please specify: Example Text

27.2 Please describe total amount of blood that will be collected for research purposes per blood draw, the total at each visit, and the total for the overall study. Please justify the blood volumes provided above.

Example Text

27.3 Please describe specimen collection process.

Include as applicable how the specimens will be collected, how many attempts will be made if venipuncture, who will collect them, how they will be transported, where they will be stored.

Example Text

28.0 Incidental Findings

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

◉ Yes ○ No

28.2 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

28.3 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.

Example Text

28.4 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).

Example Text

28.5 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.

Example Text

28.6 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.

Example Text

29.0 Imaging

29.1 Select the imaging procedures that will be completed for research purposes.

- ☐ X-ray
- ☐ CT scan
- ☐ Fluoroscopy
- ☐ Bone Density by X-ray Absorptiometry (DEXA)
- ☐ MRI/functional MRI
- ☐ Ultrasound
- ☐ Other

Please specify: Example Text

29.2 Provide a detailed description of the use of therapeutic or diagnostic radiation being administered for research purposes.

You may go to: https://vmw-oesoapps.duhs.duke.edu/radsafety/consents/irbcf_asp/default.asp for computation of Effective Dose Equivalent, and also a risk statement to be incorporated into the informed consent document.

If applicable, upload a Radiation Safety Approval letter to the Initial Submission Packet.

Example Text

30.0 Audio or Video Recording

30.1 Describe the type of recording that will be utilized and the uses of the recording(s), including educational or commercial purposes, transcription and/or analysis by the research team, etc.

Example Text

30.2 Describe the specific identifiers that will be recorded, e.g., partial facial features, full facial features, subject's name, other identifying information.

Example Text

30.3 Describe who will have access to the recordings and the mechanisms in place to protect the confidentiality of the person(s) being recorded.

Example Text

30.4 State when the recording(s) will be transcribed, and when they will be destroyed, or if the recording(s) will be kept indefinitely.

Example Text

30.5 State whether there will be any additional compensation to subjects for allowing themselves to be recorded.

Example Text

Please note that the informed consent document must include information that such recording will occur, and be include information about the storage, confidentiality, and future use of the resulting recordings, as well as when the recording will be destroyed.

31.0 Intervention or Procedures Involving Deception

31.1 Describe the information that will be withheld from subjects or misinformation that will be provided to subjects.

Example Text

31.2 Provide a justification for the deception.

Example Text

31.3 Describe the debriefing process for informing subjects after their participation or justify why a debriefing will not take place.

Example Text

31.4 Explain whether subjects will be able to disallow use of their data for research after debriefing, and if not, provide justification.

Example Text

Upload debriefing script in the Initial Submission Packet.
Example Text

32.0 Use of Internet

32.1 How is the internet being used in this research?

Check all that apply:

- ☐ Recruitment of subjects
- ☐ Administration of surveys
- ☐ Observation of Internet activity, including social media
- ☐ Data mining/harvesting/scraping
- ☐ Paying subjects to perform tasks via the Internet (e.g. Mechanical Turk)
- ☐ Mobile Health
- ☐ Other

32.2 List any websites or web-based tools that will be used for the research (please add a new row for each website/web-based tool).

Name of Website or Web-based Tool
List Sites here

32.3 Is the proposed research consistent with the Terms of Use or other standards or rules governing the use of the site(s) or tool (s)?

○ Yes ○ No

Please explain: Example Text

32.4 Will any measures be taken to authenticate subjects if the only interaction with them is over the internet?

○ Yes
○ No
○ N/A

Please explain: Example Text

32.5 Describe the proposed use(s) of the internet.

Example Text

32.6 Are subjects' identities known to or are subjects reasonably able to be identified by the researcher?

○ Yes ○ No

32.7 Will IP addresses, geolocation API, or other similar data be gathered that could be used or combined with other information to re-identify subjects?

○ Yes ○ No

Note: ***The default settings of many survey and other tools are set to gather IP addresses. Please verify the settings before sending your survey out to potential participants.***

32.8 Is online activity (e.g., chat rooms, Facebook, Twitter, Instagram, etc.) being observed and/or participated in for the research?

○ Yes ○ No

Example Text

33.0 Identification/Recruitment of Subjects

33.1 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.*
		Select all that apply: ☐ Treating clinicians will identify potentially eligible patients and obtain patient permission before

☐	Researchers who ARE NOT treating clinicians of potential subjects will ask treating clinicians for referrals of eligible patients interested in the study.	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:

33.2 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.

33.3 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)

33.4 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.***

Example Text

33.5 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

33.6 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.

Example Text

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

34.0 Risks and Risk Minimization and Benefits

34.1 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.

34.2 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.

Example Text

34.3 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

34.4 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

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

○ Yes ○ No

34.6 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

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

○ Yes ○ No

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

○ Yes ○ No

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

○ Yes ○ No

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

○ Yes ○ No

34.11 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

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

Example Text

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

Note: Compensation is not considered a benefit.

○ Yes ○ No

35.0 Costs and Compensation

35.1 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

35.2 Describe the costs/potential costs that subjects or their insurance may incur as a result of their participation, including the approximate cost of each.

Example Text

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

○ Yes ○ No

Explain the expenses that subjects will or may be reimbursed for (e.g., travel, parking, public transportation, etc.) and explain any potential limitations or qualifiers:

Example Text

Please describe when participants will be reimbursed (e.g. at each visit):

Example Text

35.4 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

Please ensure the following language is in the consent document:

Include if payment for the study will be less than $100 in the next calendar year: Payments made to you as compensation for your participation will be tracked by the research team. This information will be submitted to Carilion's financial department for central tracking. If you receive greater than $600 from Carilion in a calendar year, this is considered taxable compensation and will be reported to the Internal Revenue Service (IRS). You will be issued a 1099 tax form by Carilion if you meet this reporting threshold.

Include if payment for the study will be $100 or more in the next calendar year: In order to receive compensation for your participation, you will be asked to complete an Internal Revenue Service (IRS) W-9 form. Your social security number will be required to complete the IRS form. Compensation to study subjects greater than $600 in a calendar year is considered taxable compensation and is reportable to the Internal Revenue Service (IRS). Carilion will be required to provide your name, social security number, address, and amount of payment to the IRS. You will be issued a 1099 tax form by Carilion if you meet this reporting threshold. This information and your payment amount will be kept secure and confidential in our research financial records and Carilion's financial office. This information will not be associated with the study name or the research data you provide as a participant

35.5 Please describe the compensation.

Include the amount and method of payment, and the distribution plan for the payment (payment received at each visit, payment at end of study, completion bonus, etc.). If a non-monetary item will be provided, state the approximate retail value of the item, when subjects will receive the item, any conditions or requirements that must be fulfilled for subjects to receive the item(s), and a picture of or link to the item online, if possible.

Example Text

35.6 If the research involves children or adults unable to consent to participation, explain who will receive the monetary compensation or non-monetary item(s).

☐ N/A

36.0 Application Questions Complete

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

Date Completing Form:

Enter Date Completing 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.