**Carilion Clinic Institutional Review Board**

**IRB Research Application Instructions**

**NOTE: This is a protected document! Please do not remove protections.**

The Carilion Institutional Review Board (IRB) is a committee charged with protecting the rights and welfare of human subjects in research. You must submit this application and receive IRB approval if you wish to conduct human subjects research at Carilion Clinic, including the Jefferson College of Health Sciences, or if you will use Carilion patients or services as part of the research process. The entire application must be completed. If you are unsure if your research meets the definition of human subjects research, please first visit the IRB [website](https://www.carilionclinic.org/irb/process) for more information.

Research protocols may be reviewed at convened meetings of the IRB or through a single reviewer process involving the IRB Chair and staff. The type of review is determined by the nature of the project, the level of potential risk to research subjects, and the characteristics of the subject population. The final determination of the type of review applicable to a study is made by the IRB.

* **Full Board Reviews:** Greater than minimal risk research requires review at a convened meeting of the IRB. Research that involving vulnerable populations, experimental drugs or devices, invasive procedures, or deception (e.g., in behavioral research) may also require full board review. A schedule of IRB meetings and submission deadlines can be found on the [Carilion IRB website](https://www.carilionclinic.org/irb/meetings).

**Full Board submissions should be sent to Meredith Talmadge at** **mttalmadge@carilionclinic.org****. For further information, call 540-853-0728.**

* **Exempt and Expedited Reviews:** Exempt and Expedited studies involve no more than minimal risk to subjects. Federal regulations define minimal risk as the probability that the magnitude of harm or discomfort anticipated in the research are not greater in of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. The Carilion IRB must determine whether proposed studies meet the criteria for Expedited or Exempt review.

**Exempt and Expedited submissions should be sent to Janet McDowell at** **jdmcdowell@carilionclinic.org****. For further information, call 540-981-8015.**

**Signature pages may be sent electronically or faxed to (540) 985-5323. For further information call 853-0728.**

**Note: Consent Form and Information Sheets should be submitted in Word rather than in pdf, as IRB staff may need to make revisions and edits to these documents. The CV of the PI should be sent in a separate electronic document so that IRB staff can file them individually in our electronic filing system.**

**Please do not copy this page when submitting paper copies to the IRB office.**

**Carilion Clinic Institutional Review Board Application**

Registration With Department of Research & Development

**Per Institutional Policy, all IRB submissions must include the Research & Development (R&D) Authorization letter stating R&D has given you permission to submit to the IRB. Do you have your R&D Letter?**

[ ]  Yes (If yes, you MUST attach your R&D letter to this submission.)

[ ]  No (If no, do not submit this IRB application until you have your R&D letter. You may contact R&D at 540-985-8510 or go to <http://insidecarilion.org/hubs/office-sponsored-projects/rd-forms-0>.)

Financial conflict of interest Disclosure

**Per Institutional Policy, all research team members on a funded study must submit a study-specific Financial Disclosure form through the Carilion Organizational Integrity and Compliance Office. Please contact** **kecooper1@carilionclinic.org** **immediately to do so.**

\*Please note it is the PI’s responsibility to ensure all members of the research team have disclosed any financial or other relationships to the funding source.  Failure to do so may be considered serious noncompliance and result in study suspension or termination.

SECTION I: Application Data

**Date Completing Form:**

***(This date MUST be updated by you each time you make changes to this document to submit to the IRB)***

**Complete Title of Study:**

**Research Team** (All individuals participating in the conduct of research under the direction of the Carilion Principal Investigator, including investigators, coordinators, those obtaining consent, those accessing identifiable data, etc.\*. If you need additional entries, visit the IRB website [Forms page](https://www.carilionclinic.org/irb/forms).):

**Carilion Principal Investigator:** Credentials:

Department:

Inter-office address:

Mailing Address (if external):

Phone:       E-mail:       Fax:

**Other Investigator:**       Credentials:

Role & Responsibilities:

Phone:       E-mail:

**Other Investigator:**       Credentials:

Role & Responsibilities:

Phone:       E-mail:

**Study Coordinator:**       Credentials:

Role & Responsibilities:

Phone:       E-mail:

**Other Research Team Member:**       Credentials:

Role & Responsibilities:

Phone:       E-mail:

**Other Research Team Member:**       Credentials:

Role & Responsibilities:

Phone:       E-mail:

**Other Research Team Member:**       Credentials:

Role & Responsibilities:

Phone:       E-mail:

**Other Research Team Member:**       Credentials:

Role & Responsibilities:

Phone:       E-mail:

**\***If this research involves external collaborators: If non-Carilion affiliates will be obtaining IRB approval through their home institution, they should not be listed on this application. If you would like to request that one IRB to defer to another, please contact the IRB immediately to discuss the feasibility of this agreement.

**Note: All research team members must complete Carilion IRB education requirements before submitting this application.** Further information regarding education requirements can be found on the [Carilion IRB website](https://www.carilionclinic.org/institutional-review-board/required-education).

1. Has the Principal Investigator ever had any research suspended or terminated by an IRB?

[ ]  Yes [ ]  No

* + If yes, please explain:
1. Has any version of this research protocol ever been submitted to any other IRB?

[ ]  Yes [ ]  No

* + If yes, please attach a copy of all IRB correspondence

1. Has the Principal Investigator ever been convicted of a crime, disciplined by a public or private medical organization, disciplined by a licensing authority or is the Principal Investigator currently the subject of such a proceeding?

[ ]  Yes [ ]  No

* + If yes, please explain:

1. Have any of the other investigators or study team members ever been convicted of a crime, disciplined by a public or private medical organization, disciplined by a licensing authority, or are any currently the subject of such a proceeding?

[ ]  Yes [ ]  No

* + If yes, please explain:

1. **Location of Research**:
* Check the facility where research activities will take place (please check all that apply):

[ ]  CRMH [ ]  CNRVMC [ ]  JCHS [ ]  CC Physician’s Office

[ ]  CRCH [ ]  CFMH [ ]  CRMH Rehab [ ]  Other:

* List all departments within the facility where research activities will take place:
1. **Collaboration:**
* Will this research involve collaboration with another institution? [ ]  Yes [ ]  No
* If yes, name the institution(s):
* If yes, will the collaborating institution’s IRB also review the study? [ ]  Yes [ ]  No

Note: If the collaborating institution’s IRB has already approved the study, please submit their approval letter with this application.

1. **Sponsor:**
* Will this research be sponsored by an institution/entity outside of Carilion? [ ]  Yes [ ]  No
* If yes, name the institution/entity:
1. **Funding Source**: If this study is or will be funded, every research team member MUST submit a study-specific Financial Disclosure form through the Carilion Organizational Integrity and Compliance Office immediately. Please contact kecooper1@carilionclinic.org to do so. The IRB application cannot be approved until it is determined that there is not conflict, or that the conflict has been disclosed and managed.

[ ]  Carilion RAP grant

[ ]  Federal/state agency (specify):

[ ]  Other grant (specify):

[ ]  Industry/commercial (specify):

[ ]  Private, non-profit (specify):

[ ]  No funding; equipment, supplies, and/or services will be provided (specify company):

[ ]  No funding; no equipment, supplies, and/or services will be provided

[ ]  Other (specify):

1. Is this the official project of a VTCSOM medical student as required for graduation and has already undergone scientific review by VTCSOM?

[ ]  Yes [ ]  No

1. Anticipated Start Date:
2. Estimated Time Needed to Complete Study:

SECTION II: Drug, Device and Biologic Studies Only [ ]  N/A

1. What is the name(s) of the drug, device or biologic that will be used in this study:
2. Please attach documentation to confirm FDA approval of this drug, device or biologic. Check one below:

[ ]  Package Insert

[ ]  Printed Information from the FDA website confirming FDA approval

[ ]  Letter from FDA granting approval

[ ]  Not available; FDA has not approved

1. Does the research study involve an Investigational New Drug (IND) or Biologic? An IND number is required if a drug or biologic is used in a manner outside the labeling approved by the FDA.

[ ]  Yes [ ]  No

* If yes, please provide the IND number assigned by the FDA. If an IND number is not available please explain why an IND was not obtained. If you believe the drug is exempt from IND approval, please submit an IND Determination form that can be found on the IRB web site. Note: Investigators may be asked to have an IND determination application submitted to the FDA.

1. Does the research involve a device that is being used outside the labeling approved by the FDA?

[ ]  Yes [ ]  No

If yes:

* Please provide the Investigation Device Exemption (IDE) number provided by the FDA:
* Attach one of the following:

[ ]  FDA letter granting an IDE

[ ]  A letter from the sponsor or investigator/sponsor stating the study device is non-significant risk

[ ]  A letter explaining why the investigation is exempt from IDE requirements

1. Does this study meet the definition of an Applicable Clinical Trial (ACT) that requires registration on ClinicalTrials.gov? Whether yes or no, please complete the ACT Checklist and submit page 1 with your IRB application.

[ ]  Yes [ ]  No

SECTION III: Study protocol

1. **Study Abstract:** Provide a brief, non-technical summary of the study, including study purpose and methods.

1. **Background:** Summarize background information about the research question(s.) Tell why the research is needed and include the relevance of this research to the contribution of this field of study. Also, provide references to relevant articles in the literature. (If you have more than 10 references, please submit the list of references as a separate attachment. Otherwise, please insert them here.)

1. **Objectives:** 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.

1. **Study Design:** Give a description of the research design including use of placebo, randomization and an explanation of what is experimental. Include type of study: descriptive, retrospective, cross-sectional, longitudinal, prospective observational, pilot, experimental (controlled or non-controlled) or pilot.

1. **Study Population:** Describe the subject population, including age, gender, ethnic characteristics and health status. State the inclusion/exclusion criteria along with how this was determined, and by whom. Please state whether pregnant women, children, or other vulnerable groups will be included or excluded. Provide rationale for using or excluding special populations. State the number of subjects or subject records necessary to complete the research.

1. **Methodology:** List all activities or procedures that will be performed (pre-treatment tests and medications, tests and medications used during therapy, diagnostic tests, x-rays, lab tests, questionnaires and other forms, interviews, chart reviews etc.) Describe how, when and where research activities will be administered and analyzed. **Distinguish any standard processes from those that are research.** Please describe activities/procedures in a 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.

1. **Data Collection:** Describe below the data collection methods and how data be compiled for assessment. Attach a copy of your data collection tool or spreadsheet listing exactly what data is to be gathered during this research study. If all data is retrospective, please state date range from which data will be collected and note that data must be in existence at time of submission of this application.

1. **Statistical Analysis:** State how qualitative and/or quantitative data will be analyzed. This must include a statement from a statistician that there is sufficient power to determine the primary study outcome or objective. Other outcomes may be listed as secondary and descriptive. If this is a proof of concept or feasibility study that includes limited efficacy testing, there must be a statistician statement that the appropriate design is in place to determine whether an intervention should be recommended for broader efficacy testing. If a study is meant to be solely descriptive, then results apply only to the sample being studied and conclusions cannot be drawn about the larger population; therefore, the primary outcome or objective must be limited in scope.

Statistical review was conducted by:  (name of statistician)

  (Department/Institution of statistician)

If no statistical review was done, explain why:

SECTION IV: Risks and Benefits

1. Summarize the possible risks to subjects and how they have been minimized in the study design. Include risk of psychosocial harm (e.g., emotional distress, embarrassment, breach of confidentiality), economic harm (e.g., loss of employment or insurability, loss of professional standing or reputation, loss of standing within the community) and legal jeopardy (e.g., disclosure of illegal activity or negligence), as well as known side effects of study medication, if applicable, and risk of pain and physical injury. Define the level of risk (minimal risk, risk but with potential benefit to patient, risk but no benefit to patient). Describe any procedures that will be used to prevent or minimize risks or discomforts. Note: Most studies create at least a small risk of breach of confidentiality or privacy.

1. Describe all costs, if any, subjects may incur as a result of being in this study.

1. Describe how subjects will be compensated for injury incurred as a result of being in the study.

1. Is any deception used in the study or any aspect of the study kept secret from the subjects, such as the full purpose of the study?

[ ]  Yes [ ]  No

* If yes, describe the deception involved and the debriefing procedures:
1. Describe any direct benefit to individual subjects, to the group of individuals with the disease process you are researching, and/or to society based on scientific knowledge gained. Explain how the potential benefits offered by this research outweigh the risks. (Please note: payments, gifts, or other free services given as a token for participation are not benefits, but instead are classified as compensation.)

SECTION V: Recruitment

1. Number of Subjects/Enrollment Goal. The enrollment goal must match the number of subjects needed to meet the primary outcome. If this is a retrospective record review, this figure is the number of records that will be used for analysis. Prior IRB approval must be given to exceed the enrollment goal.

Locally:  At all Sites:

**\*\*\*If this study is a retrospective record review only, you may skip to Section VII\*\*\***

1. Will subjects receive any compensation or gifts to participate?

[ ]  Yes [ ]  No [ ]  N/A

* If yes, specify payment amount, how it will be prorated and how payment will be made:
1. Will you, the sponsor, or Contract Research Organization offer any fee to physicians for the referral of potential subjects?

[ ]  Yes [ ]  No

1. Will recruitment materials be used?

[ ]  Yes [ ]  No

If yes, check all that apply and include with this submission:

[ ]  Brochure [ ]  Radio/Television script

[ ]  E-mail [ ]  Newspaper Ad

[ ]  Recruitment letter [ ]  Website advertisement (including Facebook, Craigslist, etc.)

[ ]  Flyer/Poster [ ]  Telephone or in-person script

[ ]  Clinical trial website posting [ ]  Other (please specify):

**STEP 1: IDENTIFICATION OF POTENTIAL SUBJECTS**

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

1. How do you plan to identify potential subjects? (check all that apply)

[ ]  Medical Chart Review, Clinic Schedule Review, or QA-QI Database Review (own patient population)

 \**Study team requests Waiver of Informed Consent and, if any HIPAA identifiers are collected, a Waiver of*

 *HIPAA Authorization for recruitment purposes*

[ ]  Medical Chart Review, Clinic Schedule Review, or QA-QI Database Review (other physicians/practices patient population)

 *\*Study team requests Waiver of Informed Consent/HIPAA Authorization for recruitment purposes*

[ ]  Potential subjects will not be directly identified by the researchers. The potential subject will obtain IRB- approved written information about the study from his or her health care provider/faculty or from an advertisement, flyer, brochure, website, etc. The potential subject would then contact the researcher if he or she is interested.

[ ]  Researchers who ARE NOT treating clinicians of potential subjects will ask treating clinicians for referrals of eligible patients interested in the study. Treating clinicians identify potentially eligible patients and provide researchers with patient contact information with patient permission documented (e.g. email/letter to researcher from treating clinician states patient permission given. Researcher documents permission in research record.)

 *\*Study team requests Waiver of Informed Consent/HIPAA Authorization for recruitment purposes*

[ ]  Contact information will be provided by a patient’s Carilion health care provider without the patient’s knowledge to the researchers AND this is a minimal risk study that does not involve investigative drugs, devices, biologics or medical or surgical procedures.

 *\*Study team requests Waiver of Informed Consent /HIPAA Authorization for recruitment purposes*

[ ]  Review of Registry/Database in which individuals have previously signed a consent giving their permission to be contacted for future studies

[ ]  Student Records

 *\*Study team requests Waiver of Informed Consent for recruitment purposes*

[ ]  Other – please explain:

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

1. Who will conduct the identification process?

[ ]  Principal investigator

[ ]  Other investigator (specify):

[ ]  Research coordinator (specify):

[ ]  Other research team member (specify):

**STEP 2: CONTACTING OF POTENTIAL SUBJECTS**

*To “contact” a potential subject refers to the initial contact method you plan to use to reach a potential subject to determine if he or she would be interested in taking part in your study.*

1. How will potential subjects be contacted? (please check all that apply)

[ ]  Direct in-person contact

[ ]  Telephone call

[ ]  Letter

[ ]  E-mail

[ ]  Potential subject will not be contacted. Potential subject will contact the researchers by responding to a flyer, brochure, e-mail, etc.) **(Please skip to #39.)**

1. Who will contact the potential subject? (please check all that apply and ensure they are listed as a member of the study team)

[ ]  Principal investigator

[ ]  Other investigator (specify names):

[ ]  Research coordinator (specify names):

[ ]  Other research team member (specify names):

1. If potential subjects are patients of Carilion Clinic, please check the appropriate scenario:

[ ]  **Patients will be contacted by the researcher who is also the treating clinician** or by a member of his/her treatment personnel or by his/her Carilion research personnel. Potential subjects will be

 assured that their decision will not affect their treatment or care or relationship with the treating clinician.

 *\*Submit letter, email, or phone script (if applicable) using appropriate IRB template.*

[ ]  **Patients will be contacted by their treating clinician who is not the researcher** by letter with information about the research study. *\* Submit letter using appropriate IRB template.*

 *Check all that apply:*

[ ]  The letter will be co-signed by the principal investigator and sent by the research team.

 *\*Study team requests Waiver of Informed Consent/HIPAA Authorization for recruitment purposes*

[ ]  The letter will indicate that the patient will be called by researchers to discuss study. The letter will include a telephone number to call or post card to return to indicate patient does not want to be contacted. *\*Submit phone recruitment script.*

[ ]  The research involves the collection of sensitive information (e.g. illegal behavior, drug, or alcohol use; mental illness; sexual behavior.) The letter will include a telephone number to call or post card to return if patient is interested in learning more. Patient will not be contacted until he/she calls or returns post card.

[ ]  **Researchers who ARE NOT treating clinicians of patients will contact patients**:

[ ]  after patients have given permission to a treating clinician to share contact information with the research team and permission is documented

[ ]  without the patients’ prior permission AND this is a minimal risk study that does not involve investigative drugs, biologics or surgical procedures. *Check one:*

[ ]  **Contact will be via letter, phone, direct-email. \**Submit letter, email, phone script using the appropriate IRB template.***

[ ]  **Potential subjects will be approached in person while at a Carilion Clinic hospital or clinic.**

 **\**Submit recruitment script using the appropriate IRB template.***

1. Describe what will be said to potential subjects to introduce them to the research. If an investigator has direct authority over potential subjects who are students, medical residents or employees, then explain how recruitment will avoid undue influence. For example, someone from the research team who does not have direct authority will make the initial contact OR potential subjects will be assured a decision not to participate in the research will not affect grades or job evaluations. Submit any letter, email, phone or other recruitment script that will be used.

**STEP 3: SCREENING OF POTENTIAL SUBJECTS**

*To “screen” a potential subject refers to additional information that will be collected or activities that will take place after he or she has been identified and contacted and prior to obtaining informed consent for the study. This could include asking questions to a potential subject to determine whether he or she meets eligibility criteria. Note: To comply with HIPAA regulations, only the minimum necessary protected health information may be collected at this time. This means only questions relating to the inclusion and exclusion criteria may be asked.*

1. Please describe the screening process for your study. Please include whether you plan to ask potential subjects to do anything or answer questions prior to signing an informed consent document. 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.

[ ]  N/A **(If N/A, please skip to Section VI)**

1. Who will conduct the screening?

[ ]  Principal investigator

[ ]  Other investigator (specify):

[ ]  Research coordinator (specify):

[ ]  Other research team member (specify):

1. List all information you plan to record during the screening process. (Attach screening data collection tool or an inclusion/exclusion checklist.) \**Study team requests Waiver of Informed Consent and, if any HIPAA identifiers are collected, a Waiver of HIPAA Authorization for recruitment purposes.*

SECTION VI: Study Populations

1. Does the research involve intervention or interaction with individuals? (Examples include physical procedures, written or verbal communication with individuals, or surveys.)

[ ]  Yes [ ]  No

**\*\*\*If no, you may skip the remainder of this section and go directly to Section VII\*\*\***

1. Which vulnerable populations may be included in this study? Check all that apply:

[ ]  Children/Minors (less than 18 years old)

[ ]  Wards of State

[ ]  Pregnant women

[ ]  Fetuses

[ ]  Neonates of uncertain viability OR non-viable neonates

[ ]  Prisoners (Please contact IRB prior to submission of application.)

[ ]  Mentally disabled persons\*

[ ]  Cognitively impaired persons\*

[ ]  Limited or non-readers

[ ]  Non-English speakers (You must use either a translated consent form or short form. Contact IRB office.)

[ ]  Economically disadvantaged persons

[ ]  Educationally disadvantaged persons

[ ]  Employees under the investigator’s supervision or authority

[ ]  Students under the investigator’s supervision or authority

[ ]  Patients in emergency situations

[ ]  Terminally ill patients

[ ]  Others that may be vulnerable to coercion:

*\*If persons are without decision making capacity, please submit a Legally Authorized Representative Investigator Assurance Form. This form is located on the IRB website.*

1. If persons in any of the vulnerable groups checked above will be enrolled into this study, please explain the additional safeguards that will be used to protect the rights and welfare of those subjects. Check all that apply:

[ ]  For economically disadvantaged subjects, there will be no financial screening of potential subjects and any eligible patient will be allowed to enroll regardless of financial standing or insurance status.

[ ]  For educationally disadvantaged subjects, additional time will be spent with them to ensure their understanding of the research participation by answering questions and clarifying any issues. The consent form will be read to them if necessary.

[ ]  For limited or non-readers, the consent will be read to them and additional time will be spent with them to ensure their understanding of the research participation by answering questions and clarifying any issues. This process and the subject’s signature will be witnessed by someone who is not part of the research team.

[ ]  For students, medical residents, or employees under investigator’s authority, an investigator, research coordinator, or other member of the research team that does not have direct authority over the students or employees will obtain informed consent.

[ ]  Other (specify):

1. If this research does not exclude children, please assess the level of risk involved (check only one):

[ ]  N/A

[ ]  Minimal risk (no greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations)

[ ]  Greater than minimal risk but has potential benefit

[ ]  Greater than minimal risk but no foreseen benefit

1. For research involving children, will an assent form be used? Assent is not required if the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the child and is available only in the context of research. Please note: if the child is <7 years of age, a discussion is not required.

[ ]  Yes [ ]  No [ ]  N/A

1. Do you request a waiver of assent?

[ ]  Yes [ ]  No [ ]  N/A

If yes, please justify:

1. Does the research exclude pregnant women? [ ]  Yes [ ]  No

**If you marked No above, then please affirm the following by marking each box:**

[ ]  Preclinical studies and clinical studies have been conducted and provide data for assessing potential risks to pregnant women and fetuses, **or** it is not scientifically appropriate to do this.

[ ]  The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman and/or fetus; **or,** if there is no such prospect of benefit, the risk to the fetus is minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means.

[ ]  Any risk is the least possible for achieving the objectives of the research.

[ ]  The research holds out the prospect of direct benefit to the pregnant woman and/or fetus, **or** no benefit for the woman nor fetus **and** risk to the fetus is minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means.

[ ]  Each individual providing consent will be fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate.

[ ]  No inducements, monetary or otherwise, will be offered to terminate a pregnancy.

[ ]  Individuals engaged in the research will have no part in any decisions as to the timing, method or procedures used to terminate a pregnancy.

[ ]  Individuals engaged in the research will have no part in determining the viability of a neonate.

**Please affirm the following by marking each box if they apply to your research**:

[ ]  If the research holds out the prospect of direct benefit solely to the fetus, then the consent of the pregnant woman and the father will be obtained (father’s consent need not be obtained if he is unavailable, incompetent, or temporarily incapacitated; or the pregnancy resulted from rape or incest).

[ ]  For children who are pregnant, assent and permission will be obtained.

1. If you plan to enroll subjects that may be cognitively impaired, describe how you plan to assess decision making capacity prior to consent:
* Will consent be obtained from a surrogate decision-maker for incompetent subjects?

[ ]  Yes [ ]  No

|  |
| --- |
| SECTION VII: Informed Consent |

For guidance on required elements for a Carilion informed consent document, please visit the [Carilion IRB website](https://www.carilionclinic.org/irb/policies); see New Submissions, Section 2, Informed Consent Guidelines.

1. Are you planning to obtain written (signed) informed consent from subjects for this research?

[ ]  Yes, I am planning to obtain consent and signature using a consent form **(If yes, please skip to #54)**

[ ]  No, I am planning to obtain consent without a signature using an information sheet **(Please go to #53)**

[ ]  No, I am planning to obtain only verbal consent **(Please go to #53)**

[ ]  No, I am requesting a Waiver of Informed Consent **(Please skip to #61)**

**Waiver of the Requirement to Obtain Signed Consent**

1. Please answer the following questions to request a Waiver of the Requirement to Obtain Signed Consent:
	* Is the informed consent document the only record linking the subject and the research, and is the principal risk the potential harm resulting from a breach of confidentiality?

[ ]  Yes [ ]  No

If yes, you must ask the participant if they want documentation linking them to the research, and the subject’s wishes shall govern.

* + Does the research involve greater than minimal risk or any procedure for which written consent is normally required outside of the research context?

[ ]  Yes [ ]  No

* Will you provide the subject with a written statement regarding the research?

[ ]  Yes [ ]  No

* Are the subjects or their legally authorized representatives members of a distinct cultural group or community in which signing forms is not the norm, and is there is an appropriate alternative mechanism for documenting that informed consent was obtained?

[ ]  Yes [ ]  No

1. Describe the process of obtaining informed consent, parental permission, and/or assent from the subject in detail (ex: who, when, where, how), and how this process will be documented.

1. Who will conduct the consent discussion with the subject? (Check all that apply):

[ ]  Principal investigator

[ ]  Other investigator (specify):

[ ]  Research coordinator (specify):

[ ]  Other research team member (specify):

[ ]  For Survey Studies only: Information sheet will be mailed and no discussion will take place

1. Will a student (VTCSOM, Jefferson College, other college or university) be obtaining consent from subjects? (This does not include questionnaire or survey studies.)

[ ]  Yes [ ]  No

If yes, then the Principal Investigator must sign an attestation of training at the end of this form.

1. Where will informed consent process take place:

[ ]  In a private room

[ ]  In a waiting room

[ ]  In an open ward

[ ]  In a group setting (Group consent is allowed only in special situations. Explain process):

[ ]  At potential subject’s residence

[ ]  In emergency situations (Explain process):

[ ]  Online (Explain process):

[ ]  Over the phone (Phone consent is allowed only in special situations. Explain process):

[ ]  Other (specify):

1. How will you assure there is sufficient opportunity for the subject to consider whether to take part? Check all that apply:

[ ]  Subjects will be allowed to take home unsigned consent form for consideration prior to signing it

[ ]  Subjects will be allowed a waiting period of  hours to consider their decision

[ ]  Other (specify):

1. What questions will be asked to assess the subjects’ understanding of informed consent? Check all that apply:

[ ]  What is the purpose of this research?

[ ]  What are the risks and benefits of being in this study?

[ ]  How is being in this study different from ordinary treatment?

[ ]  How long will you be in this study?

[ ]  Other (specify):

1. Please use Carilion IRB Informed Consent Templates located on our website. How will you assure the consent form or information sheet is written at a level that can be understood by the research subjects?

[ ]  Determine grade level and reading ease by using spelling and grammar function in Microsoft Word

 Provide Scores Here:

[ ]  Use another readability formula or index (specify type used and results here):

 Note: Consent Forms with difficult reading scores may be returned for editing and may delay IRB review

**\*\*\*If you are not requesting a Waiver of Consent for any participants, you may skip the remainder of this section and go directly to Section VIII\*\*\***

**Waiver of Informed Consent**

1. Does the research involve more than minimal risk (no greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations) to subjects or to their privacy?

[ ]  Yes [ ]  No

1. If the research involves using identifiable private information or identifiable biospecimens, could the research be carried out without using such information or biospecimens in an identifiable format?

[ ]  Yes [ ]  No [ ]  N/A (no identifiable data or specimens being used)

If no, please describe why identifiers are necessary to answer the research question:

1. Will the waiver adversely affect the rights and welfare of the subjects?

[ ]  Yes [ ]  No

1. Please check the appropriate option below describing why obtaining consent is impracticable. Note, by choosing any option in this category, you confirm that data will not include psychotherapy notes and that the study is not subject to FDA research regulations.
* This study is a retrospective medical record review and/or retrospective review of specimens collected for purposes other than this research. Obtaining informed consent is impracticable because of the large number of records and/or specimens involved. Note: If data/specimens are sought from a small group of patients, obtaining consent may be considered practicable even it is inconvenient.

[ ]  Yes [ ]  No

* Obtaining informed consent is impracticable because the sample size is so large (e.g. population-base studies or epidemiology trials) that including only those samples/records/data for which consent can be obtained would prohibit conclusions to be drawn or bias the sample such that conclusions would be skewed.

[ ]  Yes [ ]  No

* Obtaining informed consent is impracticable because the research is looking at issues such as outcomes/morbidity data where not having access to data from all subjects would affect the statistical outcome of the study.

[ ]  Yes [ ]  No

* Other reason obtaining informed consent is impracticable:
1. Will the research yield information of direct clinical relevance for the subjects?

[ ]  Yes [ ]  No

1. Will subjects or their Legally Authorized Representative be provided with additional pertinent information after participation?

[ ]  Yes [ ]  No

SECTION VIII: HIPAA for Protected Health Information (PHI)

1. Will this study require the creation, use, access, or disclosure of a Carilion Clinic patient’s Protected Health Information (PHI), including access their medical record for screening or recruitment?

[ ]  Yes [ ]  No **(If no, please skip to #69)**

1. Please check whether these items will be collected, recorded, or created from a Carilion healthcare record:
* name [ ]  Yes [ ]  No
* a geographic subdivision smaller than state except for the first

three digits of the zip code [ ]  Yes [ ]  No

* 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 [ ]  Yes [ ]  No

* telephone numbers [ ]  Yes [ ]  No
* fax numbers [ ]  Yes [ ]  No
* electronic mail address [ ]  Yes [ ]  No
* social security number [ ]  Yes [ ]  No
* medical record number/ master patient index (MPI) [ ]  Yes [ ]  No
* health plan beneficiary numbers [ ]  Yes [ ]  No
* account numbers [ ]  Yes [ ]  No
* hospital account receivable (HAR)/contact serial number (CSN) [ ]  Yes [ ]  No
* certificate/license numbers [ ]  Yes [ ]  No
* vehicle identifiers, including license plate number [ ]  Yes [ ]  No
* device identifiers and serial numbers [ ]  Yes [ ]  No
* Web Universal Resource Locators (URLs) [ ]  Yes [ ]  No
* Internet Protocol (IP) address numbers [ ]  Yes [ ]  No
* biometric identifiers, including finger and voice prints [ ]  Yes [ ]  No
* full face photographic images and any comparable image [ ]  Yes [ ]  No
* any other unique identifying number, characteristic, code [ ]  Yes [ ]  No
1. Do you plan to collect or record individually identifiable health information about subjects from a healthcare record at any other non-Carilion healthcare provider, health plan (e.g. insurer), employer, or healthcare clearinghouse (e.g. billing service) at any point in the project? (See list of identifiers above.)

[ ]  Yes [ ]  No

* + If yes, please list all identifiers you plan to collect:
1. Will the individually identifiable data be related to or linked to the past, present, or future physical or mental health condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual?

[ ]  Yes [ ]  No [ ]  N/A, we are not collecting or recording any identifiers listed above

1. Will the individually identifiable data be created or received by any person or entity that is a health care provider or an employee of any part of Carilion?

[ ]  Yes [ ]  No [ ]  N/A, we are not collecting or recording any identifiers listed above

**If you answered “yes” to #67 OR if you answered “yes” to #69, #70, AND #71 then you must either 1) obtain written HIPAA authorization from each research subject (in the informed consent form) or 2) request a HIPAA waiver.**

1. Do you request a HIPAA waiver to conduct your research? [ ]  Yes [ ]  No

**\*\*\*\*If no, please skip to Section IX\*\*\***

**A HIPAA waiver can only be granted if the research cannot practicably be conducted without the waiver and the use of the PHI poses no more than minimal risk to the privacy of the individuals.**

**Waiver of Authorization (HIPAA Waiver)**

1. Describe how the use of PHI in this study poses no greater than minimal risk to participants’ privacy.

1. Could the research be carried out practicably without the use of PHI?

[ ]  Yes [ ]  No

1. Is the waiver needed because obtaining HIPAA authorization is impracticable? Please check the appropriate option below.
* This study is a retrospective medical record review and/or retrospective review of specimens collected for purposes other than this research. Obtaining HIPAA authorization is impracticable because of the large number of records and/or specimens involved. Note: If data/specimens are sought from a small group of patients, obtaining consent may be considered practicable even it is inconvenient.

[ ]  Yes [ ]  No

* Obtaining HIPAA authorization is impracticable because the sample size is so large (e.g. population-base studies or epidemiology trials) that including only those samples/records/data for which consent can be obtained would prohibit conclusions to be drawn or bias the sample such that conclusions would be skewed.

[ ]  Yes [ ]  No

* Obtaining HIPAA authorization is impracticable because the research is looking at issues such as outcomes/morbidity data where not having access to data from all subjects would affect the statistical outcome of the study.

[ ]  Yes [ ]  No

* Other reason obtaining authorization is impracticable:
1. Do you assure that any data identifying subjects used in this study will not be disclosed to anyone other than the research team, sponsor, and oversight groups?

[ ]  Yes [ ]  No

1. Do you assure that you will not use this data for any other research unless you receive IRB approval?

[ ]  Yes [ ]  No

|  |
| --- |
| SECTION IX: Data Protection Plan |

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

[ ]  Yes [ ]  No [ ]  N/A

1. What records or data will you be using or collecting? Check all that apply:

[ ]  New data for this study

[ ]  Data already collected for another research study

[ ]  Data already collected for administrative purposes

[ ]  Medical records; approximately how many records:

[ ]  Electronic information from clinical database

[ ]  Other:

1. Will any sensitive information be collected, such as information regarding sexual behavior, HIV status, recreational drug use, illegal behaviors, physical abuse, mental health disorders, etc.?

[ ]  Yes [ ]  No

* If yes, what sensitive information will you be collecting?
* If yes, will you be obtaining a Certificate of Confidentiality? [ ]  Yes [ ]  No
1. Where will data be stored? Please note that **no other storage options are permitted,** including the use of Carilion provided or personal laptops, encrypted flash drives or other portable devices. Data must not be placed in a cloud or other hosted environment. Any exceptions must first be approved by the Carilion Privacy and Information Security Officer and documentation provided to the IRB.

Please check all that apply:

[ ]  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)

* Select the software to be used: [ ]  Excel [ ]  Access [ ]  Other: Describe

[ ]  REDCap (contact mmtenzer@carilionclinic.org to discuss use of REDCap). If all data, including the code link, will be stored in REDCap, skip to #82.

1. The standard at Carilion to protect identifiable data used in research is to use a code and link system.Two files should be kept in two separate secure locations. One file should use a unique code for each subject in connection with any sensitive or health information. The other file (the link) associates the unique code with subject identifiers (e.g. name, medical record number). Please describe how you will store data using the options below.

[ ]  **Retrospective Record Review Research Only:** The master list will contain direct subject identifiers such as name and MRN along with a unique subject code. It will be stored separately from the coded research data set at all times. The research data set will not include any HIPAA identifiers with the exception of a date.

[ ]  **Prospective Collection of Data**, including surveys or collection of new data: While initial collection of research data may contain identifying information, it must be stored using a code linked to the subject’s identity using a master list, or will include only anonymous or de-identified data. All HIPAA identifiers will be stripped from the initial research data collection data tools and replaced with a unique subject code.

[ ]  **Prospective Collection of Sensitive Data**, including surveys or collection of new data: Research data will be linked to identifiers by a unique subject code at all times. The code will be linked to a master list that contains identifying information. The master list and coded research data will be stored in separate locations.

1. Please describe how you plan to protect identifying information from improper use and disclosure by answering the questions below.

a) Who will have access to identifiers?

b) How will you limit access to the identifiers?

1. When will study files, including informed consent documents, study documents, and the code link with identifiers be destroyed?

Please note that you must retain research records for the greater of:

* + - At least three years after completion of the research.
		- If the study involves Protected Health Information, research records must be maintained for a minimum of six years after the completion of the research.
		- For drug studies conducted under an IND, two years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until two years after the investigation is discontinued and FDA is notified.
		- For device studies conducted under an IDE or abbreviated IDE, two years after the latter of the following two dates: The date on which the investigation is terminated or completed, or the date that the records are no longer required for purposes of supporting a premarket approval application or a notice of completion of a product development protocol.
		- The retention period required by the sponsor
		- The retention period required by local, state, or international law.
		- The retention period required by a site that is not part of Carilion Clinic.

[ ]   Years after the study has been closed with the IRB (enter # of years)

[ ]  Other (please specify):

SECTION X: Media Use

1. Will any media be used to record subjects’ voice or image?

 [ ]  Yes [ ]  No

* If yes, describe what media will be used, how the media will be used, and justify why it is necessary to use the media to collect data:
1. Will the subjects’ voice or image be recorded without their knowledge?

 [ ]  Yes [ ]  No

* If yes, describe the deception and the debrief procedures:

SECTION XI: Safety & Monitoring

1. Describe the process for dealing with adverse events and unanticipated problems.

1. Is there a Data Safety Monitoring Board or other safety oversight committee?

[ ]  Yes [ ]  No

* **If yes:**

What is the name of the board or committee?

If the DSMB is local, please name the members.

How frequently will the data be reviewed for safety?

[ ]  Every 3 months [ ]  Every 6 months [ ]  Annually [ ]  Other:

* **If no:**

How will the data be monitored to ensure the safety of subjects?

1. Are there plans for visits by sponsor monitors or auditors to review study documents for regulatory requirements?

[ ]  Yes [ ]  No [ ]  N/A

* If yes, Identify the group that will be conducting the monitoring/auditing visit(s) and the number of times you anticipate this occurring over the next year:
1. Does this project involve research using any of the following?

[ ]  Yes [ ]  No Mammalian cell/tissue culture (includes established cell lines or primary isolation of cell lines from tissue, blood, etc.)

[ ]  Yes [ ]  No Cultivated microorganisms (isolated, grown *in vitro* and used for non-diagnostic research, i.e. isolation of biohazardous organisms from patient samples)

[ ]  Yes [ ]  No Research animals

[ ]  Yes [ ]  No Molecular cloning, recombinant DNA or gene therapy techniques

**If you checked yes on any of the above boxes, you are required to contact the Carilion Clinic Research Safety Committee at 985-8510 for important guidance.**

SECTION XII: Stored Data and Human Biological Materials Repositories

Databases and specimen repositories, also known as registries or banks, are used to store data and/or specimens for future use. When the use is for clinical purposes or quality improvement, IRB approval is not required. However, when the use is for research purposes, the databases/repositories must be approved by the IRB (45 CFR 46 and 45 CFR 160 & 164).

1. Will this research collect and store data/specimens (blood, urine, biopsy tissue, saliva, etc.) for future research beyond the parameters of this study?

[ ]  Yes [ ]  No

**\*\*\*If no, you may skip the remainder of this section and go directly to Section XIII\*\*\***

1. Will the data/specimens collected for this research be stored in an existing repository at Carilion that is used for future research?

[ ]  Yes [ ]  No

* If yes, provide repository name:
1. Will the data/specimens collected for this research be stored in a non-Carilion repository that is used for future research?

[ ]  Yes [ ]  No

* If yes, attach a protocol or other information describing the repository operations.
1. Will the data/specimens collected be stored in a repository for future research that will be developed and operated by the researcher(s)?

[ ]  Yes [ ]  No

* If yes, you must also submit a Specimen/Data Repository Application to the IRB

SECTION XIII: Submission Inclusions

Please check which of the following required materials you are including with this submission. If information is submitted electronically, signature pages must be faxed or hand delivered (mailed).

[ ]  Protocol (Not required for investigator-initiated research; this application serves as protocol.)

[ ]  Grant application

[ ]  Main consent form(s), or Information Sheet

[ ]  Tissue banking consent form

[ ]  Assent form, if required for research involving children

[ ]  Legally Authorized Representative Investigator Assurance Form

[ ]  Recruitment script or other recruitment materials

[ ]  Any subject questionnaire or survey

[ ]  Any data collection tool that will be used to record subject information

[ ]  Inclusion/Exclusion Checklist

[ ]  Applicable Clinical Trial (ACT) Checklist, if study involves drugs, devices, or biologics

[ ]  Investigator brochure for drug studies

[ ]  Completed Form 1572 for drug studies

[ ]  Manufacturer reference material for device studies

[ ]  Curriculum Vitae for PI

[ ]  IRB fee, if applicable:

[ ]  $1,500 application fee for full-board industry-sponsored research

[ ]  $750 application fee for expedited industry-sponsored research

SECTION XIV: Certifications

**Certification of Principal Investigator:**

By signing this document I confirm that I have read and will carry out my responsibilities as Principal Investigator as outlined in [INVESTIGATOR GUIDANCE: Investigator Obligations (IRB-800).](https://www.carilionclinic.org/irb/policies)

Carilion Principal Investigator (signature) Date

Carilion Principal Investigator name (printed)

**Certification of Department Chair:**

My signature indicates that this project has been reviewed by the appropriate departmental parties who have judged that 1) there is a scholarly and scientific justification for the protocol, that the study is feasible, and that the proposed methods are scientifically valid, 2) the PI is sufficiently qualified by training and experience to conduct the research, 3) that the department has made the space and time commitment necessary to carry out the project, 4) that the financial implications of the research have been considered and deemed acceptable to the department.

Department Chair or designee (signature) Date

Department Chair or designee name and title (printed)

**Principal Investigator Attestation of Informed Consent Training for Students:**I certify that the following student(s) who will be obtaining informed consent for this study will have observed a mock informed consent discussion or actual informed consent discussion conducted by an experienced research team member and have been observed conducting a mock informed consent discussion or actual informed consent discussion by an experienced research team member before being allowed to interact with study subjects. In addition, I certify these students have 1) Completed the Cornerstone research modules on “The Informed Consent Process for Clinical Research” and “Recruitment of Study Subjects.” 2) Viewed the video General Informed Consent Requirements” posted on the Education tab of the Office for Human Protections website <https://www.hhs.gov/ohrp/education/training/ded_video.html> 3) Viewed the 3 informed consent videos posted on the IRB website.

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Student name (printed) Name of School

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Student name (printed) Name of School

      \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_     \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Student name (printed) Name of School

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Principal Investigator (signature) Date

      \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Principal Investigator name (printed)