Carilion Clinic Institutional Review Board (IRB) and Reliance Agreements

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Charles J. Schleupner, MD, MSc, FACP, FIDSA, FSHEA
Chair, Institutional Review Board

Presenting on behalf of

Carilion Clinic Human Subjects Protections Office (HRPO)

VTC | Virginia Tech Carilion School of Medicine

CARILION CLINIC

VIRGINIA TECH

Human Research Protections Office (HRPO) Overview

- HRPO is comprised of 3 distinct components:
  - Institutional Review Board (IRB)
  - Education & Outreach
  - Quality Assurance & Improvement Activities

Carilion IRB has oversight authority for research involving **Carilion patients, employees, or facilities.**

- Protect the rights and welfare of Carilion research participants.
- Ensure that proposed and ongoing research meets federal, state, and institutional requirements.

Reliance Agreement

- Carilion has a Memorandum of Understanding (MOU) with Virginia Tech
- The MOU includes IRB reliance and IRB review responsibilities
- This formalized agreement includes reliance for exempt and non-exempt human subjects research

Early communications about study requirements are strongly recommended.

Planning purposes

When Carilion Clinic will serve as the IRB of record:

- The study team must proceed with the Carilion IRB submission process and requirements
- Detailed information about external collaborators must be described in the Collaboration section within the IRB application
- Only Carilion Clinic employees holding a full-time position may be designated as Principal Investigator (PI) or Co-Investigator

Closer look at Application Process

The following will display screenshots of how a **Carilion Clinic** employee will complete research application to show collaboration specifications.

PRIS3M Submission System

- **PRIS3M** is the online submission system for research applications to the Carilion Clinic IRB
- To access the PRIS3M system, an individual must have a Carilion Clinic active directory username and password
- For those collaborators who do not have a Carilion Clinic active directory username and password, the Carilion PI/ Carilion Research Team Members will be responsible for completing the application in PRIS3M

Provide Name(s) of Collaborating Institutions, Lead PI, co-investigators and their Contact Information

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.	
Virginia Tech John Smith, PhD, Lead PI jsmith@vtc.vt.edu	

Is this study a Multicenter Site Study?

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

When not a multi-center, Study Team Members Under Jurisdiction of Another IRB (VTCSOM, VT, Fralin, RU, VCOM) should be listed, with their study responsibilities

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

○ Yes ◉ No

Note: If the researcher selects “no” for multicenter study (question 9.3) then the application will branch to question 9.7.

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.

Verdana 11

Carilion will be the first point of contact with potential subjects for study participation and VT research team members will only discuss the study and obtain informed consent along with initial screening information only after the potential subject has given Carilion permission which will be documented.

Virginia Tech

John Smith, PhD, **jsmith@vtc.vt.edu,** Lead PI

-data analysis (identifiable)
-conduct of study procedures that result in research data
-adverse event documenting and reporting
-data entry
-regulatory document maintenance
- responsible for training research team members

PRIS3M

Carilion Clinic

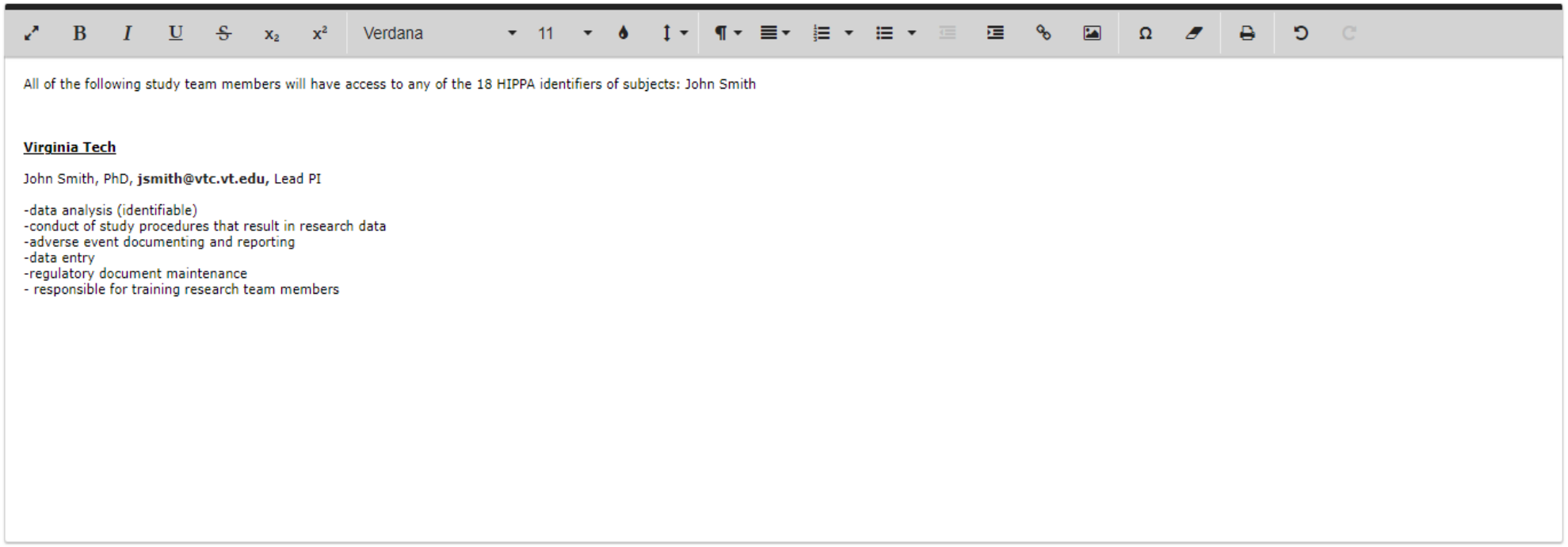
When requesting that Carilion serve as the IRB of Record, External Team Members and their Collaborating Sites, Roles, and their Access to Data should be listed.

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.



P R I S 3 M

Carilion Clinic

If there is no External Funding, Initial and Ongoing Training about the study will be documented.

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

- [ ] Yes
- [ ] No
- [x] N/A - study does not have external funding or support

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

The research team will be trained on the IRB-approved protocol. The collaborating co-investigators will work directly with the research team on initial and ongoing protocol training through regular meetings. Communication will be through meetings (face-to-face or virtual), phone call, or via secure and encrypted Carilion clinic email.

PRIS3M

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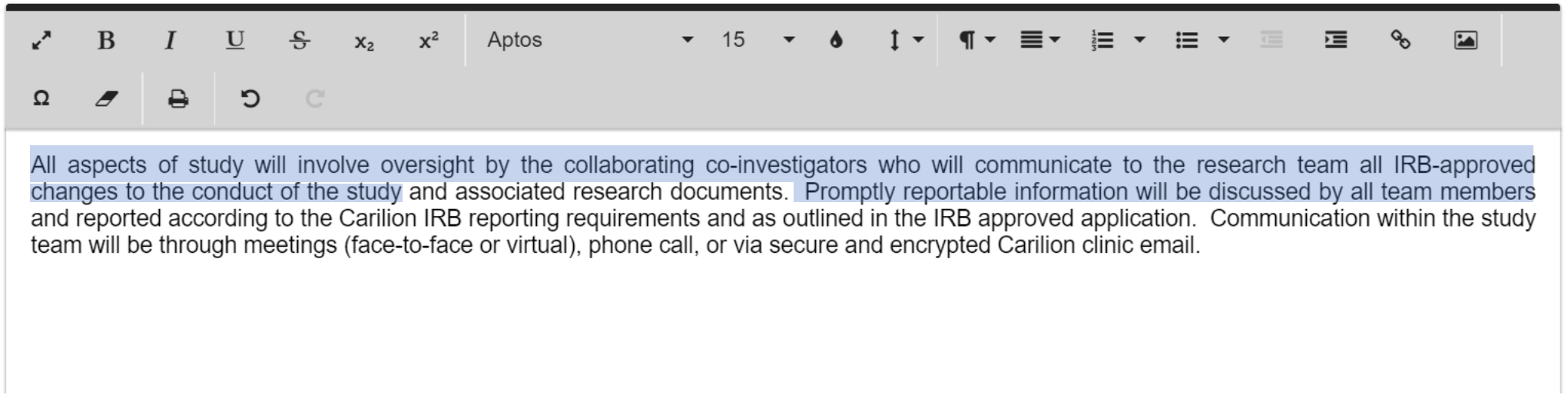
Communication Plans with External Team Members and their Site will be documented.

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.

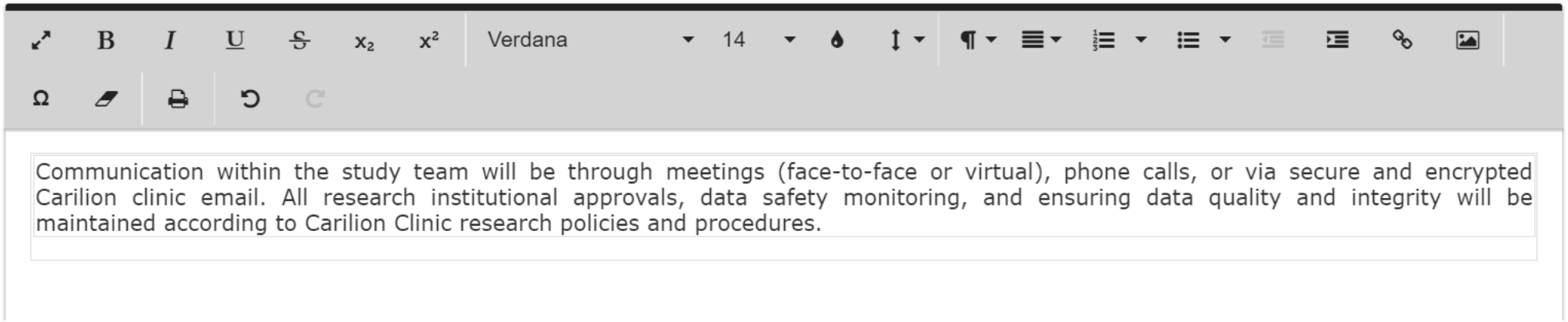
For FDA-regulated clinical trials, the plan must include the plan for reporting serious adverse events or serious adverse device effects, significant new risk information, and any other reports mandated by regulation or policy.



Document the Carilion PI's Plan for Oversight of all Research Activities.

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.



Communication within the study team will be through meetings (face-to-face or virtual), phone calls, or via secure and encrypted Carilion clinic email. All research institutional approvals, data safety monitoring, and ensuring data quality and integrity will be maintained according to Carilion Clinic research policies and procedures.

P R I S 3 M

Carilion Clinic

When Data are shared, specifics about data Transfer and Transmission outside of Carilion Clinic must be documented.

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.

Aptos 15

Protected Health Information (PHI) from medical records that are needed in identifying and screening subjects will be shared only with those who have this assigned role as outlined in the IRB approved application. This information will be shared using Carilion REDCap.

All study data to be used in data management and analysis will be coded using assigned participation code which will contain no information that can be linked to individual subjects. The key for study codes will be stored in a secure Carilion server accessible only by limited authorized personnel. Any screening forms collected on paper will be stored in a locked filing cabinet, in a locked office while all electronic data collected will be stored on secure Carilion servers

Reminders about Collaborator commitments:

1. Virginia Tech collaborators must adhere to Virginia Tech IRB requirements, including:
    - Completing necessary training
    - Disclosing potential conflicts of interest (COI)

2. Both Carilion Clinic and Virginia Tech IRBs verify compliance with these requirements before final approval of a joint study proposal.

3. Collaborator responsibilities:
    - Maintain communication with the Principal Investigator (PI) and study staff as outlined in approved IRB application
    - Follow study procedures exactly as described in IRB-approved application

Carilion Clinic and Virginia Tech have a Memorandum of Understanding (MOU), necessitating adherence to both institutions' guidelines.

Carilion Clinic IRB Leadership

IRB Chair

Charles J. Schleupner, M.D., MSc.
Internal Medicine/Infections Diseases

Vice Chair: Committee A

Glenn Edwards, M.D.
Pediatric Hematology/Oncology

Vice Chair: Committee B

Elvis Pagan, M.D.
Internal Medicine

Need help or have questions? HRPO Team

For general questions:
irb@carilionclinic.org

Meredith Talmadge, Director (Study Development, Request to Rely Submissions)
mttalmadge@carilionclinic.org
540-224-5878

Eric Wines, IRB Regulatory Affairs Administrator (Facilitate Submissions)
ekwines@carilionclinic.org
540-224-5885

Brooke Blevins, IRB Regulatory Affairs Administrator (Facilitate Submissions)
bblevins@carilionclinic.org
540-224-5882

Hilary Hedrick, HRPO Education Manager (Educational Needs)
hhhedrick@carilionclinic.org
540-224-5890

Tanner Harmon, HRPO Operations Consultant (PRISM Support, Personnel Requests, Conclusions, Admin Needs)
tharmon@carilionclinic.org
540-224-5883