

Monthly updates from the Human Research Protections Office

Helpful Tips: Study Population

A key aspect of research design that is carefully evaluated is targeted population. Targeted population refers to the specific group of individuals that researchers intend to study or include in their research. IRBs pay close attention to whether the research involves vulnerable populations such as children, prisoners, pregnant women, individuals with cognitive impairments, or other groups who may need additional protections.

In the application, our analysts look closely at subject population. In most studies, several selections need to be chosen in this section to fully identify and explain the population(s) being targeted. See the notes below to help ensure a thorough understanding of how we protect our participants.

Partial view of Application	Entire view of the Application
- General Information - Setup Department(s) Access - Grant Key Personnel access to the study - Key Study Personnel (KSP) Info - Application Type - Funding Information and Outside Services - Regulatory Compliance - Conflict of Interest - Collaboration - Human Subjects Research Description Subject Population - Informed Consent for Adult Subjects - Privacy and Confidentiality - Request for Partial Waiver, Full Waiver, or Alteration of HI ... - Sharing of Research Data/Specimens - Research Settings/Performance Sites - Applicable Regulations for ClinicalTrials.gov	11.0 Subject Population 11.1 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 ☐ 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 11.2 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.

1. These selections are broad categories to identify population(s).

2. These selections have more protections required and may need to be included depending on study criteria.

Example: A study with chart review may have "Medical Chart Review of patients only (no in-person contact)" selected AND still need to check/select "children" in section below (found in box #2 in this visual aid).

Maintaining Research Integrity in a Changing Environment

Webinar
Friday, May 9, 2025



Carilion's Institutional Research Officer, Dr. Trestman, will discuss maintaining research integrity during expansion, offering valuable perspectives on navigating challenges and opportunities.



Dr. Trestman Webinar Recording Uploaded

The recording and presentation of our Friday, May 9 webinar, *Maintaining Research Integrity in a Changing Environment*, is now available on our [website](#) and [YouTube channel](#).

These are great resources for both experienced and new researchers to hear strategic plans and direction of expanding research at Carilion Clinic.

Monthly PRIS3M Class

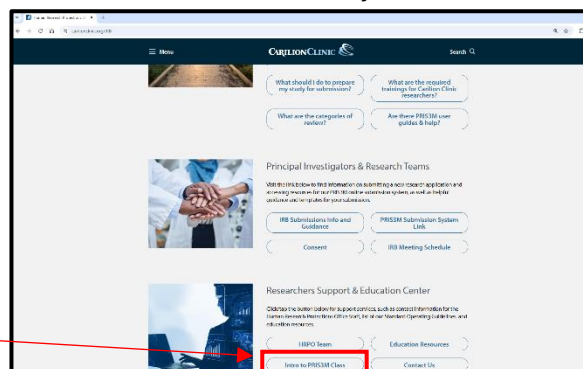


This month, Hilary Hedrick, our education manager, will begin offering an Intro to PRIS3M class. Researchers can learn the basics of navigating PRIS3M and beginning a study submission application. The first 30 minutes will be led by Hilary to take you through an overview of PRIS3M. The remaining 30 minutes will be dedicated to questions and addressing specific needs from attendees. You must register to attend. These classes will be offered on different days and times to try to accommodate differing schedules of our research community.

Register [here](#) for **Wednesday, May 21 from 8:30-9:30 AM**. You will need to use your Carilion Active Directory credentials to register for class.

A button has been added to our website to sign up for the monthly class. Usually, the class will be offered within the last two weeks of each month.

The button for **Intro to PRIS3M** class is located under the “**Researchers Support & Educational Center**.”



Resources Center

PRIS3M Application Reminders:

- **Study delays?** The study dashboard is a good place to start to see what is delaying the process. Don't forget that we have new user guides to help route Department Chair or Principal Investigator signoffs--[PRIS3M user guides](#).
- **Questions about IRB feedback?** The IRB analyst for your submission is listed in the **Pre-Review Correction Form** under “Requested Revisions and Comments.” The first stipulation will state the analyst's name along with their email address to book a time to meet with them to go over feedback and corrections.

Human Research Protections Office Personalized Services

Contact our office at irb@carilionclinic.org for the following:

- New to IRB study submission
- Consultations for studies
- Specific study questions
- In-service/training request
- Guided help for PRISM
- Assistance with IRB regulatory requirements
- General questions

★ We tailor our support to each researcher's schedule and expertise level, ensuring they receive exactly the assistance they need.

