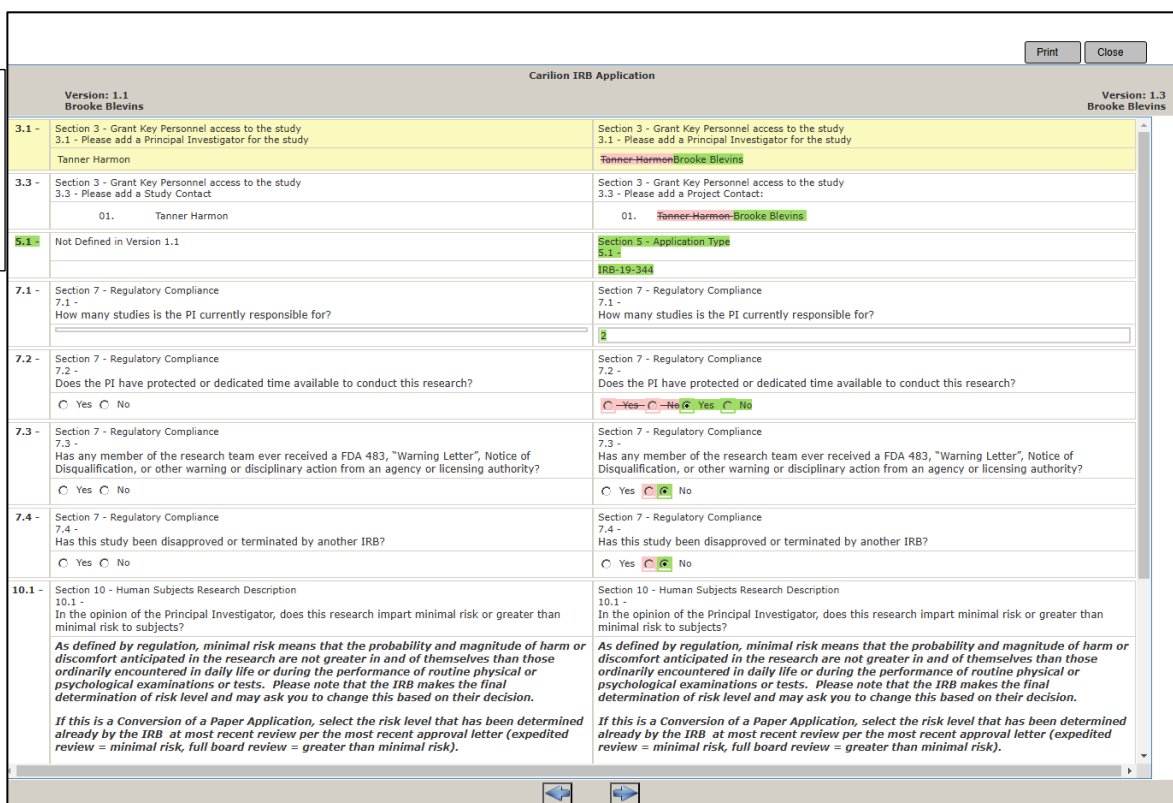


Monthly updates from the Human Research Protections Office

Comparing Two Versions of Application

PRISM has a feature that allows users to view changes between different versions of a study application. This functionality is particularly useful when submitting a change/update form and reviewing any updates that a study team member may have made previously. PRISM user guides are available on our [website](#). Please see below for screenshot of this feature.

The user guide for accessing this screen is available at this [link](#).



The screenshot displays the 'Carilion IRB Application' interface, comparing two versions of a study application. The interface is divided into two main columns, each representing a different version of the application. The left column is labeled 'Version: 1.1 Brooke Blevins' and the right column is labeled 'Version: 1.3 Brooke Blevins'. The comparison is organized into sections, with each section containing a list of questions and their corresponding answers. The sections include:

- Section 3 - Grant Key Personnel access to the study**: This section compares the Principal Investigator (PI) and Project Contact information. In Version 1.1, the PI is Tanner Harmon. In Version 1.3, the PI is Tanner Harmon Brooke Blevins.
- Section 5 - Application Type**: This section compares the application type. In Version 1.1, it is 'Not Defined in Version 1.1'. In Version 1.3, it is 'IRB-19-344'.
- Section 7 - Regulatory Compliance**: This section compares regulatory compliance questions. Questions 7.1, 7.2, 7.3, and 7.4 are compared. In Version 1.1, the answers are '2', 'No', 'No', and 'No' respectively. In Version 1.3, the answers are '2', 'No', 'No', and 'No' respectively.
- Section 10 - Human Subjects Research Description**: This section compares the research description. In Version 1.1, it is '10.1 - In the opinion of the Principal Investigator, does this research impart minimal risk or greater than minimal risk to subjects?'. In Version 1.3, it is '10.1 - In the opinion of the Principal Investigator, does this research impart minimal risk or greater than minimal risk to subjects?'. The description text is identical in both versions.

The interface includes a 'Print' button and a 'Close' button in the top right corner. The bottom of the screen shows navigation arrows.

Webinar recording and presentations

The recording of our January 17 webinar, "Future-Forward: Navigating Artificial Intelligence Ethics in Research," is now available on our [website](#). Dr. Vitak and Dr. Silverman were kind enough to share their presentations as a valuable resource on pervasive data and best practices for using AI in research.

Stay tuned for upcoming Masterminds webinars!



Jessica Vitak, PhD

Jessica Vitak is a professor in the College of Information and director of the Human-Computer Interaction Lab (HCIL) at the University of Maryland. Her research evaluates the privacy and ethical implications of new technologies that collect data in our homes, schools, workplaces, and beyond. She seeks to understand how privacy concerns play a role in technology adoption and use, and she develops tools and resources to help children and adults make more informed decisions when using technology and sharing sensitive data. For more information, visit <https://pearl.umd.edu>.



Benjamin Silverman, MD

Benjamin C. Silverman, M.D. is the Senior IRB Chair at Mass General Brigham, Human Research Affairs. Additionally, Dr. Silverman is currently the Chair of the Mass General Brigham Embryonic Stem Cell Research Oversight (ESCRO) Committee, Director of Ethics for the Institute for Technology in Psychiatry at McLean Hospital, and a Faculty Member in the Center for Bioethics. Dr. Silverman received his medical degree from the Johns Hopkins University School of Medicine, completed his psychiatry residency at the MGH McLean Adult Psychiatry Residency Training program, and completed sub-specialty fellowship training in addiction psychiatry through Mass General Brigham.

Future-Forward: Navigating Artificial Intelligence (AI) Ethics in Research

Brought to you by



Human Research
Protections Office

Have you used the Question Mark Button in PRISM?

The question mark button provides guidance as you complete a study submission. Located beside each section, this button opens a pop-out screen with detailed information about the field you are filling out. See the screenshot below, which shows the button circled in red and the pop-out screen shown for 5.2 in study application.

Account: Hilary Hedrick
Department: CC - Institutional Review Board
Path: Home > study mgmt.

My Workspaces: IRB Number: IRB-25-1702, Study Alias: HH, PI: Hedrick, Hilary

Study Assistant: Carilion IRB Application (Version 1.0)

Section view of Application: Entire view of the Application

1.0 General Information
2.0 Setup Department(s) Access
3.0 Grant Key Personnel access to the study
4.0 Key Study Personnel (KSP) Info
5.0 Application Type

5.0 Application Type

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, Advanra etc.)
- ☐ Conversion of a paper application due for Continuing Review or Annual Check-In

Description of Application Types - Work - Microsoft Edge

https://carilionclinic-test.imedris.net/35651860/System_Help_Win.jsp?ts=101010101

Print Close

Human Subject Research Study: This application type should be selected for work that is a systematic investigation, including research development, testing, and evaluation, that involves a living individual about whom a research investigator obtains data through intervention or interaction with the individual or from individually identifiable information, and which is designed to develop or contribute to generalizable knowledge.

Determination of Human Subjects Research (including QA/QI Determination): This application type should be selected if you are unsure if your project meets the definition of human subjects research, or if you wish to receive a formal determination from the IRB, as some journals and conferences will require a written statement from the IRB regarding their determination.

Establishing a prospective Data or Specimens Research Repository: This application type should be selected if your project will involve the collection and storage of information and/or biological specimens over time for future research.

Humanitarian Use Device (non-research use): This application type should be selected if a physician/clinician would like to use an approved HUD device according to its labeling for clinical treatment with the intent to benefit patients in the treatment and diagnosis of diseases or conditions that affect or is manifested in fewer than 8,000 individuals in the United States per year.

Expanded Access or Compassionate Use (non-research use): This application type should be selected for expanded access (sometimes called "compassionate use"), which provides a path to accessing investigational devices that have not received FDA approval or clearance for patients for whom the treating physician believes the device may provide a benefit in treating and/or diagnosing their disease or condition. Expanded access may be appropriate when all the following apply:

- Patient has a serious disease or condition, or whose life is immediately threatened by their disease or condition.
- There is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition.
- Patient enrollment in a clinical trial is not possible.
- Potential patient benefit justifies the potential risks of treatment.
- Providing the investigational medical product will not interfere with investigational trials that could support a medical product's development or marketing approval for the treatment indication.

Single Patient Emergency Use: This application type should be selected when a patient has a serious or life-threatening condition that is not addressed by current approved treatments (no other available alternatives), options exist to use an investigational medical device (i.e., one that has not been approved or cleared by FDA) to treat the patient, and there is no time to obtain FDA approval.

Preparatory to Research Application: This application type should be selected for activities involved in preparing for research. Under this, PHI may be used or disclosed to a researcher without an individual's authorization, a waiver or an alteration of authorization, or a data use agreement, however, the use or disclosure is requested solely to review PHI as necessary to prepare a research protocol or for similar purposes preparatory to research. The PHI will not be removed from the covered entity in the course of review, and the PHI for which use or access is requested is necessary for the research.

IRB Grant Review ONLY for preliminary approval if required by funder: This application type should be selected when Grant sponsors require that the grant be reviewed and approved by the IRB prior to submission of the grant. The principal investigator should verify the sponsor's requirements regarding IRB review prior to submission of a grant. Once the grant is funded, the principal investigator will need to submit another complete Human Subjects Research application to the IRB before work on the grant may begin.

Requesting Carilion Clinic RELY on another IRB of Record (WIRB, CIRB, VT, UVA, SMART IRB Alliance, etc.): This application type should be selected to request Carilion Clinic rely on another IRB. A reliance agreement (also called an IRB Authorization Agreement) is a document signed by two or more institutions engaged in human subjects research that permit one or more institutions to rely on another IRB. A reliance agreement avoids duplicate IRB initial review and continued oversight when multiple IRBs have jurisdiction for the same multi-site research protocol. Once the agreement is executed, it can lessen the administrative burden and regulatory oversight of multiple institutions' IRBs.

Resources Center

Guidance links for Frequently Asked Questions

[How do I submit a study to the IRB?](#)

[What are education requirements for Principal Investigators?](#)

[What do I need to know for multi-site research, or collaborating with institutions outside of Carilion?](#)

[What training is available for the informed consent process?](#)

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.

