IRB Review: June 2023, 4th edition

Join us on Thursday June 8th from 12pm to 1pm via Teams: See above for link

Advancing justice, equity and inclusion of community perspectives in clinical research.

With Megan Kasimatis Singleton, JD, MBE, CIP, Associate Dean for Human Research Protections and Director of the Human Research Protections Program at Johns Hopkins University School of Medicine.

Change/Update Submissions

When making a change to your study, be sure that you address ALL changes on the change/update form and within all applicable document(s). You may need to make changes to the IRB application, consent forms, and/or attachments.

Below are a few examples of when to submit a change/update form

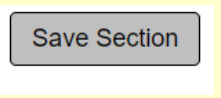
- **Changes to personnel**
- **Changes to study procedures**
- **Changes to the consent process**
- **Changes in funding**
- **Drug/device: changes in brochure, package insert, or device label**

Please DO NOT implement any changes to study procedures or personnel until you have received an approval letter from the IRB.

Things to Know for Your Application

The PRIS3M system is not designed for storage of protected health information. Please do not upload or store any PHI in PRIS3M. Always be sure to remove any and all of the 18 HIPAA identifiers before uploading a document.

When making changes to your application, choose the



button before moving to the next section as new fields may populate as a result of your changes.

When revising previously submitted study documents be sure to update the date in the footer to match the revision date. The revised date should appear on the left side of your document because the IRB stamps the approval on the right side.

Keep reading for participant quotes from the recent Research Participant Survey!

For ongoing quality assessment and improvement, the Human Research Protections Office conducts a periodic Research Participant Survey.
Below are quotes from individuals who responded to the survey.

- [Participating in the study] *made me appreciated that Carilion does research and I was pleased to be getting care from a research/teaching hospital.*
- *It was a very worthwhile study. It eliminated almost two hours of travel time.*

- *The Physician and his research team were very professional and informative.*
- *Loved it would do it again!*
- *It was great.*

- *The* [research coordinator] *was a nice* [person] *and very professional and I appreciated the interaction.*
- *I hope that taking part in this research study will help.*

- *I liked my* [Clinician] *a lot and* [they] *helped me feel encouraged and successful and basically the whole experience was very good.*
- *It was excellent and I would do it again, it saved me a lot of travel time and money* 😊.

- *Carilion is a very well managed and coordinated place, the wait times, and the service you get, and everything was exceptional.*
- *It was easy and very well managed.*

- *It's nice to get a little extra attention from someone and I liked the [research coordinator] and was happy to help out.*
- *People were very kind and understanding.*