

Monthly updates from the Human Research Protections Office

HRPO Welcomes New IRB Regulatory Affairs Administrator



Our office would like to welcome and introduce Lesley McNeil, IRB Regulatory Affairs Administrator.

Lesley has been a Certified Clinical Research Coordinator since 2008 and earned her BSN in 2012. She joined HRPO in February 2025. Lesley began her research career in 2006 after completing a newly established program at that time, Clinical Research Professional. She has worked in Nephrology and Dermatology throughout most of her research career. Lesley looks forward to assisting our research community in achieving their respective research goals.

What is the difference between *Deidentified Data* and *Limited Data Set*?

It is common to confuse deidentified data and limited data sets. While both categories involve removing certain identifiers, they differ significantly. Below is a chart created from our SOGs that will provide clarification and serve as a helpful reference guide.

Data	
Deidentified Data	Limited Data Set
- Contains no identifying information that could reasonably be used to identify an individual - All 18 HIPAA identifiers are removed (including names, addresses, dates, phone numbers, etc.) - Organization cannot have actual knowledge that the remaining information could be used to identify subjects - Data is no longer subject to HIPAA regulations	- Contains limited identifiers - May include dates such as admission, discharge, date of birth; city, state, zip code (not street address); and age - Requires a Data Use Agreement - Falls under HIPAA regulation and requires more IRB oversight than fully deidentified data - Often used when temporal or geographic information is critical to the research

***Key practical difference** is limited data sets retain some potentially useful identifiers for research purposes while still providing some privacy protection, whereas deidentified data have essentially all identifying information removed.

Helpful Reminder: When uploading supplemental documents to your study, remember not to use special characters [@, #, \$, %, &, ^, *, +, -, _, =, +, \, |, {, }, ;, : /, ?, >, etc.] when naming documents. Special characters do not convert properly into PRIS3M. Each document (Word file) will need to be uploaded individually. The screenshot below is a visual example of when study team members will upload documents. The screenshot was taken from our updated [How to Submit a New Application in PRIS3M](#).

Upload all required supplemental documents (as applicable):

1. Add other supporting documents—recruitment materials, eligibility checklists, case report forms, full protocol, grant application, etc.

2. Be sure the document is clearly labeled and does not include any special characters. The title will display in the system as it is labeled when uploaded.

3. Assign a category to the document for easy identification. *Clear labeling of documents is important for ease of access later and IRB review & approval.

4. Be sure to save after **each** upload.

5. Click here when **all** documents are uploaded and have been verified and clearly labeled.

Resources Center

Important Notes:

- **March 24, 10 AM-3PM: PRIS3M Office Hours** with Hilary. Learn the basics of PRIS3M or go over specific task(s) in the submission system. Email hhedrick@carilionclinic.org to reserve your spot.
- **External IRB Approval Letters:** Remember to submit all external IRB approval letters to irb@carilionclinic.org. *This does not apply to WCG or Advarra studies.
- **Contact Us button:** We have added a [Contact Us](#) option to our website. Our website is your up-to-date educational hub with on-demand resources.

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.

