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Subject:	WVU OHRP July 2024 Newsletter
Date:	Monday, July 15, 2024 7:50:34 AM
Attachments:	image001.png image005.png image006.png image007.png

July 2024 Newsletter

In this email:

Data Protection Form – Research vs Not Research

The Data Protection process ensures institutional compliance related to confidentiality and data storage. Projects that are submitted but do not meet the federal definition of research are not subject to the same requirements as projects that meet the federal definition of research. As a result, study teams **must** accurately identify these projects on the Data Protection Form. The relevant question is highlighted below:

Is this project one of the following?

WVU Health System Quality Improvement
WVU Quality Improvement
Evidence-Based Practice
Non-Clinical Oral History
None of the above

To learn more about the projects that do not meet the federal definition of research, please visit: https://human.research.wvu.edu/get-started/determine-protocol-type/nhsr

Federal OHRP Resources

Federal OHRP offers a series of free online trainings on the Common Rule regulatory requirements at 45 CFR 46.

1. 5-part Human Research Protection Foundational Training

2. Interactive Participant-Centered Informed Consent Training

3. Interactive Trainings for IRB Reviewers and Researchers

4. Various Webinars About 45 CFR 46 (The Common Rule)

NIH Certificate of Confidentiality (CoC) Reminder

As outlined in the excerpt, study teams with NIH CoCs must consider the terms and conditions of third-party software to ensure compliance with NIH award terms.

Institutions issued a CoC agree to protect participants' identifiable, sensitive information from compelled disclosure and support and defend the authority of the Certificate against legal challenges. In keeping with this agreement, institutions issued a CoC need to consider these protections when selecting third parties or entities (such as contractors and online platform vendors) and utilize those that can and will protect covered information against compelled disclosure. Remember that the institution holding the CoC is ultimately responsible for safeguarding all the information covered by the Certificate against compelled disclosure. For NIH funded studies, failure to comply with CoC protections is a violation of the terms and conditions of their award.

Visit Investigator and Institutional CoC Responsibilities | grants.nih.gov for more information.

Reminders

Review times vary: WVU continues to provide IRB review and approval faster than the national median; however, review times are variable. Turnaround times vary based on current workload, reviewer availability, review type, vulnerable populations included, etc. Study teams are encouraged to submit studies as early as possible and to budget sufficient time for IRB review when planning research projects/timelines.

Contacting OHRP: To allow for better and more efficient assistance, always include your study's protocol number when emailing WVU OHRP. The most reliable way to search in WVU+kc is by protocol number and providing your protocol number allows WVU OHRP staff to review information about the submission and most accurately respond to any questions/concerns.

Research Data Guidance: Visit https://researchdata.wvu.edu/ to review updated resources about data requirements at WVU. Guidance specific to Human Research is available including information/guidance about the Data Protection Process.

Learning Center: Check out the Learning Center which is designed to assist researchers who are new to WVU, who are new to human subjects research,

student-researchers, and others who want specific guidance to supplement WVU OHRP's Get Started page. **WVU OHRP recently added a new guidance document: *Researcher Guide for Amendments and Renewals*.**

WVU+kc Clean Up: As stated in WVU OHRP's January 2024 Newsletter, WVU OHRP is administratively closing WVU+kc protocols with principal investigators (PIs) no longer at WVU. A 6-month grace period is in effect (e.g., if the PI separated from WVU in March 2024, the protocol will not be closed until September 2024).

If study teams receive a closure notice for a study that is active, the study team must resubmit the study with a new PI and all research activities must stop until the new approval is received. If study teams know of active protocols with a PI who is no longer with WVU, they are encouraged to proactively resubmit as a new protocol for exempt, flex, and NHSR submissions or to submit the required amendment to change the PI for expedited, full board, or CIRB studies. For questions or concerns, please email irb@mail.wvu.edu.

For more information about PI transition requirements, please review WVU OHRP SOP 005 - Principal Investigators Transitioning Research To and From WVU.

Follow us on Twitter @WVUOHRP – Tips and Tricks published most Tuesdays

Contact us at IRB@mail.wvu.edu