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Subject:	WVU OHRP May 2024 Newsletter
Date:	Monday, May 20, 2024 8:51:00 AM
Attachments:	image001.png image002.png image003.png image004.png

May 2024 Newsletter

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Study Management – Renewal/Resubmission Reminders

WVU+kc provides courtesy notices to study teams regarding expiration of IRB approval. Study teams receive renewal reminders at 90 days, 60 days, 30 days, 15 days, 7 days, and 3 days before a study's expiration. WVU+kc will send a notice of expiration if the team does not submit a renewal and the approval expires.

Study teams are also encouraged to externally track their study expirations as these reminders may go to Junk or Other folders in Outlook. Ultimately, it is the responsibility of the principal investigator (PI) to ensure appropriate oversight and compliance of the research, including submission of renewals.

For **Full Board** protocols, renewals should be submitted to the IRB at least **30 days prior** to the expiration date to ensure sufficient time for review. If extenuating circumstances necessitate a renewal submission less than 30 days before the expiration, please reach out to WVU OHRP. Visit WVU OHRP website to review IRB meeting dates and agenda deadlines.

Expedited protocols should also submit renewals at least **30 days prior** to the expiration date to ensure sufficient time for review. Depending on the category of the expedited protocol, studies are issued a one-year or five-year approval period.

Exempt or **Flex** protocols must submit a **new, initial protocol** to continue the research beyond the expiration date. Renewals are not permitted for Exempt or Flex protocols. No action is required if the study has concluded.

Consent Development Tools

Please ensure consent documents are appropriately formatted (i.e., consistent font type, uniform color, etc.) and proofread prior to submission to the IRB. As a reminder, consent documents should not include information copied directly from the protocol, should be written for the participant's perspective, and should be written at no higher than an 8th grade reading level. If your consent forms do not meet these guidelines, your submission may be returned with a general comment about readability/formatting.

Additionally, WVU OHRP has the following tools to facilitate readability: https://human.research.wvu.edu/guidance/consent-form-development-guidance

New Staff Member in WVU OHRP

Please join us in welcoming Nancy McGill to WVU OHRP. Nancy recently joined WVU OHRP as the Continuous Quality Improvement and Education Coordinator and is excited for the opportunity to contribute to and support the WVU community.

Originally hailing from eastern Kentucky, Nancy attended the University of Kentucky to study Animal Science. After obtaining her bachelor's degree, she worked for the Kentucky Cooperative Extension Service delivering science-based educational programming to the public. This shaped her work philosophy and fostered a deep dedication to public service and education.

Nancy then moved into the UK Office of Research Integrity where she spent 5 years supporting the IRB, researchers, and fellow staff. During her time there, Nancy was involved in IRB protocol management, educational programming, and quality improvement processes. She's thrilled to be able to continue helping researchers, IRB members, and the rest of the university community in her new role at WVU.

Reminders

IRB Protocol: To initiate an IRB submission, navigate to "IRB" in WVU+kc. **Do not** select Proposals, as this is used for the Office of Sponsored Programs (OSP) at WVU.

NIJ Funded Studies: WVU will cede IRB review and oversight to an external IRB on studies that involve NIJ involvement and funding. For more information, please see April 4, 2024 announcement.

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+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 December 2023, the protocol will not be closed until June 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