From: <u>Kasandra Lambert</u>

To: <u>eastdiv-som@listserv.wvu.edu</u>; <u>HFFMResidents@wvumedicine.org</u>

Subject: WVU OHRP January 2024 Newsletter

Date: Tuesday, January 16, 2024 8:39:48 AM

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January 2024 Newsletter

In this email:

New: Learning Center

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<u>Reminder</u>

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New: Learning Center

The <u>Learning Center</u> 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 <u>Get Started page</u>.

Visit the <u>Learning Center</u> and provide feedback/request specific videos/guidance by emailing <u>irb@mail.wvu.edu</u>.

New: WVU+kc Cleanup

WVU OHRP will be administratively closing WVU+kc protocols with principal investigators (Pls) no longer at WVU. A 6-month grace period is in effect (e.g., if the PI separated from WVU in August 2023, the protocol will not be closed until February 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 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 <u>WVU</u>

OHRP SOP 005 - Principal Investigators Transitioning Research To and From WVU.

Reminder: Requirements Vary Based on Protocol Type

Please familiarize yourself with submission requirements for each IRB submission type.

Information can be found here: https://human.research.wvu.edu/guidance/wvu-submission-quidance/protocol-types

NHSR, Flex, and Exempt submissions require the submission of a new protocol if (1) the changes to the project result in increased risk, (2) the changes require a change in review type (ex. if a flex project receives federal funding, a new exempt or expedited submission is required), or (3) if the study team wishes to document a specific change (ex. Pl change).

Expedited and Full Board protocols **require** amendments for any change and those **changes must be approved by the IRB prior to implementation**. Failure to obtain IRB approval prior to initiating a change is noncompliance and may result in reporting to funding or federal agencies, depending on the circumstances.

Consent Documents: Tools and Tips

Please ensure consent documents are appropriately formatted (i.e., consistent font type, uniform color, removal of template instruction verbiage language in red or purple, etc.) and proofread prior to submission to the IRB. As a reminder, consent documents should not include copy and pasted information from the protocol, should be written from the participant's perspective, and should be written at no higher than an 8th grade reading level. Your submission may be returned with a general comment about readability/formatting, if appropriate.

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

Student Researchers

WVU OHRP welcomes and encourages questions from WVU student researchers. When submitting a question to irb@mail.wvu.edu or specific staff at WVU OHRP, please be sure to copy the faculty advisor on the correspondence as they are required to serve as the principal investigator (PI) for any student project. If not copied, WVU OHRP may ask for the PI/faculty advisor's information from the student or add the PI to email correspondence when replying.

Spring Office Hours

The WVU Office of Human Research Protections is offering Office Hours via Zoom to provide support to the research community. Investigators, research staff, and/or students are encouraged to drop into these sessions at their convenience with questions about ongoing research, developing research projects, the WVU+kc system, general IRB considerations, etc. A variety of staff from OHRP will be available to answer questions and provide support.

Wednesday, February 21st at 11 am

Wednesday, March 20th at 11 am

Wednesday, April 17th at 11 am

WVU OHRP Office Hours Zoom. No RSVP required.

For more information, visit:

https://human.research.wvu.edu/updates/2024/01/10/spring-2024-office-hours-dates





Contact us at IRB@mail.wvu.edu