From: <u>Kasandra Lambert</u>

To: wvukc users@listserv.wvu.edu

Subject: WVU OHRP November/December Newsletter

Date: Monday, December 11, 2023 7:36:08 AM

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November/December 2023 Newsletter

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Happy Holidays from WVU OHRP

Reminder: Changes to CIRB Amendment Requirements and Fees

The following changes are being made to Central IRB (CIRB) amendment requirements and fees in WVU+kc.

WVU researchers are responsible for notifying both the local WVU IRB as well as the reviewing IRB when the PI on the study changes. Study staff should submit an amendment to the local CIRB protocol in WVU+kc to notify the WVU OHRP of any change to the PI.

Changes to study staff other than the PI no longer require local amendment submissions. However, the WVU PI is responsible for ensuring all study staff have completed the required human subjects training before beginning work on the research protocol.

Beginning **January 1, 2024**, WVU OHRP will charge a fee of \$100 for amendments to CIRB protocols that meet OHRP billing requirements. As a reminder, fees apply to private or industry-sponsored research. Fees do not apply to government agency, non-profit, personally funded, or WVU-sponsored research. Refer to the <u>Fees page</u> for more details.

The current IRB fee schedule for CIRBs will remain the same until **January 1**, **2024**. At that time, the charge for CIRB amendments (including those to change the PI) will be reduced to \$100. As the PI is responsible for ensuring local staff compliance, changes to co-investigators and study staff will no

longer be required.

As amendment fees to change the PI will be waived until **January 1**, **2024**, we encourage all researchers who are utilizing CIRBs to update the local PI before the deadline. **Any changes to the PI received on and after January 1**, **2024**, will be charged \$100.

Notify IRBs-Notifications fees for required reporting* will remain the same at \$200. *Note: see <u>WVU OHRP SOP-010 Single IRB Reliance</u> for details.

If you have any questions, please reach out to this office at irb@mail.wvu.edu

Keep Study Information Up to Date – Principal Investigators

Please ensure active projects in WVU+kc have the correct Principal Investigator (PI) listed.

- 1. For **Expedited** and **Full Board** studies, an amendment must be submitted and approved prior to the new PI taking over study activities.
- 2. For **Flex** and **Exempt** studies, please contact <u>irb@mail.wvu.edu</u> to initiate the PI change process or submit a new protocol with the new PI (preferred method).

Additionally, a closure request should be submitted when your study has reached data analysis activities and/or when the study is completed/will no longer continue (ex. when a PI leaves). Guidance can be found here: https://human.research.wvu.edu/guidance/wvu-submission-guidance/close-an-active-protocol and the protocol closure request form link can be found here: https://human.research.wvu.edu/forms#approvedstudies

This is especially important for expedited and full board studies subject to the Common Rule and/or FDA regulations/oversight. If you are unable to close a study in WVU+kc or have any questions, please email irb@mail.wvu.edu

Happy Holidays from WVU OHRP

As a reminder, WVU OHRP is closed for the following WVU holidays:

Friday, December 22 Monday, December 25 Tuesday, December 26 Monday, January 1





Contact us at IRB@mail.wvu.edu