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September 2023 Newsletter

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Coming Soon: Processes for NHR and other projects will be simplified starting Nov. 14

Beginning Tuesday, Nov. 14, the WVU Office of Human Research Protections will simplify processes for Not Human Subjects Research (NHR) and for projects that don't require IRB review because they don't meet the [federal definition](#) of research.

The current Data Protection application will be updated to determine the project type and to generate a Letter of Determination. This will save researchers time and clearly indicate when there is no need for a WVU+kc protocol submission.

ACTION NEEDED: Any new and pending NHR protocol submissions should be submitted by Tuesday, Oct. 31 to allow for sufficient time for processing ahead of the Nov. 14 transition date. WVU+kc will not accept NHR protocol submissions after Nov. 14, 2023.

Please note the process for Flex submissions is NOT changing because those submissions do meet the definition of Human Subjects Research.

Find more information and [register for an information session here](#).

Reminder: Please take note of changes to renewal

reminders and expiration notices

Study teams will now receive renewal reminders at **90 days, 60 days, 30 days, 15 days, 7 days, and 3 days** before a study's expiration. **A notice of expiration will also be sent if a renewal is not submitted.**

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, study teams are encouraged to reach out to WVU OHRP to try to avoid a lapse in IRB approval. Please visit [WVU OHRP website](#) to review IRB meeting dates and agenda deadlines.

Expedited protocols should also submit renewals no later than **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.

If you have any questions or concerns about the renewal reminders/expiration notice, please email irb@mail.wvu.edu

Updates

1. Changes to Human Subject Payment and Prepaid Card Program Guidelines

In an effort to update existing guidelines, the [Procurement Contracting and Payment Services](#) team has revised the WVU [Human Subject Payment and Prepaid Card Program](#) guidelines.

Highlights of the updated Human Subject Payment Guidelines include:

- Expansion of approved third-party payment processors;
- Removal of prepaid cards as an option for most participant payments where the participant will receive \$500 or less cumulatively in the calendar year from a study or studies in the lab;
- Removal of the requirement to include the WVU ID number of employees/students on the Human Gift Card and Cash Reconciliation Log; and
- Updated tax reporting guidelines.

Additionally, the Prepaid Card Program Guidelines now further outline:

- Reminders to promptly return unused cards;
- Communication expectations with the PCPS and Tax Services teams;
- Designated uses for prepaid cards; and
- The maximum number of prepaid cards provided for one request, which is 50.

The full, updated documents can be accessed online ([Human Subject Payment](#) and [Prepaid Card Program](#)).

Please contact the PCPS team at pcps@mail.wvu.edu with any questions.

2. 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 [Fees page](#) 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 [WVU OHRP SOP-010 Single IRB Reliance](#) for details.

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



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Contact us at IRB@mail.wvu.edu