West Virginia University
OFFICE OF HUMAN RESEARCH PROTECTIONS

December 2024 Newsletter

In this email:

Delayed: New Submission Process for NHSR and projects that do not require IRB review

The WVU Office of Human Research Protections will delay previously announced process changes for Not Human Subjects Research (NHSR) and for projects that don't require IRB review until Monday, Feb. 17. This decision is based on initial findings and feedback during user acceptance testing.

The extra time will allow for additional requested enhancements. Meanwhile, study teams can continue to submit (optional) NHSR submissions in WVU+kc.

Additional information will be communicated via WVU OHRP's website, WVU OHRP Newsletters, X.com, and the Research Community LISTSERV.

If you have any questions, please email irb@mail.wvu.edu

New Resource Available: A Faculty Mentor's Guide to the IRB

WVU OHRP has recently published a new guidance document, A Faculty Mentor's Guide to the IRB, in the Learning Center. This guidance document serves as a valuable resource for both mentors and mentees to better understand roles and responsibilities, information regarding the IRB process, and considerations for student projects (e.g., timelines, complexity, and

oversight).

Training on the new WVU Research Administration Portal starts Monday, November 18

Faculty, staff, and students are encouraged to register for a training session on Zoom in preparation for the Jan. 13 launch of the new WVU Research Administration Portal (WRAP). The series starts Monday, Nov. 18 and runs through Friday, March 28 to prepare system users for the launch of **Grants, Agreements and Conflict of Interest (COI).** The Research Office will continue to offer instructor-led training on WRAP throughout the year, but on a less frequent cadence after March 2025. (Please note: The IRB module will remain in WVU+kc at this time.)

For the latest information on the Research Connect program, please visit https://researchoperations.wvu.edu/research-connect-program.

Upcoming University Closures

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

Tuesday, December 24 – Thursday, December 26: Winter Holiday/Christmas
Tuesday, December 31 – Wednesday, January 1: Winter Holiday/New Year's Day

As always, study teams are encouraged to submit studies as early as possible and to budget sufficient time for IRB review when planning research projects/timelines.

Specifically for renewals, study teams are encouraged to submit as soon as an automated reminder is received from WVU+kc. As stated in WVU+kc automated emails, renewals submitted less than 30 days prior to expiration may not leave sufficient time for IRB review.

Reminders

NHSR and FLEX are different: Due to system limitations with WVU+kc, NHSR and FLEX are merged in the WVU+kc drop drown but represent two different submission types. NHSR (not human subjects research) is a designation assigned to projects that do not meet the federal definition of research and/or human subjects. The categories of NHSR can be found on WVU OHRP's website. Submissions for NHSR are **not required**. These projects **do not** undergo IRB review but rather are administratively reviewed and receive a determination of "IRB review not required." This is in contrast to FLEX, which is human subjects research. FLEX projects **must** be submitted for IRB review and approval prior to initiation. WVU OHRP also has guidance related to FLEX projects. Study teams should know whether their project is NHSR or FLEX as these are distinct submission types with very different requirements and

expectations.

Participant payment/funding listing in WVU+kc questionnaire: If participants are being paid, a funding source must be listed in the WVU+kc questionnaire under Funding Source. This includes when Departmental or Personal funds are being used.

Adding Study Personnel to Expedited or Full Board Protocols: When adding or removing study personnel via an amendment or at continuing review, please ensure the personnel are added or removed under the "Personnel" tab of WVU+kc in addition to listing them in the "Amendment" or "Continuing Review" section of the questionnaire. Changes should also be made to other applicable sections and/or attached documents.

WVU Health System Only Employees: Personnel who are only affiliated with WVU health system (with no dual appointment with WVU) are considered **WVU-affiliated** for the purposes of IRB review. However, WVU health system only personnel are **not** automatically listed under the WVU affiliate search in WVU+kc. To be included on a WVU+kc protocol, WVU health system personnel must follow specific steps to be added to the system.

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.

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

 Contact us at IRB@mail.wvu.edu