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To:	Information for research systems, technology, and data management at WVU
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### West Virginia University OFFICE OF HUMAN RESEARCH PROTECTIONS

#### January 2025 Newsletter

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New Educational Resource Available: CITI Program Webinars Reminder: New Submission Process for NHSR and projects that do not require IRB review New Resource Available: A Faculty Mentor's Guide to the IRB Reminders

### New Educational Resource Available: CITI Program Webinars

The WVU Office of Human Research Protections is now offering updated educational webinars through the CITI Program. WVU researchers may access CITI program webinars by navigating to <u>CITI</u> and selecting "Add a Course" after logging in. Available webinars are listed under Question 17 and include topics like Data Management and Security for Student Researchers: An Overview, FERPA: A Quick Review of the Law for Researchers and IRBs, Improving the Clinical Trial Participant's Experience: From Recruitment through Study Closure, and many more.

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

The WVU Office of Human Research Protections delayed the 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 <u>WVU OHRP's website</u>, WVU OHRP Newsletters, <u>X.com</u>, and the Research Community LISTSERV.

Join WVU OHRP for an overview at <u>upcoming information sessions or review</u>

the available recording to find out more.

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, <u>A Faculty</u> <u>Mentor's Guide to the IRB</u>, in the <u>Learning Center</u>. 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).

### Reminders

**NHSR and FLEX are different:** Due to system limitations with WVU+kc, NHSR and FLEX are merged in the WVU+kc drop down 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 <u>WVU OHRP's website</u>. 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, <u>WVU health system personnel must follow specific steps to be added to the system</u>.

**Review times vary:** WVU continues to provide IRB review and approval faster than the <u>national median</u>; 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 <u>https://researchdata.wvu.edu/</u> to review updated resources about data requirements at WVU. Guidance specific to <u>Human Research</u> is available including information/guidance about the <u>Data</u> <u>Protection Process</u>.

**Learning Center:** Check out the <u>Learning Center</u> 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 <u>Get Started page</u>.

Follow us on X.com @WVUOHRP - Tips and Tricks published most

Tuesdays



Contact us at IRB@mail.wvu.edu