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Subject: WVU OHRP March 2025 Newsletter
Date: Monday, March 17, 2025 7:55:00 AM
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March 2025 Newsletter

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Now Live: New Submission Process for NHR and projects that do not require IRB review

The WVU Office of Human Research Protections has simplified the processes for projects that do not require IRB review, including Not Human Subjects Research (NHR). WVU+kc no longer accepts NHR protocol submissions. Any pending NHR protocol submissions must be refiled using the new process.

The R02 Data Protection form has been updated and renamed R03 Data Protection and Determination and now includes questions to determine which projects do not require IRB review. This change saves researchers time and clearly indicates when there is no need for a WVU+kc protocol submission.

Researchers must answer questions correctly to obtain a valid determination.

Researchers still receive a Data Protection Certificate for human subjects research through the application.

Get more information about categories affected by this change at <https://human.research.wvu.edu/get-started/determine-protocol-type/nhr>. Please note that while the process has changed, the categories, regulatory definitions, and institutional requirements remain the same.

The R03 Data Protection and Determination form can be accessed on [WVU OHRP's Get Started page](#). A [Frequently Asked Questions](#) page is also available, and additional questions can be sent to irb@mail.wvu.edu.

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

Review the [recorded information session](#) for additional information. If you

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

Continuing Reviews: Plan Ahead and Submit Early

Starting at 90 days before protocol expiration, WVU+kc sends numerous automated reminders to study teams. Continuing reviews submitted less than 30 days before expiration may not be reviewed in time to avoid expiration, leading to extra work for you and more review time to reopen the study. To keep the process moving smoothly for both study teams and the IRB, **submit continuing reviews after receiving the first reminder and no later than 60 days prior to expiration.**

Reminders

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 and should be added as affiliated personnel on IRB submissions. 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.](#)

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).

New Educational Resource: 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 [CITI](#) 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.

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.

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.

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](#).

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Contact us at IRB@mail.wvu.edu