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To:	Information for research systems, technology, and data management at WVU
Subject:	May 2025 WVU OHRP Newsletter
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May 2025 Newsletter

In this email:

Federal Updates

NIH Certificates of Confidentiality (CoC) – Not Available for Research Not Funded by NIH: NIH cannot accept submissions for requests for CoCs for research not funded by NIH. CoCs for NIH-funded studies are not affected.

Federal OHRP – Reporting Requirement Reminder: The following incidents must be reported to Federal OHRP for federally funded research.

1. any unanticipated problems involving risks to subjects or others;
2. any serious or continuing noncompliance with 45 CFR part 46 or the requirements or determinations of the IRB; and
3. any suspension or termination of IRB approval (pre-2018 Requirements at 45 CFR 46.103(a) and (b)(5) and 45 CFR 46.113, and the 2018 Requirements at 45 CFR 46.108(a)(4) and 45 CFR 46.113).

The WVU IRB will review any submitted incident in WVU+kc to determine if it meets the federal reporting requirement. Please review WVU OHRP Reporting Events Page and WVU OHRP SOP 031 Research-Related Event Reporting and SOP 034 Reporting to Federal Agencies for additional guidance. **Please note that loss of federal funding *may* represent an unanticipated problem involving risk to subjects or others, depending on the current status of the research, associated risks, and category of research. Please promptly report loss of funding to WVU OHRP.**

Available WVU OHRP Resources

WVU OHRP has a variety of resources available for the WVU research

community. Researchers are encouraged to review and utilize available resources and guidance when initiating an IRB submission. Resources include:

Get Started: A step-by-step guide for requirements when submitting to the WVU IRB in WVU+kc
Forms: Comprehensive listing of required and optional forms for IRB submissions (includes consent documents, study management resources, special approvals, etc.)
A-Z: Guidance by topic
Learning Center: Guides and documents for specific aspects of IRB requirements and guidance videos, cultivated for new researchers (including students) but also useful to seasoned researchers for a refresher.

For questions or clarifications about available information and guidance, 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 requiring 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

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.

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

Contact us at IRB@mail.wvu.edu