From:	Kasandra Lambert
To:	Information for research systems, technology, and data management at WVU
Subject:	WVU OHRP February 2025 Newsletter
Date:	Monday, February 10, 2025 8:21:00 AM
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February 2025 Newsletter

In this email:

New Federal OHRP/FDA Draft Guidance

Federal OHRP and the FDA have shared a draft guidance for review titled, "Considerations for Including Tissue Biopsies in Clinical Trials: Guidance for Industry, Investigators, Institutions, and IRBs," that provides recommendations for the inclusion of tissue biopsies as part of clinical trials and considerations to determine if the included biopsies should be required or optional.

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

Beginning Monday, Feb. 17, the WVU Office of Human Research Protections will simplify processes for Not Human Subjects Research (NHSR) and for projects that don't require IRB review. WVU+kc will not accept NHSR protocol submissions as of Feb. 17. Any NHSR protocol submissions still pending as of Feb. 17 must be refiled using the new process.

Get more information about the affected categories associated with this change at https://human.research.wvu.edu/get-started/determine-protocol-type/nhsr.

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.

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.

Complete COI disclosures in WRAP now to avoid submission delays

With the launch of the new WVU Research Administration Portal (WRAP), it is now a priority that individuals with in-progress, upcoming, or existing IRB submissions complete a conflict of Interest (COI) disclosure in WRAP. Completing this disclosure as soon as possible will help avoid delays with submissions. More information can be found on the Research Connect website. Please review system guidance under "Conflict of Interest (COI)" or contact coi@mail.wvu.edu with any questions.

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).

Reminders

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.

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

Contact us at IRB@mail.wvu.edu