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September 2024 Newsletter

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Non-Affiliate Researchers

Researchers or study personnel who are not affiliated with WVU or associated health systems and are engaged in human subjects research should not be added to the personnel section of any WVU+kc IRB protocol. **These changes do not limit the ability of WVU researchers to work with external individuals but instead ensure appropriate oversight.**

Requirements for working with non-affiliated personnel are based on IRB review type:

Not Human Subjects Research, FLEX, Exempt:

Requirements for these review types depend on your collaborators' affiliations, and whether they are associated with an organization with its own IRB.

Organizations with an IRB (universities, medical systems, or other institutions): Each non-affiliated researcher must seek guidance from their organization for review requirements. These individuals should not be listed on the WVU+kc protocol and are not covered by WVU IRB review and oversight. In this circumstance, each institution is responsible for its own IRB review and oversight.

Organizations without an IRB and community members: If the non-affiliated researcher is not associated with an institution with its own IRB, then the PI may choose to include an attachment listing non-affiliated personnel to note their involvement. WVU Principal investigators are responsible for ensuring all

personnel, including non-affiliates, have appropriate training/oversight.

Expedited/Full Board

Non-affiliated researchers are only covered by WVU IRB when a reliance agreement is in place. In general, WVU IRB will only serve as the IRB of Record for other institutions in limited circumstances and/or when required by a federal single IRB mandate. If reliance does not apply, each institution involved will be responsible for IRB review and oversight for their researchers (when applicable).

For any questions or concerns, please email irb@mail.wvu.edu or visit https://human.research.wvu.edu/guidance/non-affiliated-personnel. Frequently asked questions section coming soon.

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

A new submission process for NHSR and other projects that do not require IRB review will be in effect on December 9th. The process for Flex submissions will remain the same. As a reminder, while shown as NHSR/Flex in WVU+kc, these are two unique protocol types—NHSR and Flex. These two protocol types were initially combined into one (NHSR/Flex) submission process in WVU+kc because of system limitations when the Flex protocol type was rolled out in 2018. Any new and pending NHSR protocol submissions should be submitted by November 22nd to allow for sufficient time for processing ahead of the transition. Information on the new process will be communicated soon! If you have any questions, please email irb@mail.wvu.edu.

Updated Flex Guidance

WVU OHRP has recently updated the guidance for Flex protocol submission.

Changes include:

1. Not Eligible for Flex: Research that includes stigmatizing/controversial topics, as determined by WVU OHRP/IRB.

2. Emphasis added to remind researchers when changes to a Flex protocol **require a new protocol submission**:

a. Addition of federal funding

b. Change in risk

c. Change in scope of project (new or changed goal/hypothesis)

d. Significant change to research procedures (e.g., addition of prospective component to a retrospective chart review; adding a vulnerable population;

etc.)

Researchers are encouraged to review the guidance document and bookmark it for reference.

New LISTSERV

A new LISTSERV was created to expand and streamline communication with the WVU research community. This new email group includes those who were previously subscribed to WVUKC_USERS@LISTSERV.WVU.EDU, as well as WVU Medicine employees who use the research administration portal. This newsletter was sent via the updated LISTSERV.

Other people may sign up by following these instructions: https://researchoperations.wvu.edu/research-connect-program/subscribe-to-listserv
The Research Office and Information Technology Services will be using this communications channel to share important information on a variety of topics such as the new WVU Research Administration Portal (WRAP).

As WVU prepares for the Jan. 13, 2025, launch of Grants, Agreements, Conflict of Interest (COI), and WV CTSI Clinical Trial Center of Excellence (COE), we will have important information about informational sessions, training, support and more.

For the latest on this part of the WVU Modernization Program, please visit the Research Connect website at https://researchoperations.wvu.edu/research-connect-program

Reminders

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 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 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.

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Contact us at IRB@mail.wvu.edu