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To: wvukc_users@listserv.wvu.edu
Subject: WVU OHRP November/December 2022 Newsletter
Date: Monday, December 12, 2022 9:47:00 AM
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West Virginia University®

OFFICE OF HUMAN RESEARCH PROTECTIONS



November/December 2022 Newsletter



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Guidance for Changing PI/Study Staff/Etc. for NHSR, Flex, and Exempt Protocols:

Study teams are not able to submit amendments to protocols acknowledged as NHSR or Exempt or approved as Flex. As a reminder, amendments to these protocol types were eliminated to reduce investigator burden associated with protocol changes that do not alter protocol type or risk level. WVU OHRP/IRB allows study teams to make minor changes without notification to the IRB. Any change that may alter the review category, risk level, or is otherwise necessary as deemed by the study team, requires the **submission of a new protocol**. Study teams can use the "Copy to New Document" tool under Protocol Actions in the WVU+kc protocol and re-upload study attachments to copy the protocol and submit to WVU OHRP/IRB.

Electronic Informed Consent Assistance Now Available!

WVU OHRP and the WVU Research Office have launched a joint service to assist study teams interested in using electronic informed consent. Please visit [WVU OHRP's electronic informed consent webpage](#) for additional information. As part of this service, staff from the WVU OHRP and Research Office can assist

study teams in completing the WVU OHRP-45 eIC Submission Worksheet, will help the study team identify what electronic template and process may best fit their project, and will build the electronic informed consent framework in REDCap/Qualtrics. *Please note that this process is in its pilot phase and the process may be adjusted/changed as more researchers utilize the service. Study teams are also encouraged to submit any support request early in their protocol development process to avoid delays.*

Spring Office Hours Announced!

WVU OHRP Office Hours: *Investigators, research staff, and/or students are encouraged to drop into these Zoom sessions at their convenience with questions about ongoing research, developing research projects, the WVU+kc system, general IRB considerations, etc. A variety of staff from OHRP will be available to answer questions and provide support.*

Wednesday, January 18th, 11 am - 12 pm

Thursday, February 2nd 1-2 pm

Monday, February 13th 1:30-2:30 pm

Tuesday, March 7th 12-1 pm

Wednesday, March 29th 1-2 pm

Friday, April 14th 10:30-11:30 am

Monday, April 24th 1:30-2:30pm

See Announcement [here](#) for more details.

Stay up to date by visiting the [OHRP calendar](#) periodically and keep an eye out for email reminders from the WVU+kc users listserv.

Reminders:

- 1. Researchers should familiarize themselves with WVU OHRP Reporting Requirements to ensure compliance with federal regulations and institutional policies.** Please review [WVU OHRP SOP 031- Research Related Event Reporting](#) and [WVU OHRP's Reporting Events Webpage](#) for guidance. When in doubt, please report the event or contact us at irb@mail.wvu.edu for assistance.
 - 2. Do you need to submit a protocol in WVU+kc?** Please note that while projects that meet the definition of human subjects research (flex, exempt, expedited, full protocols) ALWAYS require submission to the IRB for review and approval before study initiation, projects that fall under "Not Human Subjects Research" DO NOT require a protocol submission in WVU+kc. Researchers can familiarize themselves with NHR categories by reviewing [WVU OHRP's Not Human Subject Research page](#) or by using [WVU OHRP's Build Form](#) to determine if a protocol is required. The tool is linked [here](#) and can be found under Step 1 of [WVU OHRP's Get Started page](#). Please take care in reviewing the material and completing the Build form to ensure you receive the correct guidance and reach out to WVU OHRP with any questions or projects that you are unsure about.
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Tips and Tricks

1. **Search for a protocol in WVU+kc.** Scroll to top of the page, on the IRB tab select, "Search Protocol" enter the Protocol number and add an * at the end of the number. Active Renewals, Amendments, or base Protocols will be displayed.
 2. **CITI Training.** To ensure your Human Subjects Research Protection Training in CITI is linked to WVU+kc, you must select West Virginia University as your affiliated institution, and use the same contact email that is listed in WVU+kc.
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