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Subject: WVU OHRP April 2024 Newsletter
Date: Monday, April 15, 2024 10:30:00 AM
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West Virginia University®

OFFICE OF HUMAN RESEARCH PROTECTIONS

April 2024 Newsletter

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Resources FDA Regulated Studies

WVU OHRP has numerous resources for study teams related to FDA-regulated studies/submissions. Please review the following links and bookmark for future use.

Drugs:

<https://human.research.wvu.edu/fda-regulated-drugs-and-biologics-used-in-research>
<https://human.research.wvu.edu/sop-022-research-involving-investigational-drugs-and-biologics>

Devices:

<https://human.research.wvu.edu/fda-regulated-devices-used-in-research>
<https://human.research.wvu.edu/sop-023-research-involving-investigational-devices-and-huds>

Humanitarian Use Device:

<https://human.research.wvu.edu/sop-023-research-involving-investigational-devices-and-huds>

Compassionate Use/Expanded Access:

<https://human.research.wvu.edu/expanded-access>
<https://human.research.wvu.edu/sop-023-research-involving-investigational-devices-and-huds>
<https://human.research.wvu.edu/sop-022-research-involving-investigational-drugs-and-biologics>

Emergency Use:

<https://human.research.wvu.edu/emergency-use>

<https://human.research.wvu.edu/sop-053-emergency-use-of-investigational-drugs-biologics-or-devices>

WVU OHRP also recommends reviewing the Regulatory Guidance for Academic Research of Drugs and Device (REGARDD) website:

<https://www.regardd.org/>

Future Use – Children as Subjects

WVU OHRP/IRB has recently updated the following informed consent templates on [WVU OHRP's Forms page](#):

WVU OHRP-36 Parent-Guardian Consent Form Template

WVU OHRP-37 Combined Parent-Guardian and Child Consent Form Template

Under “**Will your information be used for future research?**” if the study team selects:

Identifying information might be removed from your private information or biospecimens collected as part of this research. The information or biospecimens could be used for future research or distributed to another Principal Investigator for future research without obtaining additional informed consent.

Children are a vulnerable population and parental permission is generally necessary for participation of children in research. While children may assent (agree to participate), this is not consent for themselves. As a result, WVU OHRP/IRB now requires study teams to justify the future use of pediatric samples to respect the autonomy of the minor participants. The template also includes optional checkboxes for participants to opt in or out if this option is selected.

Reminders

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](#).

WVU+kc Clean Up: As stated in WVU OHRP's January 2024 Newsletter, WVU OHRP is administratively closing WVU+kc protocols with principal investigators (PIs) no longer at WVU. A 6-month grace period is in effect (e.g., if the PI separated from WVU in October 2023, the protocol will not be closed until April 2024).

If study teams receive a closure notice for a study that is active, the study team must resubmit the study with a new PI and all research activities must stop until the new approval is received. If study teams know of active protocols with a PI who is no longer with WVU, they are encouraged to proactively resubmit as a new protocol for exempt, flex, and NHSR submissions or to submit the required amendment to change the PI for expedited, full board, or CIRB studies. For questions or concerns, please email irb@mail.wvu.edu.

For more information about PI transition requirements, please review [WVU OHRP SOP 005](#) - Principal Investigators Transitioning Research To and From WVU.

Events

WVU OHRP Office Hours: The WVU Office of Human Research Protections is offering Office Hours via Zoom to provide support to the research community. Investigators, research staff, and/or students are encouraged to drop into these 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, April 17th at 11 am

[WVU OHRP Office Hours Zoom](#). No RSVP required. For more information, visit: <https://human.research.wvu.edu/updates/2024/01/10/spring-2024-office-hours-dates>



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