From:	Kasandra Lambert
To:	wvukc_users@listserv.wvu.edu
Subject:	WVU OHRP October Newsletter
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October 2023 Newsletter

In this email:

Update - Revised NHSR process on hold:

Implementation of the revised Not Human Subjects Research submission process is being rescheduled until next year (2024). Currently, no changes will be made to the existing NHSR/Flex submission process. If you have questions or concerns, please contact the OHRP office at irb@mail.wvu.edu.

Federal Agency Updates/Reminders:

1. FDA recently issued Warning Letter documenting AI software constitutes medical device
    a. The following guidance is available for determining whether an AI tool may meet the definition of a medical device:
        i. FDA Clinical Decision Support Software Guidance for Industry and Food and Drug Administration Staff
        ii. Regulatory Guidance for Academic Research of Drugs and Devices
2. NIH Request of Information: Guidance about Digital Health Technologies – NIH has issued a request for information regarding digital health technologies and provided preliminary guidance for consent language when these technologies are utilized.

Tips and Tricks:

1. **WVU OHRP Forms:** Always visit the WVU OHRP Forms page when starting a new study. Forms change from time to time and the forms page will always host the most up-to-date content to ensure regulatory compliance.

2. **Submission Tracking in WVU+kc:** You can track the review process and see where your protocol is by clicking the "Protocol Actions" tab in your WVU+kc submission. Click "Route Log" and navigate to "Pending Actions Request" to see who has the submission.

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Contact us at IRB@mail.wvu.edu