From:	Kasandra Lambert
To:	wvukc_users@listserv.wvu.edu
Subject:	WVU OHRP May 2023 Newsletter
Date:	Monday, May 8, 2023 9:30:00 AM
Attachments:	image005.png image006.png image008.png image009.png image001.png

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May 2023 Newsletter

In this email:

Reminder: WVU IRB does not accept amendments for **NHSR, Flex, or Exempt** protocols. While the WVU+kc system may erroneously allow you create an amendment, it will not be accepted and if submitted, will be returned for withdrawal. Changes that may change the review type or significantly alter the study (e.g., a retrospective study that will add a prospective component) require a new submission in WVU+kc.

This policy was initiated in 2020 and WVU OHRP highly recommends study teams manage their study documentation (e.g., initial approval, changes to study staff, updates to cover letters, etc.) outside of WVU+kc.

Important:

Radiation Drug Research Committee (RDRC): For studies involving the administration of radioactive drugs to human subjects for scientific objectives, when these radioactive drugs do not already have FDA approval and/or are not being used under an IND, RDRC review is required. Study teams will be reminded in their WVU+kc IRB approval or revisions letters, when applicable, to submit their study to RDRC before recruiting any participants. Please visit https://www.hsc.wvu.edu/rsafety/wvuh-rdrc-radioactive-drug-research-committee/ for more information.

eConsent: For expedited and full board studies utilizing eConsent, study teams must upload (1) a pdf of the consent document and (2) the eICF worksheet. Question 1 of the worksheet requires a link to the eConsent framework, customized for the specific study. The study team **should not**

upload the draft consent but instead allow for review of the consent and the framework during the IRB review process. After the protocol has been approved, the study team must then upload the watermarked consent into the IRB approved eConsent framework. For more information or to submit a support request, please visit https://human.research.wvu.edu/electronic-informed-consent.

In the News

Retraction Watch – Case Study Retractions:
https://retractionwatch.com/2021/04/23/two-retractions-spotlight-the-ethical-challenges-of-consent-for-case-reports/

Tips and Tricks

1. **Study Personnel Change via Amendment:** When submitting an amendment for expedited or full board studies to add or remove study personnel, you must enter the names of the study personnel being removed or added in the Amendment Section of the WVU+kc questionnaire in addition to changes the study personnel section. This facilitates documentation of the change in the system.

2. **Continuation Reviews/Amendments:** Study teams may be asked to make additional changes/updates at the time of CR or amendment to comply with updated policies and procedures, for clarity, or as a result of updated regulations. WVU OHRP/IRB has the discretion to review the entire submission when changes are being made or the protocol is being renewed.

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