COMPLIANCE CONNECTIONS

ECU RESEARCH ADMINISTRATION AND COMPLIANCE

A quarterly newsletter from the Division of Research, Economic Development and Engagement's research compliance offices

University and Medical Center Institutional Review Board (UMCIRB)

Virtual Operations

The UMCIRB continues to hold IRB meetings by WebEx at their regularly scheduled times. The UMCIRB office staff is available by email, phone, WebEx or Microsoft Teams to assist investigators with any questions they may have. Reach out at **umcirb@ecu.edu** or by phone at 252-744-2914.

Amendments

Any changes to your IRB approved processes or procedures must be approved by submitting an amendment to the UMCIRB office. This includes changes related to moving a study to a virtual environment secondary to COVID restrictions, changing the method of paying participants from gift cards to the Greenphire debit card, or adding new study team members. The UMCIRB must approve the amendment before initiating any changes unless the changes are immediately necessary to protect the participants' safety. However, the UMCIRB must be notified within 24 hours of implementing these changes.

Post-IRB Approval Monitoring (PAM)

The purpose of this program is to provide internal oversight and monitoring of compliance issues relating to the performance of human research studies while assuring human subject safety in research and success of the investigators and their study teams.

How is monitoring defined for the post-IRB approval monitoring program at ECU?

Monitoring can be defined as overseeing the process of human subject research, including clinical trials, ensuring the research is conducted, recorded and reported in accordance with the protocol, standard operating procedures, best practices, and applicable regulatory requirements.

Are there different types of monitoring?

Yes, three types of monitoring may occur:

- Routine post-IRB approval monitoring is a compliance review of the conduct of IRB-approved studies that are meant to be educational to help improve research practices. Those monitored are selected without bias on specific and objective criteria, which may include studies that are federally funded, internally funded, pose greater than minimal risk, are overseen by an external IRB for review and approval, or are led by a principal investigator (PI) with minimal experience. Routine monitoring may also be requested by the PI or study team.
- Focused monitoring is the review of an IRB-approved study where the monitoring focuses only on one aspect of the study. For example, review of only the consent documents and process, review of inclusion or exclusion criteria, etc.
- For-cause monitoring of a study occurs when there are perceived or confirmed ethics or compliance violations. For-cause monitoring may be requested by a department, study team member(s), UMCIRB staff, the IRB, or other institutional officials. For-cause monitoring visits are requested generally due to concerns regarding study compliance or subject rights and welfare. It may also be initiated due to complaints, repeated errors, or a lack of PI responsiveness to IRB requests.

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