October 28, 2020

Re: Common Information Requested by Sponsors

Dear Principal Investigator:

This information is being provided in response to common requests from sponsors. Please forward this letter to sponsors as needed.

Federalwide Assurance (FWA) and Institutional Review Board (IRB) Registration:

East Carolina University holds FWA number 00000658. With this FWA, ECU assures that it will meet all requirements of Title 45, Part 46 of the Code of Federal Regulations (45 CFR 46) for all human subjects research supported by the federal government.

ECU is in compliance with both Department of Health and Human Services (DHHS) regulations at 45 CFR 46 Subpart E and Food and Drug Administration (FDA) regulations at 21 CFR 56 requiring IRB registration with DHHS. Sponsors may verify the ECU FWA and IRB registrations online.

IRB Membership:

ECU IRBs meet membership requirements of both DHHS (45 CFR 46.107) and FDA (21 CFR 56.107) regulations. Sponsors may access the current member rosters on the UMIRB website. Furthermore, the ECU IRBs comply with both set of regulations stating that “No IRB may have a member participate in the IRB’s initial or continuing review of any project in which the member has a conflicting interest except to provide information requested by the IRB.” Members with a conflicting interest are asked to leave the room during discussions and voting, although they may be invited to provide information to the IRB before its discussions or vote. Please refer to the standard operating Practice (SOP) entitled IRB Membership on the UMIRB website for additional information if needed.

Electronic IRB System and Documentation of IRB Approval:

All UMIRB review and approval activities are conducted in a web-based electronic submission and tracking system (ePIRATE). Applications are no longer accepted in other formats.

ePIRATE is a closed system designed with securities to 1) allow only appropriate individuals to execute approval activities and 2) to log the author and time for all approvals issued. The approval notices do not contain an actual signature as they are created, issued, and stored electronically in compliance with FDA regulations at 21 CFR 11.

I hope the above information will answer your study sponsor’s questions. If there are other questions, please refer your sponsor to the UMIRB office at 252-744-2914 or umirb@ecu.edu.

Sincerely,

Suzanne Sparrow
Director, Human Research Protections
University and Medical Center Institutional Review Board (UMIRB)