Western IRB (WIRB) Review and Approval of Sponsored Clinical Trials at East Carolina University

East Carolina University (ECU) has entered into an agreement wherein reliance on WIRB for review and approval of sponsored clinical trials is permitted. This document provides the reader with the information needed regarding this agreement and the process for relying on WIRB for review and approval of a sponsored clinical trial.

For the purposes of this document a sponsored clinical trial is one that is funded by an industry sponsor **AND** the sponsor of the study has selected WIRB to be the IRB of record for review and approval of their clinical trial.

Process:

After thorough consideration of feasibility you have made the decision to open a sponsored clinical trial (as defined above) locally for eligible participants.

Step #1 – Register to use WIRB's electronic IRB submission portal, wcgConnexus (aka Connexus).

Persons serving as investigators and other key study personnel must be registered to use WIRB's electronic IRB submission system, Connexus. Click Here for instructions on how to register. **PLEASE NOTE:** Your registration is processed by the staff at WIRB, NOT by the Office of Research Integrity & Compliance (ORIC) staff. If you have questions about the registration process or the status of your registration you should contact: JayLynn Geiger-Goddard at jgoddard@wirb.com or 1-360-252-2493.

Step #2 – Familiarize yourself with WIRB processes and the use of Connexus via training materials found on the Connexus site.

After your registration has been processed and access granted, you may log in and begin using Connexus. Once logged into Connexus you will have access to training documents and materials as well as links which will take you to the WIRB electronic IRB submission application. These documents, materials and links all appear on your Connexus Home Page. One of the documents available for your review/use is titled "Guide for Researchers". This is a 171 page guide providing a comprehensive overview of WIRB's processes as well as clinical research issues. To locate this guide, click on the link (on your Connexus home page) titled "IRB Info and guides". Clicking on this link will take you to a screen where you will find the document under the heading "WIRB".

Step #3 – Submit for WIRB review and approval the request to allow you to conduct the clinical trial at your site.

Once you have completed the self-guided training you may submit an application for approval of your site to be included in the clinical trial. **REMINDER** – The consent documents which you will submit to WIRB for review and approval must contain the required ECU boilerplate language that has always been required. Click Here to view the required boilerplate language. Once your study has received approval from WIRB **AND BEFORE** you initiate the study locally, your study must undergo local institutional Ancillary Review and receive approval from all required ancillary reviewers.

Step #4 – Submit your WIRB approved study for local Ancillary Review via ePIRATE.

Review and approval by WIRB, of a sponsored clinical trial, does not do away with the requirement for review and approval by local institutional officials (aka Ancillary Review). This review will continue to be conducted via ePIRATE. In the case of studies reviewed and approved by WIRB, after receipt of WIRB IRB approval, you will access ePIRATE and "Create a New Study". You will complete all required screen views in Section I – Study Identification of the ePIRATE study smart form. In screen view 1.5 – Study Locations, you will respond "Yes" to question #6.0. Responding "Yes" to this question will require that you complete screen view 1.53 – External IRB wherein you will upload all of the applicable WIRB approved study documents and approval dates. When you click "Continue" in this screen view you will be directed to screen view 11.0 – Institutional Ancillary Approval where you will need to accurately respond to questions 1.0 - 5.0 and continue onward through the remainder of the required screen views providing responses required for ancillary review. Once you have completed this abbreviated submission for ancillary review you will exit the smart form and click

"Submit Study". This will forward the study for Ancillary Review only. Once all ancillary reviews are completed and approvals granted, ORIC staff will perform a limited review to ensure all information has been provided. You will receive an email from ePIRATE confirming authority over the study has been granted to an external IRB.

Step #5 – Begin your study.

You may initiate your study locally only after you have received the email, described above, from ORIC via ePIRATE.

PLEASE NOTE:

- The CITI training requirements remain unchanged. Investigators and all key study personnel must comply with the requirement to complete the training for human subject research and maintain this training by taking the refresher course every three years.

- The consent documents which you will submit to WIRB for review and approval must contain the required ECU boilerplate language that has always been required. Click Here to view the required boilerplate language.

- Once the limited ORIC review is complete and the email is generated confirming authority over the study has been granted to an external IRB you will find that your study will be in a state called "External IRB". This is a new state in ePIRATE.

- When clinical trials approved by WIRB are amended and/or receive approval for continuation you are responsible for reporting this to ORIC via ePIRATE. To provide amended documents and updated approvals from the external IRB, click the button titled "Update External IRB Status" which you will find under the heading "My Activities" on the left side of the screen of the study workspace in ePIRATE.

- Reportable Events will continue to be submitted as usual in ePIRATE.

Questions related to the agreement between ECU and WIRB should be directed to the ORIC Administrative Director at 252-744-1971.

Questions related to Connexus, WIRB processes and the status of a WIRB submission should be directed to JayLynn Geiger-Goddard at jgoddard@wirb.com or 1-360-252-2493.