Decision Tree to Help Decide Whether HIPAA Applies in Human Research Activities at ECU

Are you (or any member of the study team) a workforce member of a designated ECU Health Care Component (HCC)?

No

Will any part of your research study require the use of an ECU HCC to:

1. Obtain data for your study,
2. Conduct your study, or
3. Recruit individuals for your study

No

STOP

Your research does not use protected health information (PHI) covered by HIPAA.

Yes

Will you be using any existing Protected Health Information (PHI) to prepare your protocol or identify and recruit individuals into your study?

Yes

You must prepare a Reviews Preparatory to Research form. Contact the HIPAA Privacy Officer for additional information.

If you do not work for an ECU HCC, but wish to recruit from an ECU HCC by obtaining any PHI for an individual, you must complete an Alteration of HIPAA Authorization for Recruiting.

Does your research access, create, store, maintain or receive any PHI (whether from electronic transmissions and media; paper; verbal; photographs; audio/visual recordings; demographic information or biological specimens/tissue samples)? See the list of identifiers that make health information protected.

No

STOP

Your research does not use protected health information (PHI) covered by HIPAA.

Yes

Please complete and submit the appropriate ECU HIPAA forms. All HIPAA forms for research are located on the ORIC website under HIPAA Forms and Information. In addition, you must comply with ECU's Sensitive Data security requirements to protect PHI.

If you are not using PHI from an ECU HCC but from a HCC not under the jurisdiction of ECU or an ECU Affiliate, you must comply with the HIPAA procedures (and forms) of the covered entity where the PHI will be obtained. In addition, you must comply with ECU's Sensitive Data security requirements to protect that PHI.