Decision Tree for 2: Determining Pathway to Use PHI for Research

Use this decision tree to determine the appropriate pathway to access or use PHI in research. See Decision Tree 3 for use of PHI in recruitment activities.

Will you record any of the 18 HIPAA identifiers in your research records? — No → Submit a request to use De-identified Data with your IRB application.

Yes ↓

Will you be interacting or intervening with a living individual? — Yes → Obtain signed authorization from each research participant to use or access PHI. Submit an authorization form or combined informed consent/authorization to the IRB for review and approval.

No ↓

Are all research subjects about whom data will be collected deceased? — Yes → Submit a Research with Decedents Form to ORSP.

No ↓

Are you applying to the IRB for a waiver of consent or conducting exempt chart review research? — Yes → Apply to the IRB for a waiver of authorization.

No ↓

Will all identifiers except geographic information above street level and dates be removed from the data? — Yes → Apply to the IRB for a Limited Data Set and submit a Data Use Agreement to ORSP with your IRB application.

No ↓

Call ORSP for assistance.