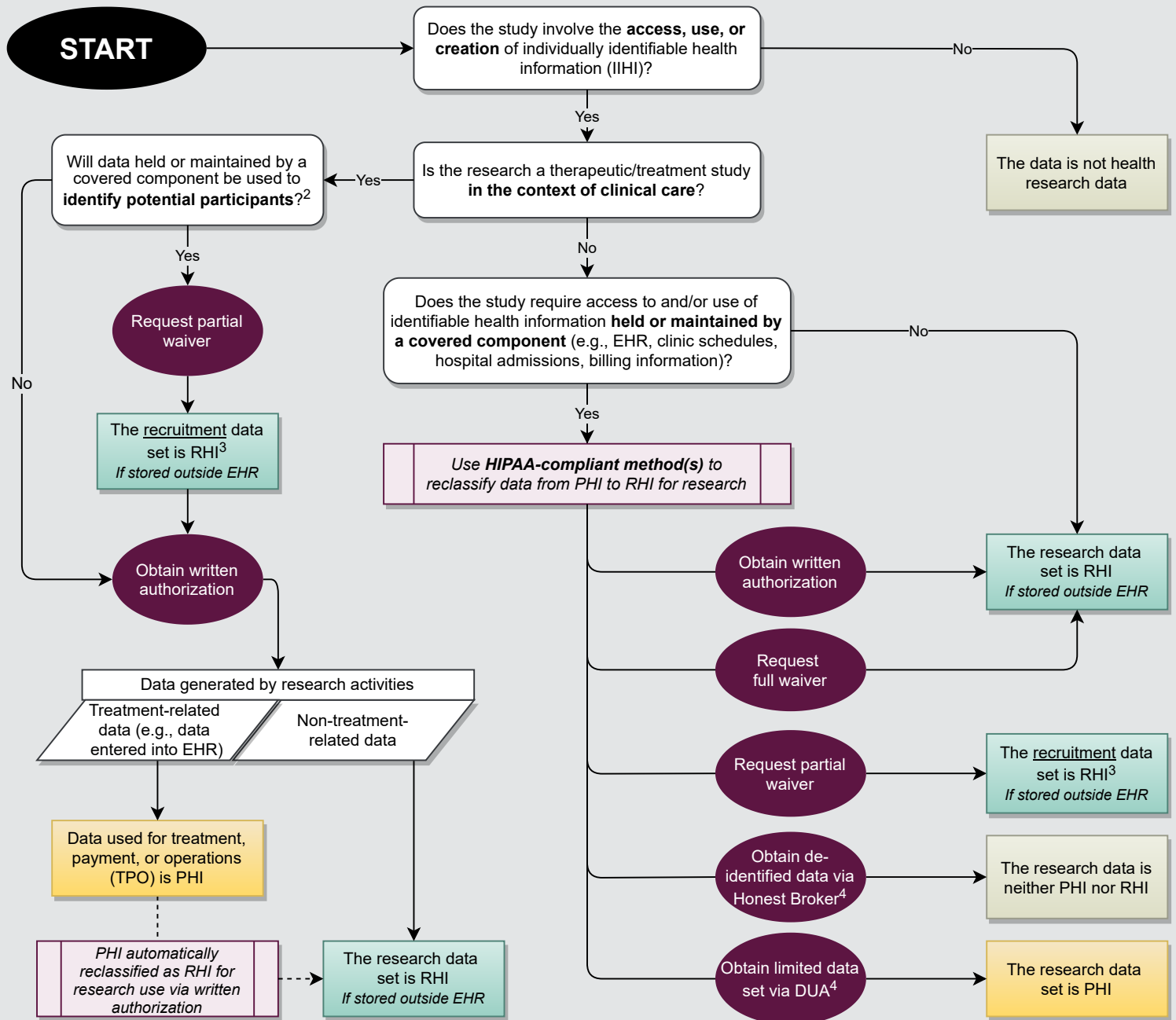


DECISION TREE: IS MY RESEARCH DATA SET PHI OR RHI?

Use the decision tree to determine if your research data set is Protected Health Information (PHI) or Research Health Information (RHI) based on the regulatory mechanism under which the data were obtained.

RESEARCHERS MUST FOLLOW UNIVERSITY AND COVERED COMPONENTS' POLICIES FOR OBTAINING PHI FOR RESEARCH PURPOSES.



Notes:

¹ This decision tree accounts for most scenarios in which Ohio State researchers access or use PHI held by one or more of the institution's covered components. Some scenarios, such as collaborative research with external institutions, may not be represented by the chart. Some studies may include multiple components that require multiple methods of reclassifying PHI as RHI for research use (e.g., a therapeutic clinical trial with a historical control arm).

² Answer "Yes" if any researcher NOT on patients' clinical care team will perform this activity. Answer "No" if clinicians will identify and recruit their own patients.

³ Data collected under a partial waiver must be destroyed at the end of the recruitment period unless HIPAA research authorization or a full waiver is obtained.

⁴ Unless FDA-regulated, research solely using data obtained via this method does not constitute human subjects research under Ohio State HRPP policy.

This decision tree is provided for educational purposes only and should not be considered an official regulatory document.