Preparatory to Research Activities Provision Guidance

Under HIPAA, "Preparatory to Research Activities" are those that involve the use of potential participants’ information for the purpose of preparing a research study, but not for the actual research itself. If your study involves the use of Protected Health Information (PHI), beyond Preparatory to Research Activities, HIPAA applies.

See following guidance about Preparatory to Research Activities:

### Acceptable Activities
- Accessing, reviewing, or collecting information from medical records, as needed, to prepare for research studies.
- Examples include identifying and recruiting potential research participants, assessing the feasibility of a study, and screening for eligibility/exclusion criteria.

### Stipulations
- Activities cannot interfere with patient care/services, medical treatment, or healthcare decisions.
- Information must be kept confidential; accessed in alignment with the Minimum Necessary Requirement (45 CFR 164.502(b), 164.514(d)); and is restricted to study team members directly involved in research preparation.

### PHI/HIPAA Authorization
- Information collected during preparatory activities is not PHI until enrollment in the study. Prior to enrollment, such activities are allowed without authorization or a waiver of authorization.
- Once a participant has been enrolled in the study, their information is PHI and a HIPAA Authorization Form is required.

For further information, please refer to the HIPCO website.