

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](#).