University of Maryland Baltimore

Human Research Protections Program (HRPP) Tip of the Month

September 2026

HIPAA Tools for Research: What You Need to Know

Protected Health Information (PHI) is health information that can be connected to a specific person. When research involves PHI, there are several ways the information may be used or shared:

- **Participant Authorization:** Signed permission from a participant specifying what PHI may be used, who may use or receive it, and other required information.

- **Full HIPAA Waiver:** Allows the research team to use or access PHI without obtaining HIPAA authorization from each participant, when the requirements for a waiver are met.

- **Partial HIPAA Waiver for Recruitment:** Allows the research team to access limited PHI before a person joins the study so they can identify people who may qualify and/or contact them about the study. The waiver is limited to the approved recruitment activities.

- **Limited Data Set (LDS) + Data Use Agreement (DUA):** Allows researchers to use health information after direct identifiers, such as names and medical record numbers, have been removed. Because the information may still contain details like dates or geographic information, a Data Use Agreement is required to ensure the data is used and protected appropriately.

- **De-identified Data:** Health information that has been stripped of all 18 HIPAA identifiers. Because the information can no longer be readily linked to an individual, it is not considered PHI under HIPAA. Whether IRB review is required is determined separately.