The U.S. Department of Health and Human Services (HHS), National Institutes of Health (NIH), has provided a detailed summary of how the Health Insurance Portability and Accountability Act (HIPAA) affects Institutional Review Boards (IRBs). Full details can be found at the following link: https://privacyruleandresearch.nih.gov/irbandprivacyrule.asp

Certain types of human subjects research involve the use of protected health information (PHI). When that occurs, it is imperative that researchers and IRB reviewers be aware of the HIPAA Privacy Rule.

Following is a summary of some of the key points of the summary in relation to IRBs. **DISCLAIMER:** The below summary is not meant to be exhaustive nor to be used for making legal decisions. Please refer researchers to the full document in the above link, and require they obtain a review of their data management plan from the HSU Office of Information Security (Josh Callahan: 707-826-3815), obtain IRB approval from all required entities, and work with the Office of Research prior to obtaining or collecting any HIPAA data.

"Institutional Review Boards and the HIPAA Privacy Rule": Summary of Major Points

- The Privacy Rule establishes a category of health information, defined as protected health information (PHI), which a covered entity may only use or disclose in certain circumstances and under certain conditions.
    - Covered entities are health plans, health care clearinghouses, and health care providers that transmit health information electronically.
    - Researchers are not themselves covered entities, unless they also provide health care and engage in covered electronic transactions.
    - A researcher who is not a covered entity or a workforce member of a covered entity may be indirectly affected by the Privacy Rule if a covered entity supplies the research data.
- The Privacy Rule requires an individual to provide signed permission, known as an Authorization, before a covered entity can use or disclose the individual's PHI for research purposes.
- A covered entity can use or disclose PHI for research without an Authorization by obtaining a waiver of the Authorization by an IRB.
    - An IRB's authority to approve a waiver or an alteration of the Privacy Rule's Authorization requirements is new and in addition to traditional IRB authority under 45 CFR part 46 (Department of Health and Human Services [HHS] Regulations for the Protection of Human Subjects).
    - A waiver in whole occurs when the IRB determines that no Authorization will be required for a covered entity to use or disclose PHI for a particular research project because certain criteria in the Privacy Rule have been met. For example, if a study involved the use of PHI pertaining to numerous individuals where contact information is unknown, the IRB could waive all of the Authorization requirements.
- An IRB may also approve a request that removes some, but not all, required elements of an Authorization (an alteration).
- The criteria for an IRB waiver or alteration of the Authorization are consistent with the criteria for IRB waiver of the informed consent requirements contained in the HHS Regulations.
    - The three criteria are:
        - The use or disclosure of PHI involves no more than a minimal risk to the privacy of individuals, based on the presence of the following elements:
            - An adequate plan to protect the identifiers from improper use and disclosure

- An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of research, unless a health or research justification for retaining the identifiers or such retention is otherwise required by law
- Adequate written assurances that the PHI will not be reused or disclosed except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be permitted by the Privacy Rule

  - The research could not practicably be conducted without the waiver or alteration.
  - The research could not practicably be conducted without access to and use of the PHI.

- When acting upon a request to waive or alter the Authorization, an IRB must use either the normal full board or expedited review procedures.
- Documentation supporting an IRB's approval of a waiver or an alteration of Authorization must include a description of the PHI without access to and use of which the IRB has determined the research could not practicably be conducted.
- The IRB is the entity that decides whether or not and the extent to which a waiver or alteration of Authorization is granted, and it is the IRB that makes the final decision regarding the description of the PHI to be included in the IRB's documentation.
- A modification to a previously approved research protocol, which only involves the addition of an Authorization for the use or disclosure of PHI to the IRB-approved informed consent, may be reviewed by the IRB through an expedited review procedure, since this is a minor change to research.

- An Authorization may be combined with the informed consent document for research. If the informed consent document is combined with an Authorization, the IRB would be required to review the combined document under 45 CFR part 46 of the HHS Regulations.
- IRBs are not required to approve stand-alone Authorizations or Authorizations combined with informed consent under the Privacy Rule. The Privacy Rule only requires that the Authorization comply with the requirements of the Privacy Rule.
- Neither the HHS nor FDA Protection of Human Subjects Regulations require IRBs to oversee investigators' compliance with the Privacy Rule.