

## HIPAA: A QUICK REVIEW

The regulations associated with HIPAA are lengthy and complex, but here are the key points:

- HIPAA's privacy protections for health information supplement those of other federal regulations and any applicable state laws.
- HIPAA protects identifiable health information -- also known as "protected health information" or PHI.
- HIPAA's rules on use and disclosure of PHI are generally "purpose-based" -- that is, governed by the intended use. The rules for activities defined as research are different from those for other covered activities.
- De-identified data are not protected, and some identifiable health information may not be considered PHI, depending on how it was generated.
- Limited data sets may be used as a middle ground between PHI and de-identified data, but require a data use agreement.

## HIPAA RESEARCH: AUTHORIZATION (CONSENT) OR NOT?

**HIPAA only applies to Health Research or any research creating medical data, using medical records/database or interacting with medical facilities.** Like the Common Rule, HIPAA begins with the premise that using PHI for research requires a subject's permission. If the data in question meet the definition of PHI and are being used for purposes that fall within HIPAA's definition of research, explicit written authorization (consent) from the subject is required.

However, HIPAA allows for research-related access to individuals' identifiable health data without authorization under certain circumstances:

1. The research involves only minimal risk. This research may request a waiver.
2. The research is used solely for activities preparatory to research. This research may request a waiver.
3. Only deceased individual's information is used.
4. It is "grandfathered" research where all legal permissions were in place before HIPAA took effect.

Data that do not identify individuals can be used for research without specific authorization if:

1. Only fully de-identified data are used (by definition, it is then no longer PHI).
2. A "limited data set" is used, under an approved "data use agreement."

**The Cherokee Nation Institutional Review Board (IRB) and Privacy Officer have the authority to make the final determination of HIPAA requirements or waivers, and may require alteration of the any study's authorization forms.**

Below is a HIPAA decision tree that will help us determine if your study need to include a HIPAA authorization form or a HIPAA waiver in your application:

# Determining When HIPAA Applies to Health Research

