

Use of Coded and Non-Coded Biospecimens and Data

Definitions

Coded: Identifying information that would enable the investigator to readily ascertain the identity of the individual to whom the specimens or data belong has been replaced with a letter, number, symbol, or combination thereof (the code), and a key to decipher the code exists that enables identification of the private information or specimens

Identifiable private information - private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

Determination of human subjects research

Research involving only coded private information or specimens is not research involving human subjects under 45CFR46.102(f) if the following conditions are met:

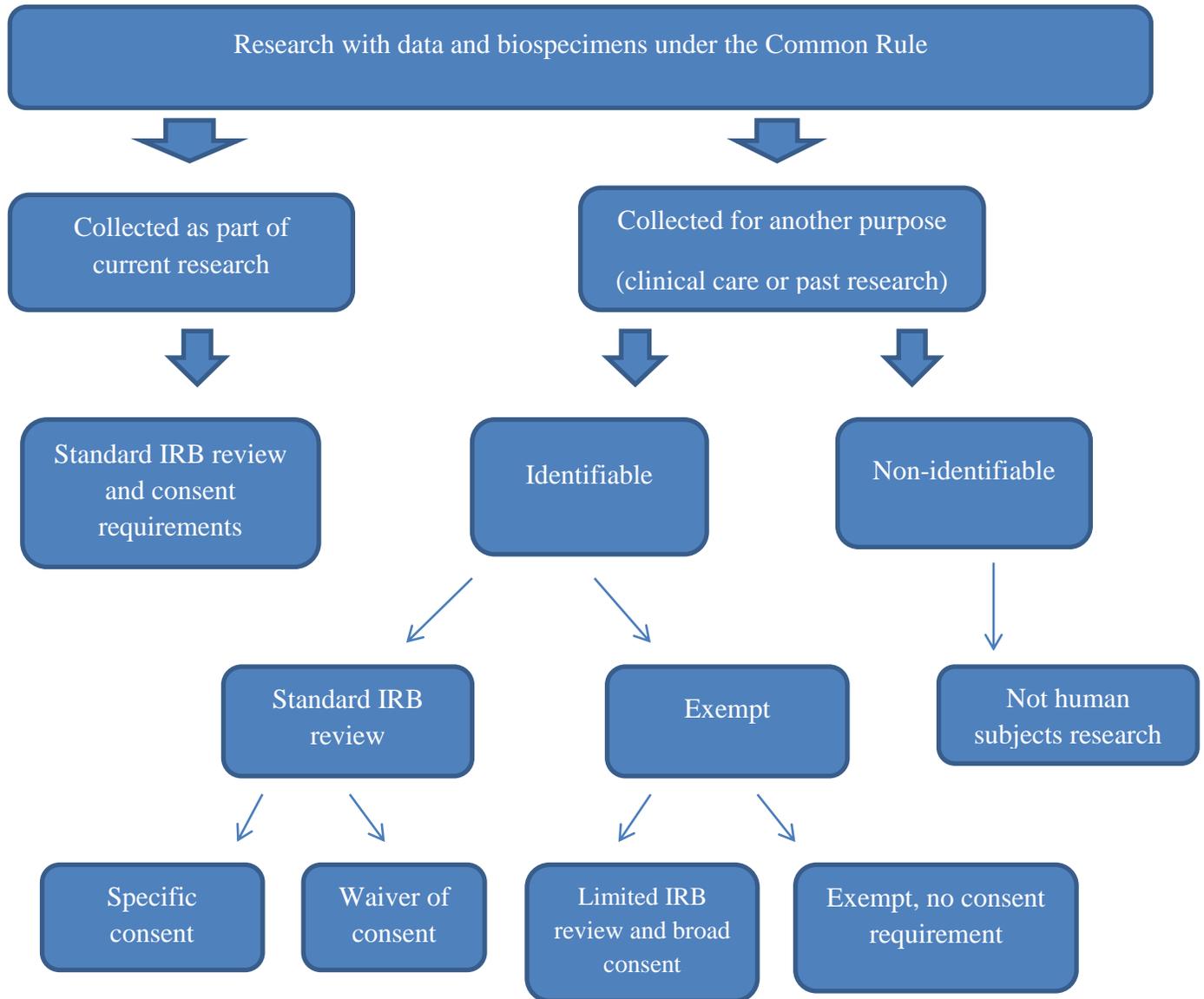
- The information or specimens were not collected specifically for the proposed research project through interaction or intervention with living individuals, AND
- The investigators cannot readily ascertain the identity of the individuals.

In order for a research study involving biological specimens to be exempt, there cannot be a link to coded specimens in existence.

Information that is coded using a link derived from identifying information or is related to information about the individual is not considered to be “individually identifiable” under HHS regulations (45CFR46.102(f)) if the investigators cannot readily ascertain the identity of the individuals. Some information coded in this manner may be considered “individually identifiable” under the Privacy Rule, but not under 45CFR46.

The Human Protections Administrator (HPA) will make the determination as to whether or not research involving coded private information or specimens constitutes human subjects research. Investigators will not make this determination. The IRB Chair will make the final determination as to if a proposed study involving private information or biospecimens is exempt under 45CFR46.101(b).

For guidance on research with data or biospecimens under the Common Rule, please consult the decision chart below:



[Providing information or biological specimens for research](#)

Providing private information or biological specimens to researchers is not research; if the provider also participates in the conduct of the research, such as study, interpretation, or analysis of data, or is an author on presentations and manuscripts, then the provider is conducting research.

Sharing coded data

Data that has all 18 HIPAA identifiers removed that has been coded using a link with a master list that is kept at Woman's may be shared with another institution. The list linking the shared list with the Woman's master list containing identifiers should be destroyed when the study is completed.