

Research Involving Private Information or Biological Specimens

Are the specimens/data obtained from living individuals?

NO, individuals are NOT living

NOT Human Subjects Research

YES, individuals ARE living

Are the specimens/data:

- Human cell lines obtained from a commercial provider (e.g. ATCC); or
- Human cells about which all information has been published; or
- Unidentifiable specimens/data obtained from a commercial provider; or
- Unidentifiable specimens/data obtained from an provider that is prohibited from releasing identifiers by established regulations or policies

NO

Were/will the specimens/data (be) collected specifically for the proposed research through an interaction or intervention with living individuals?

NO

Can the *recipient* link the specimens/data **directly** to identifiable living individuals?

NO

Can the *provider* link the specimens/data, directly or indirectly, to identifiable living individuals?

NO

NOT Human Subjects Research

YES

Does the *provider* meet the definition of an “investigator” in the recipient’s research?

NO, *provider* is “solely providing”

Are the specimens/data provided with a code linking them to identifiable living individuals?

NO

NOT Human Subjects Research

YES

Can the *recipient* readily ascertain the identities of the individuals to whom the specimens/data pertain? Examples of situations in which the recipient **cannot** link the specimens/data to living individuals include:

- the key to decipher the code is destroyed before the research begins; or
- the investigators and the holder of the key to the code enter into an agreement preventing the release of the key to investigators under any circumstances; or
- there are IRB-approved written policies in place preventing the release of the key under any circumstances; or
- there are other legal requirements prohibiting the release of the key under any circumstances.

NO

NOT Human Subjects Research

YES

NOT Human Subjects Research

YES

Human Subjects Research

YES

Human Subjects Research

YES, *provider* is collaborating in recipient’s research

Human Subjects Research

YES

Human Subjects Research