

Research Involving Private Information or Biospecimens

Are the biospecimens/information obtained from living individuals?

NO, individuals are NOT living

NOT Human Subjects Research

YES, individuals ARE living

Are the biospecimens/information:

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

NO

YES

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

NOT Human Subjects Research

NO

YES

Can the *recipient* link the biospecimens/information **directly** to identifiable private information of living individuals?

Human Subjects Research

NO

YES

Can the *provider* link the biospecimens/information **directly** to identifiable private information of living individuals?

Human Subjects Research

NO

YES

NOT Human Subjects Research

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

NO, the *provider* is “solely providing”

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

Human Subjects Research

Are the biospecimens/information provided with a code linking them to identifiable private information of living individuals?

NO

YES

NOT Human Subjects Research

Can the *recipient* readily ascertain the identities of the individuals to whom the biospecimens/information pertain? Examples of situations in which the recipient **cannot** link the biospecimens/information 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

YES

NOT Human Subjects Research

Human Subjects Research

Please note: this document is intended to be a resource only. Final decisions should be made in accordance with [45 CFR 46](#).