

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 a provider that is prohibited from releasing identifiers by established regulations or policies

NO

YES

Were/will the specimens/data (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 specimens/data **directly** to identifiable living individuals?

Human Subjects Research

NO

YES

Human Subjects Research

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

NO

YES

NOT Human Subjects Research

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

NO, *provider* is “solely providing”

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

Human Subjects Research

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

NO

YES

NOT Human Subjects Research

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

YES

NOT Human Subjects Research

Human Subjects Research

For Human Subjects Research, an investigator is defined as anyone involved in the research, including but not limited to: sponsor, co-sponsor, mentor, co-mentor, collaborator doing anything more than providing the sample, anyone who is expected to be a co-author on a publication resulting from the research.