Research Involving Private Information or Biospecimens

Are the biospecimens/information obtained from living individuals?

- NO, individuals are NOT living
  - NOT Human Subjects Research
  - 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

- YES, individuals ARE living
  - Research Involving Private Information or Biospecimens
  - Were/will the biospecimens/information (be) collected specifically for the proposed research through an interaction or intervention with living individuals?
    - NO
      - NOT Human Subjects Research
    - YES
      - Can the recipient link the biospecimens/information directly to identifiable private information of living individuals?
        - NO
          - NOT Human Subjects Research
        - YES
          - Can the provider link the biospecimens/information directly to identifiable private information of living individuals?
            - NO
              - NOT Human Subjects Research
            - YES
              - Does the provider meet the definition of an “investigator” in the recipient’s research?
                - NO, the provider is “solely providing”
                  - NOT Human Subjects Research
                - YES, the provider is collaborating in the recipient’s research
                  - Are the biospecimens/information provided with a code linking them to identifiable private information of living individuals?
                    - NO
                      - NOT Human Subjects Research
                    - YES
                      - 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.

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

NIH Office of Extramural Research - June 25, 2019