- “Repository Investigator” holds the “sample”
- “Sample” = RESEARCH data or tissue in a database or tissue bank.
- “Recipient Investigator” requests data or tissue for RESEARCH use (for a sub-study or another study).

**Repository Investigator’s Responsibilities**

**Type of Sample to be released**

- **Anonymous**
  - Repository Investigator must get the following from the Recipient Investigator:
    - a. IRB Approval or Exempt letter
    - b. HIPAA form
  - Repository Investigator can then release data/tissue. Must ensure that all samples are anonymous.

- **Coded**
  - Repository Investigator must review original consent to see if subjects agreed to future use of their data/tissue by others.
  - Did subjects specifically consent for this future research use?
    - **Yes**
      - IRB may approve a Waiver of Consent and HIPAA Waiver for release of specimens, if the new study meets the waiver criteria or the IRB could require that subjects be reconsented before samples are used in future research
    - **No**
      - Repository PI must get from Recipient PI:
        - a. IRB approval for new study
        - b. Approved HIPAA form

- **Identified with direct identifiers**
  - Repository Investigator must get the following from the Recipient Investigator:
    - a. IRB approval for new study
    - b. Approved HIPAA form