Does the research involve only the collection or the study of *existing* data, documents, records, pathological specimens or diagnostic specimens?*

("Existing" means existing *before* the research is proposed to an institutional official or the IRB to determine whether the research is exempt.)

- **Yes**
  - Are these sources *publicly available*?
    - **Yes**
      - Will information be recorded *by the investigator* in such a manner that the subjects *cannot be identified*, directly or through identifiers linked to the subjects?
        - **Yes**
          - Research is exempt under 45 CFR 46.101(b)(4) from all 45 CFR part 46 requirements
        - **No**
          - Research is **NOT** exempt under 45 CFR 46.101(b)(4) from 45 CFR part 46 requirements
          - Go to Chart 8
    - **No**
      - Research is **NOT** exempt under 45 CFR 46.101(b)(4) from 45 CFR part 46 requirements
      - Go to Chart 8

*Note: See OHRP guidance on research use of stored data or tissues and on stem cell at http://www.hhs.gov/ohrp/policy/biodata/index.html

Adapted from http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html#c5