Flowchart 1
COLLECTION AND BANKING OF SPECIMENS AND/OR ASSOCIATED DATA FOR RESEARCH

This flowchart was designed to help illustrate when the collection and banking of specimens and/or associated data for research is considered human subject research under the HHS Human Subject Protection Regulations, 45 CFR part 46 (http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm) and when it meets the criteria for Exemption #4 [45 CFR part 46.101(b)]. A second, companion flow chart (Flowchart 2) should be used for the research use of specimens and associated data obtained from a repository.

Are the individuals from whom the specimens and/or associated data are obtained alive?

Yes

Not Human Subjects Research

No

Are the specimens and/or data obtained from an interaction/intervention with the subject specifically for the research?

Yes

Human Subjects Research

No

Is identifiable private information being obtained by the investigator/repository manager?

Yes

Human Subjects Research

No

Not Human Subjects Research

Is the information/specimens pre-existing?

No

Human Subjects Research (Not Exempt)

Yes

Is the repository recording the information in such a way that the specimens and/or data cannot be identified?

No

Human Subjects Research

Yes

Exemption #4
Flow Chart 2  
RESEARCH USE OF SPECIMENS AND/OR ASSOCIATED DATA

This flowchart was designed to help illustrate when the research use of specimens and/or associated data is considered human subjects research under the HHS Human Subject Protection Regulations, 45 CFR part 46 (http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cf46.htm) and when it meets the criteria for Exemption #4 [45 CFR part 46.101(b)]. The preceding companion flowchart (Flowchart 1) should be used for evaluating the applicability of the Common Rule to collection and banking of specimens and/or associated data.

Are the individuals from whom the specimens and/or associated data are obtained alive?

- No
  Not Human Subjects Research
  Can the subjects from whom the specimens and/or data are obtained be directly or indirectly identified (e.g. through a linking code held by the repository)?

  - No
    Not Human Subjects Research
  - Yes
    Is the researcher’s access to subject identities prohibited? (e.g. by repository procedures and policies or through an agreement between the researcher and repository, etc.)

      - No
        Not Human Subjects Research
      - Yes
        Is the information/specimens pre-existing?

          - Yes
            Human Subjects Research (Not Exempt)
          - No
            Is the researcher recording the information in such a way that the specimens/data cannot be identified?

              - No
                Human Subjects Research
              - Yes
                Exemption #4

Report of the Public Responsibility in Medicine and Research (PRIM&R)
Human Tissue/Specimen Banking Working Group  March 2007
http://www.primr.org/uploadedFiles/PRIMR_Site_Home/Public_Policy/Recently_Files_Comments/Tissue%20Banking%20White%20Paper%203-7-07%20final%20combined.pdf