IRB Policy 22: Repository
Revision Date: May 15, 2007, revised October 28, 2009

I. Conditions Under Which Data and Specimens May be Collected / Accepted / Shared

An application for research involving human cell repositories should describe the condition under which data and/or specimens may be collected, accepted and/or shared. At a minimum, these conditions should stipulate that investigators collecting (or receiving) specimens or data may not be provided access to the identities of donor-subjects or to information through which the identities of donor-subjects may readily be ascertained. HIPAA regulations regarding PHI will apply.

Only the NCI-sponsored Cooperative Groups tissue banks listed on the ORD tissue banking website (http://vaww.reserach.va.gov/programs/tissue banking/default,cfm) can be used for the specified protocols without ORD approval. All research, using NCI-sponsored tissue banks, conducted at the VAMC and/or by VA personnel, shall comply will all applicable VA requirements for informed consent. (Source: Feussner, J. (8/20/01) memo to ACOS/Coordinators for R&D)

If the intent to accept, collect or share data and/or specimens is in addition to the primary research question, the informed consent addressing these particular issues, and attached as an addendum, must build upon the basic elements of informed consent and should be a clear description of (1) the procedures for collecting, accepting or sharing specimens; (2) the operation of the cell/data repository; (3) the specific types of research to be conducted; (4) the conditions under which data and specimens will be released to investigators; (5) procedures for protecting the privacy of subjects and maintaining the confidentiality of data or, if applicable, PHI, (6) any personal compensation or benefit to be gained by the investigator or the subject, and (7) whom to contact (with appropriate telephone numbers) for questions or concerns.

The ICD information describing the nature and purposes of the research should be as specific as possible. Where human genetic research is anticipated, informed consent information should include information about the (known) consequences of DNA typing (e.g., regarding possible paternity determinations). ICDs may not include any exculpatory language through which subjects are made to waive or appear to waive any legal rights. A sample ICD will be available to investigators through the IRB administrative office. HIPAA forms are available online.