Privacy, Confidentiality, and Anonymity

(a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.” 45 CFR 46.111, 21 CFR 56.111

Privacy means having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others. Confidentiality means the treatment of information that an individual has disclosed in a relationship of trust with the expectation that it will not be divulged to others in ways that are inconsistent with the understanding of the original disclosure without permission.

Methods for gathering and storing data may pose the risk of invasion of privacy and possible breach of confidentiality. To protect human subjects against such risks, investigators should use research designs that protect subjects’ privacy and confidentiality. As appropriate to the study design, this may include research procedures that provide anonymity in the data collection or de-identification of data once collected. Anonymity means that no one, including the principal investigator, is able to associate responses or other data with individual subjects. Investigators may promise anonymity only under this condition. Face to face interviews are not considered anonymous. See the Human Research Protection Program (HRPP) Manual 12-5 “Guidance on the Use of Anonymous and De-identified Data” for further explanations on anonymity.

In general, the privacy and confidentiality of subjects should not be compromised. However, legal requirements may compel a researcher to disclose subjects’ information (e.g., federal or state reporting laws, subpoenas, payments, tax laws) or allow access to the subject records (e.g., study sponsors, governmental or university officials). In certain instances, (e.g., oral history), it may be appropriate to use subjects’ names in reports or publications. In such instances, a subject’s permission for the use of his or her name should be documented in the consent process.

In order to approve research, the Institutional Review Board (IRB) will determine that, when appropriate, the research protocol or plan contains adequate provisions protect the privacy of research subjects. The IRB should consider:

- Number of individuals interacting with the subject or subject’s records
- Location of the consent process and study (public vs. private)
• Presence of individuals not associated with the study
• Sensitivity of the research
• Risk to subjects based on breach of privacy and whether safeguards are adequate

In order to approve research, the IRB will determine that, when appropriate, the research protocol or plan contains adequate provisions to maintain the confidentiality of identifiable data. The IRB should consider:
• Number of individuals with access to data
• Location of data storage
• Use of identifiers and storage with data (this may include Global Positioning Systems or Geography Information Systems data)
• Who has access to subject identifiers
• Length of data storage and what will be done with the data at the conclusion of the research
• Security of data (e.g. filing cabinet, password protected computer, etc.)
• Sensitivity of data
• Risk to subjects based on breach of confidentiality and whether safeguards are adequate

Absolute confidentiality may not be offered to subjects. Study sponsors, the U.S. Food and Drug Administration, and other university officials (e.g. Internal Audit, Research Integrity) have the right to access confidential records. In addition, an IRB or the Human Research Protection Program has the right to access subject records in the interest of protecting subjects’ rights.

Additional Considerations
For additional policies and procedures on privacy and confidentiality, see the following sections of the HRPP Manual:
2-3 State and Local Guidelines and Regulations
5-7 Privacy Board
6-6-A Student PID Policy
6-6-B Health Insurance Portability and Accountability Act
6-8-E HIV and AIDS
12-5 Guidance on the Use of Anonymous and De-identified Data

For research subject to the requirements of the U.S. Department of Energy and U.S. Department of Justice, see the following sections of the HRPP Manual:
2-2-C U.S. Department of Justice
2-2-E U.S. Department of Energy