 Regulations and Policies Related to the Research Use of Human Specimens & Data

US Regulations:

- HHS Human Subjects Regulations:
  45 CFR part 46
  http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html
- FDA Human Subjects Regulations:
  21 CFR parts 50, 56, 812
  http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm
- HIPAA Privacy Rule (45 CFR Part 160 and Subparts A and E of Part 164)
  http://www.hhs.gov/ocr/hipaa/
- HIPAA Security Rule (45 CFR Part 160 and Subparts A and C of Part 164)
  http://www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule/index.html
- The Combined Regulation Text (as of March 2013) of the HIPAA Administrative Simplification Regulations 45 CFR Parts 160, 162, 164. (This is an unofficial version that presents all the regulatory standards in one document)
  http://www.hhs.gov/ocr/privacy/hipaa/administrative/combined/index.html
- Privacy Act of 1974, 5 U.S.C. § 552a
- Health Information Technology for Economic and Clinical Health (HITECH) Act Breach Notification Interim Final Rule
  http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/breachnotificationifr.htm

Policy and Educational Documents Related to Human Subjects Protections, Privacy and Confidentiality:

OHRP Policy Documents and Educational Tools:

- OHRP Decision Charts for Determining Eligibility for Exemption and Expedited Review
  http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html
  http://www.hhs.gov/ohrp/policy/engage08.html
- OHRP: Guidance on Research Involving Coded Private Information or Biological Specimens, issued October 16, 2008
  http://www.hhs.gov/ohrp/policy/cdebiol.html
- OHRP Guidance on the Genetic Information Nondiscrimination Act: Implications for Investigators and Institutional Review Boards
  http://www.hhs.gov/ohrp/policy/gina.html
- OHRP Guidance on Withdrawal of Subjects from Research: Data Retention and Other Related Issues
  http://www.hhs.gov/ohrp/policy/subjectwithdrawal.html
- OHRP Video: Research Use of Human Biological Specimens and Other Private Information
  http://www.youtube.com/watch?v=yp5GzAmXIPM
  http://www.hhs.gov/ohrp/policy/fetal.html

Prepared by Marianna J. Bledsoe, 10/7/2013
• Fetal Tissue Transplantation Research, Public Law 103-43, Section 498A (1993)
• Human Embryonic Stem Cells, Germ Cells, and Cell-Derived Test Articles: OHRP Guidance (2002)

**FDA Guidance Documents:**

• FDA Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens That are Not Individually Identifiable
  http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm078384.htm
• FDA Guidance on Data Retention When Subjects Withdraw from FDA-Regulated Clinical Trials

**NIH/HHS Resources:**

• HHS Health Information Privacy Website
  http://www.hhs.gov/ocr/privacy/
• HHS Guidance Regarding Methods for De-identification of Protected Health Information in Accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule
• NIH Stem Cell Information
  http://stemcells.nih.gov/Pages/Default.aspx

**NIH information on Certificates of Confidentiality:**

• Certificates of Confidentiality Kiosk
  http://grants2.nih.gov/grants/policy/coc/

**International Human Research Protections:**

• International Compilation of Human Research Protections
  http://www.hhs.gov/ohrp/international/intlcompilation/intlcompilation.html

**HHS and NIH Policies Related to Resource and Data Sharing:**

• Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources (64 [246], 72090-72096, December 23, 1999);
• 1996 Public Health Service Policy Relating to Distribution of Unique Research Resources Produced with PHS Funding , NOT-OD-96-184, NIH Guide to Grants and Contracts,
• Final NIH Statement on Sharing Research Data, NOT-OD-03-032, NIH Guide to Grants and Contracts, February 26, 2003,

- NIH Policy on Genome-Wide Association Studies
  http://grants.nih.gov/grants/gwas/

- Draft NIH Genomic Data Sharing Policy