

Regulations and Policy Documents Related to the Research Use of Human Specimens and Data

US Regulations:

- HHS Human Subjects Regulations:
45 CFR part 46
<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>
- FDA Human Subjects Regulations:
21 CFR parts 50, 56, 812
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm>
- HIPAA Privacy Rule (45 CFR Part 160 and Subparts A and E of Part 164)
<http://www.hhs.gov/ocr/privacy/>
- HIPAA Security Rule (45 CFR Part 160 and Subparts A and C of Part 164)
http://www.cms.hhs.gov/SecurityStandard/02_Regulations.asp#TopOfPage
- Privacy Act of 1974, 5 U.S.C. § 552a
<http://www.justice.gov/opcl/privacyact1974.htm>
- HITECH Breach Notification Interim Final Rule
<http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveridentities/breachnotificationifr.html>

Policy and Educational Documents:

OHRP Policy Documents:

- OHRP: Issues to Consider in the Research Use of Stored Data or Tissues, guidance memorandum issued in November 1997
<http://www.hhs.gov/ohrp/humansubjects/guidance/reposit.htm>
- OHRP: Engagement of Institutions in Human Subjects Research, issued October 16, 2008
<http://www.dhhs.gov/ohrp/humansubjects/guidance/engage08.pdf>
- OHRP: Guidance on Research Involving Coded Private Information or Biological Specimens, issued October 16, 2008
<http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf>
- OHRP: Guidance on the Genetic Information Nondiscrimination Act: Implications for Investigators and Institutional Review Boards
<http://www.hhs.gov/ohrp/humansubjects/guidance/gina.html>
- OHRP: Frequently Asked Questions on Informed Consent
<http://www.dhhs.gov/ohrp/informconsfaq.html>
- OHRP: Guidance on Exculpatory Language in Informed Consent
<http://www.hhs.gov/ohrp/humansubjects/guidance/exculp.htm>

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>

HHS Documents:

The Department has published a number of educational documents on the HIPAA Privacy Rule and research (<http://privacyruleandresearch.nih.gov/>), including the following:

- NIH: Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule (issued April 14, 2003; revised 7/13/04)
http://privacyruleandresearch.nih.gov/pr_02.asp
- NIH: Research Repositories, Databases and the HIPAA Privacy Rule issued July 2, 2004 http://privacyruleandresearch.nih.gov/research_repositories.asp
- NIH: Institutional Review Boards and the HIPAA Privacy Rule, issued July 8, 2004 <http://privacyruleandresearch.nih.gov/irbandprivacyrule.asp>

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/HSPCompilation.pdf>