

Sources of Information on Legal and Ethical Issues Related to Human Specimens and Associated Data

Office of Human Research Protections Website:

- 45 CFR 46 Common Rule:
<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>
- Repository Guidance:
<http://www.hhs.gov/ohrp/humansubjects/guidance/reposit.htm>
- Coded Specimens Policy:
<http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf>
- Engagement guidance:
<http://www.hhs.gov/ohrp/humansubjects/assurance/engage.htm>

Cancer Diagnosis Program Website:

- Legal and ethical issues related to specimens; NCI-NAPBC model informed consent document:
<http://www.cancerdiagnosis.nci.nih.gov/specimens/legal.html>

The Office of Civil Rights Website:

- The HIPAA Privacy Rule:
<http://www.hhs.gov/ocr/hipaa/>

The National Institutes of Health website, HIPAA and the Privacy Rule: Information for Researchers:

<http://privacyruleandresearch.nih.gov/>

- Research Repositories, Databases and the HIPAA Privacy Rule:
http://privacyruleandresearch.nih.gov/research_repositories.asp
- Institutional Review Boards and the HIPAA Privacy Rule:
<http://privacyruleandresearch.nih.gov/irbandprivacyrule.asp>

The National Bioethics Advisory Commission report, “Research Involving Human Biological Materials: Ethical Issues and Policy Guidance”:

- <http://www.georgetown.edu/research/nrcbl/nbac/pubs.html>

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