



National Cancer Institute

U.S. National Institutes of Health | www.cancer.gov



Cancer Diagnosis Program (CDP) 
of the National Cancer Institute

[CDP Home](#) > [Human Specimens for Research](#) > Legal and Ethical Issues

Legal and Ethical Issues

- [Ethical Collection of Specimens](#)
- [How Federal Regulations Apply to Research on Human Specimens](#)

Ethical Collection of Specimens

- [Overview](#)
- [Informed consent](#)
- [Privacy and confidentiality](#)
- [Other information resources](#)

• Overview

Ethical issues related to the collection and use of human specimens for research purposes have been the subject of considerable discussion. Although the human subjects regulations detailed in the “Common Rule” (45CFR46) have not changed, application of the regulations are complicated by a variety of legal and social implications. The National Bioethics Advisory Commission’s report entitled “Research Involving Human Biological Materials: Ethical Issues and Policy Guidance” addresses many of the issues currently under discussion. The National Cancer Institute has worked with other NIH institutes and centers and with a variety of other groups to help clarify these issues and to provide education and models to assist the research community. The NIH has developed a brochure to help researchers understand how the human subjects regulations apply to the use of specimens for research.

For more information, please visit:

- [Federal Regulations on the Protection of Human Subjects \(45CFR46\) \(“Common Rule”\)](#)
<http://ohsr.od.nih.gov/mpa/45cfr46.php3>
- [National Bioethics Advisory Commission](#)
<http://www.georgetown.edu/research/nrcbl/nbac/>
- [Research Involving Human Biological Materials: Ethical Issues and Policy Guidance](#)
<http://www.georgetown.edu/research/nrcbl/nbac/pubs.html>
- NIH brochure: How the Human Subjects Regulations Apply to the Use of Specimens for Research
 - [HTML Version](#)
 - [PDF Version](#)

- [Adobe Acrobat Reader](#) is required to view the PDF file. If you do not have Acrobat Reader, you can download it free of charge from the Adobe Web site.

Several models exist for protecting subjects whose specimens are used for research, including the honest broker model, in which a tissue bank trustee ensures strict control of information flows associated with research using banked tissues, and a model developed by the former Office of Protection From Research Risks (now the Office of Human Research Protection).

- Merz, J.F., Sankar, P., Taube, S.E., LiVolsi, V.A., "Use of Human Tissues in Research: Clarifying Clinician and Researcher Roles and Information Flows," **Journal of Investigative Medicine**, Vol. 45, No. 5, June 1997.
- Issues to Consider in the Research Use of Stored Data or Tissue, Office of Protection from Research Risks, November 7, 1997.
<http://ohrp.osophs.dhhs.gov/humansubjects/guidance/reposit.htm>

• Informed Consent

Institutional Review Boards (IRB's) may waive consent for minimal risk research on existing specimens provided that the criteria stipulated in the federal regulations 45CFR46 have been met. For specimens that do not already exist, there is an emerging consensus that informed consent should be obtained for research use of identifiable specimens collected during routine medical care. Most believe that the consent for the collection, storage and research use of tissue should be explicit and separate from the routine surgical consent. The National Cancer Institute, together with the National Action Plan on Breast Cancer (NAPBC), developed and tested a model informed consent document and an accompanying patient information sheet to request consent for future unspecified research use of specimens collected during routine medical care. These documents can be downloaded in HTML or PDF format and modified as appropriate for use by research institutions collecting specimens for research purposes. The PDF version can be viewed using Adobe Acrobat Reader.

- Model Informed Consent
 - [HTML Version](#)
 - [PDF Version](#)
- Patient Information Sheet
 - [HTML Version](#)
 - [PDF Version](#)

• Privacy and confidentiality

Human specimen collections often contain links to patient identities and other personal information. The privacy and confidentiality of personal information associated with human specimens are important considerations. The NCI sponsored a workshop in 1999 to discuss the issues related to patient privacy and confidentiality in cancer research and developed recommendations for practices that would insure the confidentiality of identifiable data without erecting unnecessary obstacles to the conduct of research. These recommendations are summarized in "[Confidentiality, Data Security, and Cancer Research: A Workshop Report, December 1-2, 1999](#)" [<http://www3.cancer.gov/scienceresources/announcements/confintro.html>].

Identifiable data associated with specimens may also be subject to new Department of Health and Human Services (DHHS) regulations on the privacy of medical records, "[Standards for Privacy of Individually Identifiable Health Information](#)," [<http://www.hhs.gov/ocr/hipaa/>].

• Other information resources

Additional information on human subjects regulations and policy issues may be found on the following sites:

- [Office of Human Research Protections \(OHRP\)](#)
<http://ohrp.osophs.dhhs.gov/>

- [Office of Human Subjects Research \(NIH Intramural\)](http://ohsr.od.nih.gov/whatohsr.php3)
<http://ohsr.od.nih.gov/whatohsr.php3>

Other information on legal and ethical issues pertaining to research on human specimens may be obtained from:

- [National Institutes of Health \(NIH\), Bioethics Resources on the Web](http://www.nih.gov/sigs/bioethics)
<http://www.nih.gov/sigs/bioethics>

How Federal Regulations Apply to Research on Human Specimens

Federal requirements to protect human subjects apply to most research on human specimens (such as cells, blood, and urine), residual diagnostic specimens and medical information.

The NIH has developed a user-friendly brochure to help investigators understand how the human subjects regulations 45CFR46 apply to their research. You may download this brochure, entitled "Research on Human Specimens: Are You Conducting Research Using Human Subjects?"

- [Federal Regulations on the Protection of Human Subjects \(45CFR46\)](http://ohsr.od.nih.gov/mpa/45cfr46.php3)
<http://ohsr.od.nih.gov/mpa/45cfr46.php3>
- User-Friendly Brochure "Research on Human Specimens: Are You Conducting Research Using Human Subjects?"
 - [HTML Version](#)
 - [PDF Version](#)
 - [Adobe Acrobat Reader](#) is required to view the PDF file. If you do not have Acrobat Reader, you can download it free of charge from the Adobe Web site.

Section Last Updated: 07/25/07

[CDP Home](#) • [Contact Us](#) • [About This Site](#) • [Accessibility](#) • [Privacy Policy](#)



<http://www.cancerdiagnosis.nci.nih.gov/specimens/legal.htm>
accessed 2-13-2009