

What is a Biospecimen Resource?

NCI defines a biospecimen resource as a collection of human specimens and associated data for research purposes, the physical structure where the collection is stored, and all relevant processes and policies. Biospecimen resources vary considerably, ranging from formal organizations to informal collections of materials in an individual researcher's freezer.

NCI's Biospecimen Activities

2008

- Symposium "Advancing Cancer Research Through Biospecimen Science"
- National education and outreach program about the NCI Best Practices

2007

- Workshop "Custodianship and Ownership Issues in Biospecimen Research"
- FGGs revised based on public comments and renamed NCI Best Practices for Biospecimen Resources

2006

- First-Generation Guidelines for NCI-Supported Biorepositories (FGGs) published in Federal Register

2005

- caBIG™ software tools for biorepositories developed

2004

- Analysis of NCI-supported biospecimen resources conducted
- Trans-NCI Biorepository Coordinating Committee (BCC) formed

2003

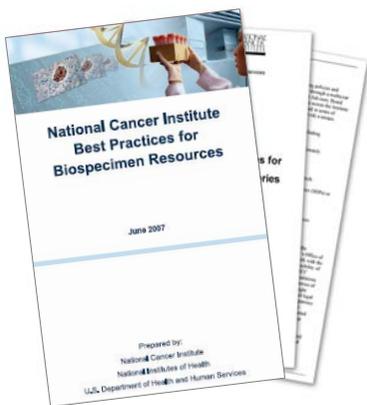
- Case Studies of Existing Human Tissue Repositories published
- National Biospecimen Network (NBN) Blueprint published

2002

- Internal and external review of biorepository issues begun
- Biospecimen resources identified as critical resources for cancer research

Release of 2007

NCI Best Practices for Biospecimen Resources



Objective: Unify technical, operational, ethical and legal policies and procedures for NCI-supported biospecimen resources

Originally released in June 2007 after revision based on expert and public comment

Revising the NCI Best Practices

New Interactive Format

The new format includes additional features such as:

- Hyperlinks to outside resources and references
- Internal links between various sections within the *NCI Best Practices*
- Search functionality of *NCI Best Practices* content

The new format also includes interactive features to encourage stakeholder input. Features include:

- Feedback form
- Polls
- Sign-up form for updates on the Best Practices

To use the interactive Best Practices, please visit:



<http://biospecimens.cancer.gov/bestpractices>

Next Steps for the Web-based Format

- The use of interactive and new media tools will continue to be expanded to keep NCI and OBBR in touch with stakeholder needs
- The web-based format will allow addition of new tools and resources as they are developed
- Printable versions of the NCI Best Practices will continue to be available
- Updates to the NCI Best Practices will be communicated via the OBBR website and the Best Practice update email list

Highlights of Revisions to NCI Best Practices

The 2007 NCI Best Practices were revised and updated by a trans-NCI committee. Revisions were based on public comments received during the NCI Best Practices forums held in 2007-2008, changes in federal regulations/guidance, harmonization with NIH policies and biobanking recommendations, and current biospecimen science literature.

Technical and Operational Best Practices

- Addition of a new section "Biospecimen Resource Management and Operations"
- Updated references & websites for further information throughout

Ethical, Legal and Policy Issues

- Expanded Custodianship section based on the findings of a 2007 NCI workshop
- Revised informed consent and privacy recommendations to reflect current federal guidance
- Added new section on "Conflicts of Interest"

New Appendices

- Minimal Clinical Data Set
- Template Governance Plan
- Compilation of Resources Related to Ethical, Legal and Policy Issues in Biospecimen Resources

Next Steps

- Comments from relevant NIH and HHS offices are being incorporated into the revised version
- Public comment on the Best Practices will be sought through a Federal Register notice and solicitation of comments from outside subject experts
- Will continue to use an online format and will focus on providing additional appendices/resources for detailed information
- NCI is committed to continuing outreach and public engagement activities

For more information, please visit:



<http://biospecimens.cancer.gov/>