

# **NCI Best Practices for Biospecimen Resources**

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**Technical and Operational Best Practices**

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# International Responses

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- **International Biobanking Standards**

- **ISBER [www.isber.org](http://www.isber.org)**

- Best Practices for Repositories I: Collection, Storage, and Retrieval of Human Biological Materials for Research*

- (Cell Preservation Technology, Vol 3, 2005)

- **Marble Arch**

- **P3G**

- **NCI Best Practices**

# What is a Biospecimen Resource?

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- **Collection of human specimens and associated data for research purposes**
- **Physical entity where the collection is stored**
- **Variability**
  - **Formal organizations**
  - **Informal collections (individual researchers)**

# Specimen Collection and Processing

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- **Handling appropriate for specimen type and study design**
- **Minimize collection and processing time**
- **Standard Operating Procedures**
  - **Quality management system**
  - **Document all protocols**
  - **Training programs**
- **Annotate specimens**
  - **Alphanumeric code**
  - **Barcode**

# Monitoring and Storage

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- **Tracking system for inventory**
- **Store specimens in a “stabilized state”**
  - **Appropriate temperature**
  - **Aliquots**
  - **Minimize thawing and refreezing**
- **Disposal according to SOPs**
- **Monitor and document storage equipment**

# Biosafety Procedures

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- **Identify risks and hazards**
  - **Infectious**
  - **Radiation**
  - **Chemical**
  - **Toxic**
- **Record exposure incidents**
- **Provide treatment**
- **Indemnification agreements**

# Packaging, and Shipping

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- **Packaging procedures**
- **Records of specimen distribution**
- **Shipping procedures**
  - **Appropriate temperature**
  - **Length of time**
- **Train personnel**

# Collecting and Managing Clinical Data

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- **Relevant clinical data**
- **Relevant epidemiologic data**
- **Longitudinal data**
- **Informatics system for tracking all aspects of collection, processing and distribution**
- **Comply with privacy rules and human subjects regulations**
- **Informatics tools (caBIG, etc)**



# Record Keeping

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- **Type of Consent/exemption**
- **Living subject or date of death?**
- **Date of Collection**
  - **Archived specimens prior to the era of molecular medicine**
  - **Prior to HIPAA (April 14, 2003)**

# Biobanking in the 21<sup>st</sup> Century

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- **International Standards**
- **Respect for Human Rights and Personal Autonomy**
- **Improvements in Technology**
  - **Processing, Storage and Retrieval of Tissue Samples**
  - **Data Sets**
  - **Information Technology:**
    - **Firewalls and Security**
    - **Interoperability**

# **(US) OHRP Guidance: Components of Repositories**

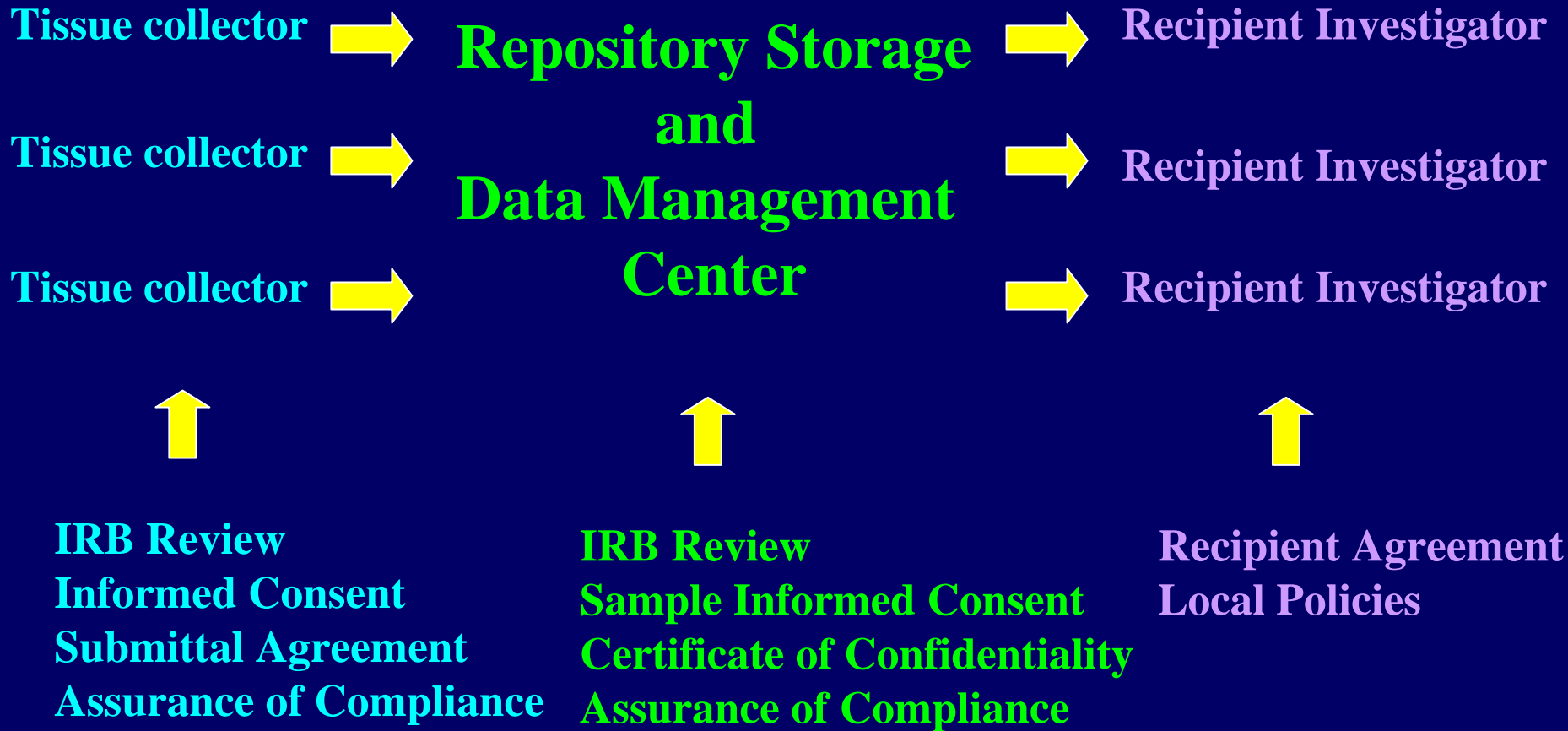
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**Repository activities involve three components, each of which must satisfy certain requirements:**

- **collectors of tissue samples**
- **repository storage and data management center**
- **recipient investigators**

# OHRP Repository Guidance

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# OHRP Guidance: Usage Agreements

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- If recipient-investigators receive identifiable, private information, they are engaged in human subjects research and need to obtain an Assurance of Compliance and IRB review of the proposed research
- When recipient-investigators are not provided access to the identities of donors or to information through which the identities of donors may readily be ascertained, human subjects research is **NOT** being conducted:
  - no IRB review
  - no informed consent

# HIPAA: Limited Data Sets

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- **Create and disseminate a limited data set that does not include directly identifiable information**
- **Data use agreement between the “covered entity” and the recipient:**
  - **Limited use of the data set**
  - **Ensure security of data**
  - **Do not identify the information or contact any individual**
- **A code may be assigned to allow re-identification**

# Limited Data Sets:

## Safe Harbor Method: Remove 18 Identifiers

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### ▪ Direct identifiers:

- Name, street address, social security number
- Medical chart, surgical pathology, prescription numbers

### ▪ Other identifiers:

- Birth date, admission and discharge dates, five-digit zip code (first 3 digits usually OK)

### ▪ Permitted demographic information:

- Age, gender, ethnicity