8. **Shipping conditions (eg, dry ice, ambient temperature)**
9. **Key investigators identification**
10. **Confirmation of receipt**
11. **Any discrepancies from manifest and actual shipment**
12. **Specimen damage**

BAP.13400 Specimen/Shipping Manifest Linkage **Phase II**

Specimens are labeled with a unique identifier and/or code.

NOTE: The intent of this requirement is to ensure that specimens arrive with accurate manifest of the contents of the shipping container.

BAP.13500 Reconciliation of Discrepancies **Phase II**

When specimens are retrieved from storage, any discrepancies found are recorded and reconciled prior to distribution.

BAP.13600 Pre-Distribution QC **Phase II**

A quality check is performed prior to distribution.

NOTE: Quality checks may include, but are not limited to, gross observations, labeling accuracy, condition of specimens, weight, and verification that storage temperature is appropriate for the shipping temperature.

RECORDS

Inspector Instructions:

READ

- Policy for record retention
- Policy for disposition of specimen and data
- Sampling of disposition records from the last 2 year period

BAP.13740 Record Retention - Biorepository **Phase II**

The biorepository specifies the length of time in which all records, paper and/or electronic, are retained.

NOTE: The length of time will depend on the nature of the record and is determined by the biorepository. The records include, but are not limited to, equipment maintenance and repair records, clinical and patient information, and records pertaining to closed collections.

BAP.13750 Disposition of Specimens, Data and Regulatory Documents **Phase II**

The biorepository complies with the regulations that govern the biorepository for the disposition of specimens, data, and related regulatory documents.

NOTE: Reasons for disposition may include, but are not limited to:
1. *Transfer or termination of collection*
2. *End of funding period*

3. *Depletion of the biospecimen*
4. *Research participant's request for discontinuation*
5. *Informed consent issues*
6. *IRB issues*
7. *Discrepancies between any clinical data and specimens*
8. *Quality of the physical specimen (eg, insufficient fixation or processing, hemolysis)*

DISTRIBUTION POLICIES AND AGREEMENTS

Inspector Instructions:

	• Sampling of material transfer agreements (MTAs) • End-user distribution policy
	• Who ensures that the MTA includes all the required information? • Describe the MTA process

BAP.15300 Material Transfer Agreements Criteria **Phase II**

Material transfer agreements (MTAs) define the rights and obligations of the provider (biorepository) and recipient (researcher), including allowable uses for the specimen and/ or data once transferred.

BAP.15400 MTA Areas Covered **Phase II**

The material transfer agreement (MTA) addresses each of the following areas as applicable.

1. **Future distribution of modifications and derivations made by the recipient**
2. **Records of each participant's role in the modifications or derivations**
3. **Terms of confidentiality**

BAP.15500 End-User Distribution Policy Criteria **Phase II**

The distribution policy includes confirmation that the end-user has IRB approval or there is a material transfer agreement (MTA) in place that provides relevant assurance for the appropriate use of the specimen according to appropriate ethical and legal requirements.

Evidence of Compliance:

✓ Copies of IRB approvals from end-users **OR** copies of MTA agreements