



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:

	<ul style="list-style-type: none"> <li>• Sampling of material transfer agreements (MTAs)</li> <li>• End-user distribution policy</li> </ul>
	<ul style="list-style-type: none"> <li>• Who ensures that the MTA includes all the required information?</li> <li>• Describe the MTA process</li> </ul>

#### 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