

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"> • Sampling of material transfer agreements (MTAs) • End-user distribution policy
	<ul style="list-style-type: none"> • 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