REFERENCES
1) Clinical and Laboratory Standards Institute (CLSI). *Toxicology and Drug Testing in the Medical Laboratory.* 3rd ed. CLSI guideline C52. Clinical and Laboratory Standards Institute, Wayne, PA; 2017.

BAP.01706 Biospecimen Chain of Custody **Phase II**

The biorepository has a system to track biospecimen chain of custody.

NOTE: Chain of custody is used to maintain the integrity of the biospecimen by providing records of the control, transfer, and analysis of biospecimens.

The intent of this requirement is to have a system in place to ensure adequate records of the "life history" of the biospecimen. Chain of custody provides a traceable record that guarantees unbroken control over biospecimens and its containers from initial collection to final disposition. This is achieved with accurate and effective labeling, tracking and reporting.

Chain of custody requires that from the moment the biospecimen is received every transfer between departments be recorded.

Evidence of Compliance:
- ✓ Logs or message boards showing specimen movement through biorepository **AND**
- ✓ Work flow diagrams

BAP.01709 Surgical Pathology Specimens Release for Research **Phase II**

A sample of a surgical pathology gross specimen may be submitted for research only if all of the following criteria are met:

1. **The pathologist determines that the sample(s) is not necessary for diagnostic purposes.**
2. **For laboratories subject to US regulations, formal written authorization is obtained in accordance with the requirements of HIPAA if identifiable patient information is released.**
3. **The biorepository meets other relevant requirements, including but not limited to, the requirements of the institution, the directives of any applicable institutional review board (IRB) or similar entity, and national, federal, state (or provincial), and local laws and regulations.**
4. **De-identified/anonymized sample of a surgical pathology gross specimen may be submitted for research if a waiver of consent has been obtained.**

BAP.01712 De-identification for Research **Phase II**

For specimens that are released for research, the biorepository follows a defined process for de-identifying/blinding or anonymizing specimens without compromise to research-related demographic information, when required.

BAP.01715 Coding **Phase II**

There is a defined coding system for sample identification.

BAP.01718 Participation/Donor Informed Consent **Phase II**

For specimens that are released to a biorepository, appropriate participant/donor informed consent is secured.

NOTE: This is not applicable when specimens are obtained under waiver of consent.