BAP.01778 Record Content for Sponsor Facility **Phase II**

If the biorepository is the sponsor for collections, the biorepository keeps a record of the following for each contributing site, as applicable.

1. **Principal investigator (PI)**
2. **Protocol number**
3. **Protocol title**
4. **Protocol version date**
5. **Informed consent**
6. **Informed consent version date**
7. **Study expiration date**
8. **Approval of the above by Institutional Review Board**
9. **Principal investigator signature for Protocol and version against approval letter**
10. **Signature and delegation list for employees responsible for obtaining consent from patients, sample transport, clinical data, sample processing, manifesting of samples, and coordination of shipments**
11. **Curriculum vitae of principle investigator**
12. **License or diploma (for non-US sites) of PI**
13. **Governmental approval as required for each participating site**

BAP.01781 Off-site Collection Sites QC **Phase I**

The biorepository monitors the quality of specimens and associated records received from off-site collection sites not under the direct control of the sponsor facility following a defined process approved by the biorepository director.

NOTE: The sponsor facility should perform an annual review of off-site collection QA/QC data as part of their quality management system.

BAP.01784 Contributing Sites Audits **Phase II**

If the biorepository is the sponsor for collections, the biorepository performs audits of contributing sites at defined frequencies.

NOTE: The scope of the audit is defined by the activities of the contributing facility. The type of audit (onsite, paper, etc.) and the timeframe are determined by the biorepository.

The audit is part of the sponsor facility's QC procedures to ensure contributing/collection sites are following protocols and procedures appropriately. Records required to ensure protocols and procedures are being followed should be checked and those checks recorded as part of the audit. CAP inspectors should be able to understand from audit records that policies and procedures are being followed by the contributing/collection site and monitored by the sponsor biorepository. If the contributing/collection sites are located outside of the United States, audit records should be in English and also in the official native language(s) of the contributing/ collection site country.

Evidence of Compliance:

- ✓ Written results of each audit **AND**
- ✓ Corrective action plans for issues of non-compliance and follow up on each plan