BAP.01766 Protocols **Phase II**

The biorepository follows protocols describing methods for participant identification, participant education, specimen collection and labeling, specimen preservation, and conditions for transportation, and storage before testing, consistent with good clinical practice and good laboratory practice, when applicable.

NOTE: All specimens must be labeled with a unique identifier and sufficient quality control practices must be in place to ensure appropriate linkage of that identifier to the participant. Protocols may be separate documents or included in the procedure manual.

BAP.01769 Source Facility Procedure Manual **Phase II**

The procedure manual is comprehensive and includes information on the following elements, as applicable to the scope of the biorepository.

1. **Informed consent**
2. **Equipment monitoring, calibration, maintenance, and repair**
3. **Control of biospecimen collection supplies (disposable and reagents)**
4. **Biospecimen identification and labeling conventions**
5. **Biospecimen collection and processing methods**
6. **Storage and retrieval**
7. **Shipping and receiving**
8. **Laboratory tests performed in-house including biospecimen QC**
9. **Biospecimen data collection and management (informatics)**
10. **Biosafety**
11. **Training**
12. **Security**

NOTE: A copy of the procedure manual would enable the sponsor to ensure that best practices are being followed.

BAP.01772 Off-site Contact Information **Phase I**

Contact information for off-site collection sites is readily available to personnel at all times to resolve discrepancies or other issues that may arise.

NOTE: This may include active phone numbers, email, etc.

SPONSOR FACILITY

The requirements under the Sponsor Facility section are applicable only if the biorepository is the sponsor.

If the biorepository initiated the collection, the biorepository is the sponsor and the following requirements are applicable. If an entity other than the biorepository initiated the collection, the biorepository is not the sponsor and the requirements below do not apply to those collections. It is possible that the biorepository will be the sponsor for some collections, but not others.

BAP.01775 Registration/License **Phase I**

If the biorepository is the primary requestor/sponsor for the specimen collection, the biorepository ensures that all source facilities are registered, licensed, and accredited as required by national, federal, state (or provincial), and local regulations, and appropriate for the study.