NOTE: The only exception to this is when there has been a waiver of consent.

BAP.01751 Waiver of Consent **Phase II**

A waiver of consent, in accordance with applicable laws and/or requirement and approved by the institution's ethics review committee, is obtained when informed consent is not obtained/required.

BAP.01754 Biospecimen/Data Usage **Phase II**

The biorepository ensures that the proposed use of the biospecimen/data is within the guidelines of the project and of the informed consent, when applicable.

BAP.01757 Privacy/Confidentiality **Phase II**

The biorepository ensures the privacy and confidentiality of patients/donors and their data.

BAP.01760 Procedures Available for Review **Phase II**

The biorepository's procedures for human specimen collection, processing, storage, and dissemination are available for ethics committee and/or IRB review, as needed.

SOURCE FACILITY

If the biorepository is not the source, the requirements under the Source Facility section are not applicable.

Inspector Instructions:

READ	• Sampling of protocol procedures • Sampling of record content when the biorepository is the sponsor • Sampling of source facility procedures • Sampling of collection site audits when the biorepository is the sponsor
OBSERVE	• The QC process for specimens received from collection sites not under the control of the biorepository
ASK	• How do you ensure the quality of specimens from collection sites not under the control of the biorepository? • When the biorepository is the collection sponsor, who conducts the audits, how are the audits recorded, and who ensures corrective action is appropriate when needed?

BAP.01763 Biorepository/Source Facility Responsibilities **Phase II**

The responsibilities between the facility(ies) and its sponsor are clearly defined in writing, reviewed by the biorepository within the last 24 months, and available during the inspection.