Records show that specimens were stored at the protocol-required temperatures.

NOTE: Storage of specimens must be appropriate for the type of specimens and its means of preservation. Failure to adhere to requirements could result in a specimen not being suitable for the purpose for which it was intended.

INFORMED CONSENT AND INSTITUTIONAL REVIEW BOARD

This section applies to human subjects research only.

Inspector Instructions:

	• Privacy and confidentiality policies and procedures • Informed consent criteria • Waiver of Consent criteria
	• What action is taken if a sample is received without the records of proper informed consent? • How do you ensure that the proposed use of human tissue is consistent with the informed consent?
	• Select a specimen in storage and review that the proper informed consent records are complete

BAP.01742 Informed Consent Criteria **Phase II**

The biorepository ensures that the proposed uses of human tissue with or without data shared for research purposes are consistent with the informed consent and scope of services, when applicable.

NOTE: There are some instances when informed consent and/or waiver of consent are not applicable (eg, non-human specimens).

BAP.01745 Required Approval(s) Records **Phase II**

When human specimens are to be collected, all of the required approvals (eg, IRB or other ethics committees) have been recorded and appropriate patient consent processes are complete.

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

BAP.01748 Informed Consent Records **Phase II**

Informed consent records are obtained for the collection, storage, distribution, and use of identifiable human specimens and data.

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.