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.