Guidance & Instructions for Projects using de-identified, discard specimens for the evaluation of in vitro diagnostic devices

Background:

Per the April 25, 2006 Guidance titled: Informed Consent for In Vitro Diagnostic (IVD) Device Studies Using Leftover Human Specimens that are Not Individually Identifiable Guidance for Sponsors, Institutional Review Boards, Clinical Investigators and FDA

- Individuals caring for the patients are different from and do not share information about the patient with those conducting the investigation;
- The specimens are provided for research without identifiers (codes are permissible only if neither the investigator nor anyone associated with the study has access to the code key or can identify the person who was the source of the specimen);
- Any clinical information supplied with the specimen must not be individually identifiable.
- No test results from the research may be reported to any subject or that subject's health care provider; and
- The supplier of the specimens must have established policies and procedures to prevent the release of identifying information.

Investigators who wish to conduct projects which meet these criteria must clearly articulate this within their SmartForm application and complete the Request for Approval without Informed Consent Requirements for an In Vitro Diagnostic Device Study Using Leftover Human Specimens that are Not Individually Identifiable Form & upload it in to section 52