

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 Staff](#), FDA believes that it is possible in certain circumstances for IVD device investigations to be conducted using leftover specimens obtained without informed consent while protecting the human subjects who are the source of such specimens. When IVD study sponsors use leftover specimens for which the subject cannot be identified and where results of the investigational test are not communicated to or otherwise associated with the identified subject, concerns associated with privacy are minimized. In addition, these studies do not pose new medical risks to subjects from whom the specimens were originally collected: Any risks from specimen collection were incurred prior to the involvement of the patient as a subject in an investigation, when the specimen was obtained for the patient's own clinical needs, and no risks from erroneous test results are presented because the results of the testing are not used for clinical management of the subject. Like leftover specimens that have been collected for routine clinical care, the investigational use of leftover specimens previously collected for other research purposes involves no additional medical risk, and privacy risks are mitigated by limiting the applicability of this guidance to specimens that are not identifiable.

FDA does have narrow exceptions from the general requirements of informed consent for certain emergency and military research, but FDA regulations do not contain exceptions from the requirements of informed consent on the grounds that the specimens are not identifiable and or that they are remnants of human specimens collected for routine clinical care or analysis that would otherwise have been discarded. Nor do FDA regulations allow IRBs to decide whether or not to waive informed consent for research involving leftover or unidentifiable specimens.

Procedure:

Per FDA regulations, IRBs cannot grant a waiver of consent for human subject research except in certain cases. Under the FDA's 2006 guidance, IRBs can evaluate if a project meets the criteria and make a determination to approve the project without the requirement of informed consent.

To be eligible for approval without a requirement for informed consent, FDA indicates that IVD research must meet the following criteria:

- The research must be conducted under an IRB-approved protocol;
- The research must meet criteria for an IDE exemption*
- The research must use specimens left over from clinical care, specimen repositories, or other research (i.e., the specimens may not be collected specifically for the proposed research, and no additional specimen may be collected for the purpose of research);

- 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

In addition, Investigators should mark in section 38 the following consent option: *None of the above*.

- In section 39 No Informed consent, investigators should reference the April 25 2006 FDA guidance regarding exceptions to informed consent for this narrow set of research along with confirming the project meets the criteria as identified in the Request Form to be eligible for approval without informed consent requirements.

IDE Exemption is defined under 21 CFR 812.2(c)(3). It states that Part 812 does not apply to investigations of, "A diagnostic device, if the sponsor complies with applicable requirements in 809.10(c) and if the testing:

(i) Is noninvasive,

(ii) Does not require an invasive sampling procedure that presents significant risk,

(iii) Does not by design or intention introduce energy into a subject, and

(iv) Is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure."