

WIRB®

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Request for a Waiver of Consent for In Vitro Diagnostic Device Study Using Leftover Human Specimens that are Not Individually Identifiable (see FDA guidance issued 04-25-2006)

Sponsor _____

Sponsor Protocol No. _____

Principal Investigator (PI) Information: Please provide information about the person legally responsible for the conduct of the research. WIRB must be assured that the investigator can personally oversee the conduct of the research and the protection of human subjects. [21 CFR 56.102 (h)]

1.	PI Name:		
2.	PI Company Name:		
3.	PI Mailing Address: (street, city, state/province, zip, country)		
4.	PI Phone: ()	PI Fax: ()	PI E-mail:
5.	How would the PI prefer to receive study documents? (check one) <input type="checkbox"/> Fax <input type="checkbox"/> E-mail <input type="checkbox"/> Regular Mail		

FDA intends to exercise enforcement discretion as to the informed consent requirements for clinical investigators, sponsors, and IRBs if an *in vitro* diagnostic device investigation is performed **and all of the following are true:**

- a. The investigation meets the IDE exemption criteria at 21 CFR 812.2(c)(3)? True No
[21 CFR 812.2(c)(3) 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.”]
- b. The study uses leftover specimens, that is, remnants of specimens collected for routine clinical care or analysis that would have been discarded, or specimens obtained from specimen repositories or leftover specimens that were previously collected for other research purposes? True No
- c. The specimens are not individually identifiable, i.e., the identity of the subject is not known to and may not readily be ascertained by the investigator or any other individuals associated with the investigation, including the sponsor. If the specimen is coded, it will be considered to be not individually identifiable if neither the investigator(s) nor any other individuals associated with the investigation or the sponsor can link the specimen to the subject from whom the specimen was collected, either directly or indirectly through coding systems. True No

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- d. Does any clinical information accompany the specimens? Yes* No (OK, continue to 'e')
*If yes, it does *not* make the specimen source identifiable to the investigator or any other individual associated with the investigation, including the sponsor? True No
- e. The individuals caring for the patients are different from, and do not share information about the patient with, those conducting the investigation. True No
- f. The specimens are provided to the investigator(s) without identifiers and the supplier of the specimens has established policies and procedures to prevent the release of personal information. True No

By signing this statement, I am providing written assurance that all of the above statements are true of the research for which I am requesting waiver of consent.

Signature of Principal Investigator

Date

Note to Board: Work through the HHS determinations for waiver of consent found at 45 CFR 46.116(d)