**Request for approval without Informed Consent Requirements for In Vitro Diagnostic Device Study Using Leftover Human Specimens that are Not Individually Identifiable (FDA guidance issued 04-25-2006)**

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| --- | --- |
| PI Name:       | eBridge PRO#:      |

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 specific criteria have been met**.**

***PIs by signing this form, you attest all of the following criteria are true for the above PRO#****:*

1. 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.”*

1. 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
2. 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
3. Does any clinical information accompany the specimens? [ ]  Yes**\*** [ ]  No (OK, continue to 5)

**\***If yes, the clinical information does *not* make the specimen source identifiable to the investigator or any other individual associated with the investigation, including the sponsor? [ ]  True [ ]  No

1. The individuals caring for the patients are different from, and do not share information about the patient with, those conducting the investigation. [ ]  True [ ]  No
2. 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 approval of without Informed Consent Requirements.

Signature of Principal Investigator Date