This checklist is used to determine whether the consent process can be waived for in vitro diagnostic device studies using leftover human specimens that are not individually identifiable.

All criteria in 1 must be met

1. **FDA Enforcement Discretion for Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable**

   1.1 The research is not regulated by a federal department or agency other than FDA
   1.2 The IRB has reviewed the sponsor's written documentation regarding the collection and distribution of specimens and associated data
   1.3 The research meets the criteria in "WORKSHEET: Criteria for Approval (HRP-400)"
   1.4 The research meets the IDE exemption criteria at 21 CFR 812.2(c)(3) (see "WORKSHEET: Devices (HRP-426)"
   1.5 The research uses leftover specimens, that is, remnants of specimens collected for routine clinical care or analysis that would have been discarded, uses specimens obtained from specimen repositories, or uses leftover specimens that were previously collected for other research purposes (see Footnote 1)
   1.6 The specimens may be accompanied by clinical information as long as this information does not make the specimen source identifiable to the investigator or any other individual associated with the research, including the sponsor
   1.7 The individuals caring for the patients are different from and do not share information about the patient with those conducting the research
   1.8 The specimens are provided to the investigator(s) without identifiers
   1.9 The supplier of the specimens has established policies and procedures to prevent the release of personal information

2. **Notes**

3. **Footnotes**

   3.1 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 research or the sponsor can link the specimen to the subject from whom the specimen was collected, either directly or indirectly through coding systems.
   * Coded means that: 1) a number, letter, symbol, or combination thereof (i.e., the code) has replaced identifying information (such as name or social security number) that would enable the investigator or any other individuals associated with the investigation, including the sponsor, to readily ascertain the identity of the individual to whom the specimen pertains, and 2) a key to decipher the code exists, enabling linkage of the identifying information to the specimen.

   Examples of ineligible research:
   * The study does not meet the IDE exemption criteria at 21 CFR 812.2(c)(3):
     * The specimens are individually identifiable, i.e., the identity of the subject is known to or may be readily ascertained by the investigator or any other individuals associated with the investigation, including the sponsor.
     * The specimens were collected specifically for the proposed investigation. That is, the specimens are not leftover from routine clinical care or analysis or leftover from other research.
     * The amount of specimen needed for the study is more than would be leftover from what is usually collected for routine clinical analysis.
     * The test results will be reported to the subject's health care provider. For example, in the course of comparative studies involving *B. anthracis* detection devices, it would be inappropriate not to report positive results if they occur in the course of an investigation.