The research must meet one of the following five sets of criteria

1 **Waiver or Alteration of the Consent Process** *(45 CFR §46.116(f))* (All must be **"Yes"** – Records or minutes must document protocol-specific findings justifying each of the following determinations.)

☐ **Yes** ☐ **No**	The research is **NOT** FDA-regulated.
☐ **Yes** ☐ **No**	The research does **NOT** involve non-viable neonates.
☐ **Yes** ☐ **No**	The research involves no more than Minimal Risk to the subjects. *Provide protocol specific findings justifying this determination:*
☐ **Yes** ☐ **No**	The research could **NOT** practicably be carried out without the waiver or alteration *Provide protocol specific findings justifying this determination:*
☐ **Yes** ☐ **No**	If the research involves using identifiable private information or identifiable biospecimens, the research could **NOT** practicably be carried out without using such information or biospecimens in an identifiable format. **(N/A if research does not use identifiable private information or biospecimens)** *Provide protocol specific findings justifying this determination:*
☐ **Yes** ☐ **No**	The waiver or alteration will **NOT** adversely affect the rights and welfare of the subjects. *Provide protocol specific findings justifying this determination:*
☐ **Yes** ☐ **No**	Whenever appropriate, the subjects will be provided with additional pertinent information after participation. *Provide protocol specific findings justifying this determination:*
☐ **Yes** ☐ **No** ☐ **N/A**	Waiver of consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens cannot be granted for those who refused to provide broad consent. **(N/A if broad consent not used for the research)**
☐ **Yes** ☐ **No** ☐ **N/A**	Alteration of the consent process can only omit or alter the basic and/or additional elements of consent[1]. **(N/A if waiving informed consent)**

2 **Waiver or alteration of Consent Process under FDA Guidance "IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal Risk to Human Subjects" (Check if "Yes" All must be checked)**

☐ **Yes** ☐ **No**	The research is FDA regulated
☐ **Yes** ☐ **No**	The clinical investigation involves no more than minimal risk (as defined in 21 CFR 50.39K) or 56.102(l)) to the subjects
☐ **Yes** ☐ **No**	The waiver or alteration will not adversely affect the rights and welfare of the subjects. *Provide protocol specific findings justifying this determination.*
☐ **Yes** ☐ **No**	The clinical investigation could not be practicably carried out without waiver or alteration. *Provide protocol specific findings justifying this determination.*
☐ **Yes** ☐ **No**	Whenever appropriate, the subjects will be provided with additional pertinent information after participation. *Provide protocol specific findings justifying this determination.*

[1] An IRB may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent set forth in 45 CFR 46.116(b) and (c). An IRB may not omit or alter any of the requirements described in 45 CFR 46.116(a). If a broad consent procedure is used, an IRB may not omit or alter any of the elements required under 45 CFR 46.116(d).

☐ **Yes** ☐ **No** ☐ **N/A**	Alteration of the consent process can only omit or alter basic and/or additional elements of consent. (N/A if waiving informed consent)

3 **Waiver or Alteration of the Consent Process** *(45 CFR §46.116(E) & FDA Guidance on Waiver or Alteration of Informed Consent for Minimal Risk Research dated July 2017)* **(**(All must be **"Yes"** – Records or minutes must document protocol-specific findings justifying each of the following determinations.)

☐ **Yes** ☐ **No**	The research is **NOT** FDA-regulated.
☐ **Yes** ☐ **No**	The research does **NOT** involve non-viable neonates.
☐ **Yes** ☐ **No**	The research or demonstration project is to be conducted by or subject to the approval of state or local government officials. *Provide protocol specific findings justifying this determination:*
☐ **Yes** ☐ **No**	The research or demonstration project is designed to study, evaluate, or otherwise examine one or more of the following: **(Check all boxes that are true. One must be checked)** ☐ Public benefit or service programs. ☐ Procedures for obtaining benefits or services under those programs. ☐ Possible changes in or alternatives to those programs or procedures. ☐ Possible changes in methods or levels of payment for benefits or services under those programs. *Provide protocol specific findings justifying this determination:*
☐ **Yes** ☐ **No**	The research could **NOT** practicably be carried out without the waiver or alteration. *Provide protocol specific findings justifying this determination:*
☐ **Yes** ☐ **No** ☐ **N/A**	Waiver of consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens cannot be granted for those who refused to provide broad consent **(N/A if broad consent not used for the research)**
☐ **Yes** ☐ **No** ☐ **N/A**	Alteration of the consent process can only omit or alter the basic and/or additional elements of consent. **(N/A if waiving informed consent)**

4 **Waiver of the Consent Process for FDA-Regulated Research Involving Anonymous Tissue Specimens** *(Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable – April 25, 2006)* **(All must be "Yes")**

☐ **Yes** ☐ **No**	The research does not involve Human Subjects as Defined by DHHS.
☐ **Yes** ☐ **No**	The study involves an in vitro diagnostic device investigation.
☐ **Yes** ☐ **No**	The testing is noninvasive.
☐ **Yes** ☐ **No**	The testing does not require an invasive sampling procedure that presents significant risk.
☐ **Yes** ☐ **No**	The testing does not by design or intention introduce energy into a subject.
☐ **Yes** ☐ **No**	The device is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.
☐ **Yes** ☐ **No**	For a product in the laboratory research phase of development, and not represented as an effective in vitro diagnostic product, all labeling bears the statement, prominently placed: "For Research Use Only. Not for use in diagnostic procedures."
☐ **Yes** ☐ **No**	For a product being shipped or delivered for product testing prior to full commercial marketing (for example, for use on specimens derived from humans to compare the usefulness of the product with other products or procedures which are in current use or recognized as useful), all labeling bears the statement, prominently placed: "For Investigational Use Only. The performance characteristics of this product have not been established."
☐ **Yes** ☐ **No**	The study uses one of more of the following: ☐ Specimens collected for routine clinical care or analysis that would have been discarded. ☐ Specimens obtained from specimen repositories. ☐ Leftover specimens that were previously collected for other research purposes.
☐ **Yes** ☐ **No**	The identity of the subject is not known to the investigator or any other individuals associated with the investigation, including the sponsor meaning neither the investigator nor any other individuals associated with the investigation, including the sponsor can readily ascertain the identity of the subject.

☐ **Yes** ☐ **No**	One of the following is true: ☐ Specimens are not coded where "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. ☐ 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.
☐ **Yes** ☐ **No**	One of the following is true: ☐ The specimens are not accompanied by clinical information. ☐ Clinical information that accompanies the specimens does not make the specimen source identifiable to the investigator or any other individual associated with the investigation, including the sponsor.
☐ **Yes** ☐ **No**	The individuals caring for the patients are different from those conducting the investigation and do not share information about the patient with those conducting the investigation.
☐ **Yes** ☐ **No**	The individuals caring for the patients do not share information about the patient with those conducting the investigation.
☐ **Yes** ☐ **No**	The specimens are provided to the investigator(s) without identifiers.
☐ **Yes** ☐ **No**	The supplier of the specimens has established policies and procedures to prevent the release of personal information.
5 **Waiver of Informed Consent for Planned Emergency Research (21 CFR §50.24 and 45 CFR 46 Waiver of Informed Consent Requirements in Certain Emergency Research – November 1, 1996)**	
☐ **Yes** ☐ **No**	The research meets the criteria in the **CHECKLIST – Waiver of the Consent Process for Planned Emergency Research**.