TEXAS A&M UNIVERSITY	CHECKLIST: Waiver or Alteration of Consent Process		
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The purpose of this checklist is to provide support for IRB members or the Designated Reviewer following HRP-314 – WORKSHEET - Criteria for Approval when research involves waiver or alteration of the consent process. This checklist or its equivalent form or electronic equivalent must be used for all reviews (initial, continuing, modification, review by the convened IRB, and review using the expedited procedure.)[1].

- For initial review using the expedited procedure and modifications and continuing reviews where the determinations relevant to the criteria for approval have changed, the Designated Reviewer completes this checklist or equivalent to document determinations required by the regulations along with protocol specific findings justifying those determinations. The Designated Reviewer or IRB staff attaches this checklist or equivalent to the protocol file.
- For initial review using the convened IRB and for modifications and continuing reviews where the determinations relevant to the criteria for approval have changed, one of the following two options may be used:
  1. The convened IRB completes the corresponding section of the meeting minutes to document determinations required by the regulations along with protocol specific findings justifying those determinations, in which case this checklist or equivalent form does not need to be completed or retained.
  2. The convened IRB completes this checklist or equivalent form to document determinations required by the regulations along with protocol specific findings justifying those determinations and the IRB Office uploads this checklist or equivalent form to the protocol file or uses electronic equivalent.

IRB Number:	
Study Title:	
Short Title:	
Investigator:	

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

	1 Waiver or Alteration of Consent Process[2] (Check if **"Yes"**. All must be checked)
☐	The research is **NOT** FDA-regulated.
☐	The research does **NOT** involve non-viable neonates.
☐	The research involves no more than Minimal Risk to the subjects. *Provide protocol specific findings justifying this determination:*
☐	The research could **NOT** practicably be carried out without the waiver or alteration *Provide protocol specific findings justifying this determination:*
☐	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, or if the research is not subject to the 2018 Rule.)** ☐ **N/A** *Provide protocol specific findings justifying this determination:*
☐	The waiver or alteration will **NOT** adversely affect the rights and welfare of the subjects. *Provide protocol specific findings justifying this determination:*
☐	Whenever appropriate, the subjects will be provided with additional pertinent information after participation. *Provide protocol specific findings justifying this determination:*
☐	Alteration of the consent process can only omit or alter the basic and/or additional elements of consent[3]. **(N/A if waiving informed consent, or if the research is not subject to the 2018 Rule)** ☐ **N/A**

	2 Waiver or Alteration of Consent Process[4] (Check if **"Yes"**. All must be checked)
☐	The research **IS** FDA-regulated.

[1] This document satisfies AAHRPP elements I-9, II.3.G, II.5.A, II.5.B, III.1.F

[2] 45 CFR §46.116(f)

[3] 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).

[4] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/irb-waiver-or-alteration-informed-consent-clinical-investigations-involving-no-more-minimal-risk.

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☐	The clinical investigation involves no more than Minimal Risk (as defined in 21 CFR 50.3(k) or 56.102(i)) to the subjects. *Provide protocol specific findings justifying this determination:*
☐	The waiver or alteration will not adversely affect the rights and welfare of the subjects. *Provide protocol specific findings justifying this determination:*
☐	The clinical investigation could not practicably be carried out without the waiver or alteration. *Provide protocol specific findings justifying this determination:*
☐	Whenever appropriate, the subjects will be provided with additional pertinent information after participation. *Provide protocol specific findings justifying this determination:*

3	**Waiver or Alteration of Consent Process**[5] (Check if **"Yes"**. All must be checked)
☐	The research is **NOT** FDA-regulated.
☐	The research does **NOT** involve non-viable neonates.
☐	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:*
☐	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:*
☐	The research could **NOT** practicably be carried out without the waiver or alteration. *Provide protocol specific findings justifying this determination:*
☐	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, or if the research is not subject to the 2018 Rule)** ☐ **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, or if the research is not subject to the 2018 Rule)** ☐ **N/A**

4	**Waiver of the Consent Process for FDA-Regulated Research Involving Anonymous Tissue Specimens**[6] (Check if **"Yes"**. All must be checked)
☐	The research does not involve Human Subjects as Defined by DHHS.
☐	The study involves an in vitro diagnostic device investigation.
☐	The testing is noninvasive.
☐	The testing does not require an invasive sampling procedure that presents significant risk.
☐	The testing does not by design or intention introduce energy into a subject.
☐	The device is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.
☐	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."
☐	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."

[5] 45 CFR §46.116(e)

[6] Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable – April 25, 2006

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☐	The study uses one of more of the following: **(Check all boxes that are true. One must be checked)** ☐ 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.
☐	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.
☐	One of the following is true: **(Check all boxes that are true. One must be checked)** ☐ 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.
☐	One of the following is true: **(Check all boxes that are true. One must be checked)** ☐ 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.
☐	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.
☐	The individuals caring for the patients do not share information about the patient with those conducting the investigation.
☐	The specimens are provided to the investigator(s) without identifiers.
☐	The supplier of the specimens has established policies and procedures to prevent the release of personal information.

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