

	CHECKLIST: Waiver or Alteration of the Consent Process			IRB # \$\$IRB Number\$\$
	NUMBER	DATE	PAGE	Review Type: \$\$Review\$\$
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The purpose of this checklist is to provide support for IRB members or the Designated Reviewer following “HRP 311 Worksheet: Criteria for Approval and Additional Considerations” when reviewing research involving Waiver or Alteration of the Consent Process. This checklist must be used for all reviews (initial, continuing, modification, review by the convened IRB, and review using the expedited procedure).

- For initial review using the expedited procedure and modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, the Designated Reviewer completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations. The Designated Reviewer submits this completed checklist to the IRB office. The IRB Office retains this checklist in the protocol file.

- For initial review using the convened IRB and for modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, one of the following two options may be used:

1. The IRB Analyst for the convened IRB meeting 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 does not need to be completed or retained.

2. The IRB reviewer(s) completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations and the IRB Office retains this checklist in the meeting files.

Use a separate checklist for each waiver or alteration determination for a study if more than one type of waiver/alteration applies.

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)(3)) (All must be “Yes” or “N/A”)

<input type="checkbox"/> Yes <input type="checkbox"/> No	The research is NOT FDA-regulated.
<input type="checkbox"/> Yes <input type="checkbox"/> No	The research does NOT involve non-viable neonates.
<input type="checkbox"/> Yes <input type="checkbox"/> No	The research involves no more than <u>Minimal Risk</u> to the subjects. <i>Provide protocol specific findings justifying this determination:</i>
<input type="checkbox"/> Yes <input type="checkbox"/> No	The research could NOT practicably be carried out without the waiver or alteration <i>Provide protocol specific findings justifying this determination:</i>
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	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) <i>Provide protocol specific findings justifying this determination:</i>
<input type="checkbox"/> Yes <input type="checkbox"/> No	The waiver or alteration will NOT adversely affect the rights and welfare of the subjects. <i>Provide protocol specific findings justifying this determination:</i>
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Whenever appropriate, the subjects will be provided with additional pertinent information after participation. <i>Provide protocol specific findings justifying this determination:</i>
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Alteration of the consent process only omits or alters 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 (July 2017)” (All must be “Yes” or “NA”)

<input type="checkbox"/> Yes <input type="checkbox"/> No	The research is FDA regulated
<input type="checkbox"/> Yes <input type="checkbox"/> No	The clinical investigation involves no more than minimal risk (as defined in 21 CFR 50.3(k)) to the subjects
<input type="checkbox"/> Yes <input type="checkbox"/> No	The waiver or alteration will not adversely affect the rights and welfare of the subjects. <i>Provide protocol specific findings justifying this determination:</i>

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).

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<input type="checkbox"/> Yes <input type="checkbox"/> No	The clinical investigation could not be practicably carried out without waiver or alteration. <i>Provide protocol specific findings justifying this determination:</i>			
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Whenever appropriate, the subjects will be provided with additional pertinent information after participation. <i>Provide protocol specific findings justifying this determination:</i>			
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Alteration of the consent process only omits or alters basic and/or additional elements of consent. (N/A if waiving informed consent)			
3 Waiver or Alteration of Consent - Public Demonstration Project (45 CFR 46.116(e)(3)) (All must be "Yes" – Records or minutes must document protocol-specific findings justifying each of the following determinations.)				
<input type="checkbox"/> Yes <input type="checkbox"/> No	The research is NOT FDA-regulated.			
<input type="checkbox"/> Yes <input type="checkbox"/> No	The research does NOT involve non-viable neonates.			
<input type="checkbox"/> Yes <input type="checkbox"/> No	The research or demonstration project is to be conducted by or subject to the approval of state or local government officials. <i>Provide protocol specific findings justifying this determination:</i>			
<input type="checkbox"/> Yes <input type="checkbox"/> 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) <ul style="list-style-type: none"> <input type="checkbox"/> Public benefit or service programs. <input type="checkbox"/> Procedures for obtaining benefits or services under those programs. <input type="checkbox"/> Possible changes in or alternatives to those programs or procedures. <input type="checkbox"/> Possible changes in methods or levels of payment for benefits or services under those programs. <i>Provide protocol specific findings justifying this determination:</i>			
<input type="checkbox"/> Yes <input type="checkbox"/> No	The research could NOT practicably be carried out without the waiver or alteration. <i>Provide protocol specific findings justifying this determination:</i>			
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Alteration of the consent process only omits or alters 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")				
<input type="checkbox"/> Yes <input type="checkbox"/> No	The research does not involve <u>Human Subjects as Defined by DHHS</u> .			
<input type="checkbox"/> Yes <input type="checkbox"/> No	The study involves an in vitro diagnostic device investigation.			
<input type="checkbox"/> Yes <input type="checkbox"/> No	The testing is noninvasive.			
<input type="checkbox"/> Yes <input type="checkbox"/> No	The testing does not require an invasive sampling procedure that presents significant risk.			
<input type="checkbox"/> Yes <input type="checkbox"/> No	The testing does not by design or intention introduce energy into a subject.			
<input type="checkbox"/> Yes <input type="checkbox"/> No	The device is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.			
<input type="checkbox"/> Yes <input type="checkbox"/> 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."			
<input type="checkbox"/> Yes <input type="checkbox"/> 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."			

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<input type="checkbox"/> Yes <input type="checkbox"/> No	<p>The study uses one of more of the following (check all applicable boxes):</p> <ul style="list-style-type: none"> <input type="checkbox"/> Specimens collected for routine clinical care or analysis that would have been discarded. <input type="checkbox"/> Specimens obtained from specimen repositories. <input type="checkbox"/> Leftover specimens that were previously collected for other research purposes. 			
<input type="checkbox"/> Yes <input type="checkbox"/> No	<p>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.</p>			
<input type="checkbox"/> Yes <input type="checkbox"/> No	<p>One of the following is true:</p> <ul style="list-style-type: none"> <input type="checkbox"/> 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. <input type="checkbox"/> 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. 			
<input type="checkbox"/> Yes <input type="checkbox"/> No	<p>One of the following is true:</p> <ul style="list-style-type: none"> <input type="checkbox"/> The specimens are not accompanied by clinical information. <input type="checkbox"/> 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. 			
<input type="checkbox"/> Yes <input type="checkbox"/> No	<p>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.</p>			
<input type="checkbox"/> Yes <input type="checkbox"/> No	<p>The individuals caring for the patients do not share information about the patient with those conducting the investigation.</p>			
<input type="checkbox"/> Yes <input type="checkbox"/> No	<p>The specimens are provided to the investigator(s) without identifiers.</p>			
<input type="checkbox"/> Yes <input type="checkbox"/> No	<p>The supplier of the specimens has established policies and procedures to prevent the release of personal information.</p>			