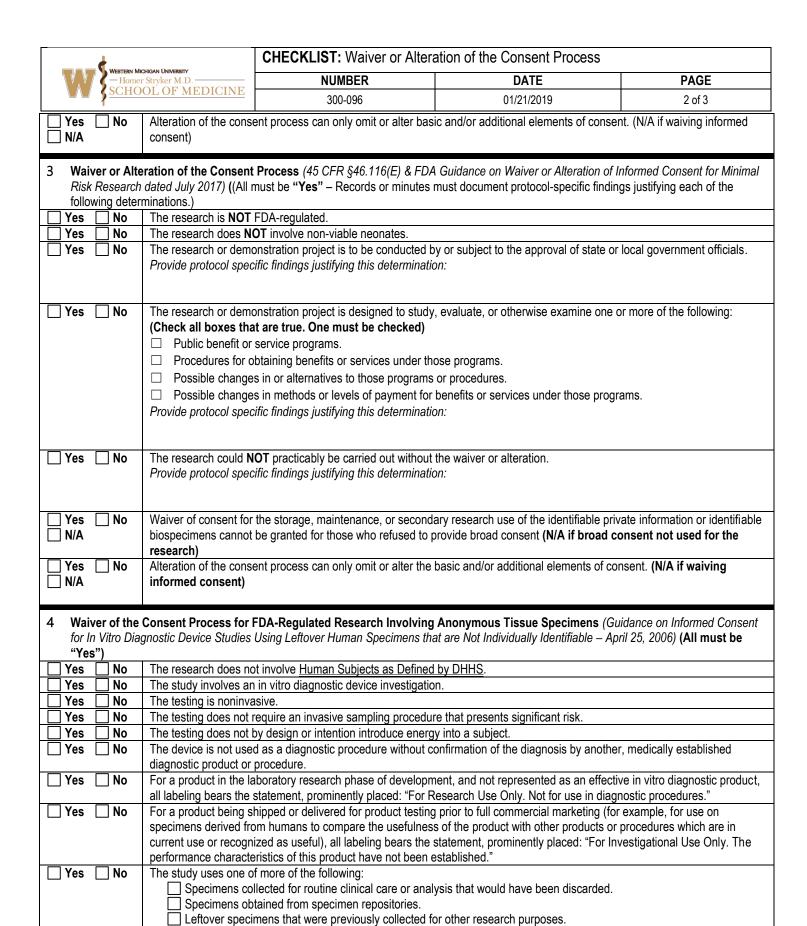


CHECKLIST: Waiver or Alteration of the Consent Process				
NUMBER	DATE	PAGE		
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The research must meet one of the following five sets of criteria					
1 Waiver or Alteration of the Consent Process (45 CFR §46.116(f)) (All must be "Yes" – Records or minutes must document protocol-specific findings justifying each of the following determinations.)					
	Yes	Ľ	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:	
_	1 1/	_	7 N.	The second of HANDT are good for the Call of the Call	
	Yes		No	The research could NOT practicably be carried out without the waiver or alteration Provide protocol specific findings justifying this determination:	
				Provide protocol specific findings justifying this determination.	
Т	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:	
_	1 3.6	_	٠		
L	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.	
	163] 110	Provide protocol specific findings justifying this determination:	
				1 Tovide protocol specific lindings justifying this determination.	
	Yes		No	Waiver of consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable	
	N/A			biospecimens cannot be granted for those who refused to provide broad consent. (N/A if broad consent not used for the	
			_	research)	
	Yes		No	Alteration of the consent process can only omit or alter the basic and/or additional elements of consent ¹ . (N/A if waiving	
	N/A			informed consent)	
2	W ₂	ivo	or alta	ration 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	<u> </u>	No No	The research is FDA regulated	
Ē	Yes	Ē	No	The clinical investigation involves no more than minimal risk (as defined in 21 CFR 50.39K) or 56.102(I)) to the subjects	
Ī	Yes	Ē	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.	
_	1 37		7		
L	Yes	L	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).

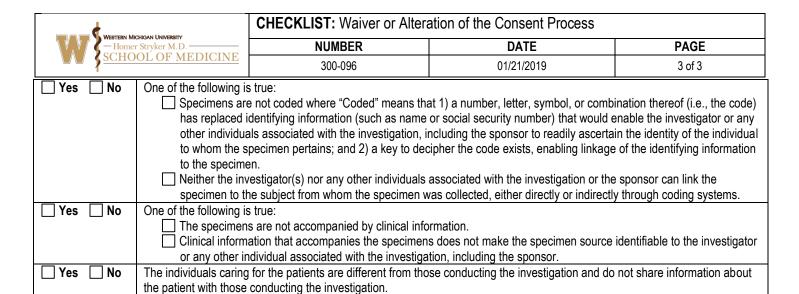


The identity of the subject is not known to the investigator or any other individuals associated with the investigation, including

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



The specimens are provided to the investigator(s) without identifiers.

Requirements in Certain Emergency Research - November 1, 1996)

Yes

Yes

Yes

Yes

No

No

No

□ No

The individuals caring for the patients do not share information about the patient with those conducting the investigation.

The supplier of the specimens has established policies and procedures to prevent the release of personal information.

The research meets the criteria in the CHECKLIST - Waiver of the Consent Process for Planned Emergency Research.

Waiver of Informed Consent for Planned Emergency Research (21 CFR §50.24 and 45 CFR 46 Waiver of Informed Consent