AdventHealth Orlando

CHECKLIST: Nonviable Neonates

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This checklist is used to determine and document whether non-exempt <Human Research> involving <Nonviable Neonates> can be approved.

Ⓟ

All criteria in 1 or 2 must be met

1. Research involving <Nonviable Neonates> as subjects *45 CFR §46.205*

1.1	☐	Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates
	ⓘ	
1.2	☐	Individuals engaged in the research will have no part in determining the viability of a neonate
	ⓘ	
1.3	☐	Vital functions of the neonate will not be artificially maintained
	ⓘ	
1.4	☐	The research will not terminate the heartbeat or respiration of the neonate
	ⓘ	
1.5	☐	There will be no added risk to the neonate resulting from the research
	ⓘ	
1.6	☐	All of the following are true:
	1.6.1 ☐	The purpose of the research is the development of important knowledge that cannot be obtained by other means
	1.6.2 ☐	One of the following is true:
		◯ The research is not subject to DHS, EPA, or VA regulation and is not HHS-funded
		◯ The important knowledge is important biomedical knowledge
	ⓘ	
1.7	☐	Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate
	ⓘ	
1.8	☐	The consent of both parents of the neonate is obtained and documented in accordance with Sections 2 and 3 of "WORKSHEET: Criteria for Approval (HRP-400)", unless one parent is unable to consent because of unavailability, incompetence, or temporary incapacity, except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest
	ⓘ	
1.9	☐	Consent will not be obtained from a LAR
	ⓘ	
1.10	☐	There is no waiver or alteration of the consent process
	ⓘ	

2. Research involving <Nonviable Neonates> as subjects that is not otherwise approvable *45 CFR §46.207*

2.1	☐	The research does not meet the above requirements
	ⓘ	
2.2	☐	The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of <Pregnant Women>, <Fetuses>, or neonates
	ⓘ	
2.3	☐	An official, after consultation with a panel of experts in pertinent disciplines and after opportunity for public review and comment, including a public meeting, has determined either that the research meets the above conditions or (1) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of <Pregnant Women>, <Fetuses> or, neonates, (2) the research will be conducted in accord with sound ethical principles; and (3) consent will be obtained and documented as required. (see Footnote 1)

3. Notes

4. Footnotes

4.1 For DHS, EPA, HHS, or VA research the official is the Department Secretary. For DOD research, the official is the Director, Defense, Research, and Engineering. For federal research, the meeting is announced in the Federal Register. For all other research , the official is the <Organizational Official>.