

	CHECKLIST: Research Involving Neonates of Uncertain Viability			IRB # \$\$IRB Number\$\$
	NUMBER	DATE	PAGE	Review Type: \$\$Review\$\$
	HRP-420	11/09/2021	1 of 2	Status: \$\$Status\$\$

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 Neonates of Uncertain Viability.
 For initial review, modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, the IRB Analyst completes this checklist.
 For expedited reviews: the Designated Reviewer reviews the completed checklist and it is retained in the protocol file.
 For review using the convened IRB: the IRB Analyst for the convened IRB meeting completes the corresponding section of the meeting minutes to document determinations required by the regulations, in which case this checklist does not need to be retained.

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

1 Research Involving Neonates of Uncertain Viability¹ (45 CFR §46.205) (All items in the left most columns 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	Where scientifically appropriate, pre-clinical and clinical studies have been conducted and provide data for assessing potential risks to neonates. <i>Provide protocol specific findings justifying this determination:</i>
<input type="checkbox"/> Yes <input type="checkbox"/> No	Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate. (“N/A” if the consent process is waived.) <input type="checkbox"/> N/A <i>Provide protocol specific findings justifying this determination:</i>
<input type="checkbox"/> Yes <input type="checkbox"/> No	Individuals engaged in the research will have no part in determining the viability of a neonate. <i>Provide protocol specific findings justifying this determination:</i>
<input type="checkbox"/> Yes <input type="checkbox"/> No	One of the following is true: (Check box that is true) <input type="checkbox"/> The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective. <input type="checkbox"/> The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research. <i>Provide protocol specific findings justifying this determination:</i>

¹ Viable, as it pertains to the neonate, means being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration.

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<input type="checkbox"/> Yes <input type="checkbox"/> No	<p>The legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained in accord with the regulations, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest. ("N/A" if the consent process is waived.) <input type="checkbox"/> N/A</p> <p><i>Provide protocol specific findings justifying this determination:</i></p>
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2 Research Involving Neonates that is Not Otherwise Approvable (45 CFR §46.207) ²	
<input type="checkbox"/> Yes <input type="checkbox"/> No	<p>The research does meets the requirements of 45 CFR §46.204 or §46.205.</p> <p><i>Provide protocol specific findings justifying this determination:</i></p>
<input type="checkbox"/> Yes <input type="checkbox"/> No	<p>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.</p> <p><i>Provide protocol specific findings justifying this determination:</i></p>

² For DHHS-regulated research, the research may proceed only after OHRP has reviewed and approved the research. For research conducted or funded by the Department of Defense (DOD), the research may proceed only after the Director, Defense, Research and Engineering has reviewed and approved the research.