

	<b>CHECKLIST: Research Involving Non-Viable Neonates</b>			<b>IRB # \$\$IRB Number\$\$</b>
	<b>NUMBER</b>	<b>DATE</b>	<b>PAGE</b>	<b>Review Type: \$\$Review\$\$</b>
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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 *Non-Viable Neonates*.

- 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 Non-Viable Neonates (45 CFR §46.205) (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	Where scientifically appropriate, preclinical 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. <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	Vital functions of the neonate will not be artificially maintained. <i>Provide protocol specific findings justifying this determination:</i>
<input type="checkbox"/> Yes <input type="checkbox"/> No	The research will not terminate the heartbeat or respiration of the neonate. <i>Provide protocol specific findings justifying this determination:</i>
<input type="checkbox"/> Yes <input type="checkbox"/> No	There will be no added risk to the neonate resulting from the research. <i>Provide protocol specific findings justifying this determination:</i>

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<input type="checkbox"/> Yes <input type="checkbox"/> No	<p>The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means.  <i>Provide protocol specific findings justifying this determination:</i></p>
<input type="checkbox"/> Yes <input type="checkbox"/> No	<p>The legally effective informed consent of both parents of the neonate is obtained, unless one parent is unable to consent because of unavailability, incompetence, or temporary incapacity and the consent of the father need not be obtained if the pregnancy resulted from rape or incest.<sup>1</sup>  <i>Provide protocol specific findings justifying this determination:</i></p>
<p><b>2 Research Involving Neonates that is Not Otherwise Approvable (45 CFR §46.207) <sup>2</sup></b> (All must be “Yes” – Records or minutes must document protocol-specific findings justifying each of the following determinations.)</p>	
<input type="checkbox"/> Yes <input type="checkbox"/> No	<p>The research does NOT meet the requirements of §46.205.  <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.  <i>Provide protocol specific findings justifying this determination:</i></p>

<sup>1</sup> For research involving Non-Viable neonates Informed Consent must be obtained in accord with the regulations at 45 CFR 46 except that the waiver and alteration provisions of 46.116(c) and (d) do not apply. The consent of a legally authorized representative of either or both of the parents of the nonviable neonate will not suffice to meet the requirements of consent.

<sup>2</sup> 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