UC San Diego
INSTITUTIONAL REVIEW BOARD ADMINISTRATION

OIA-413 CHECKLIST: Non-Viable Neonates

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The purpose of this checklist is to provide support for IRB members or the designated reviewer following the *OIA-314 WORKSHEET: Criteria for Approval and Additional Considerations*, or equivalent, when research involves non-viable neonates as subjects. This checklist, or equivalent, may be used for all reviews (initial, continuing, amendment, review by the convened IRB, and review using the expedited procedure). It does not need to be completed or retained.

IRB Number:	
Investigator:	

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

1 Research Involving Non-Viable[1] Neonates[2] (Check if **"Yes."** All must be checked)

☐	Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates. *Provide protocol specific findings justifying this determination:*
☐	Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate. *Provide protocol specific findings justifying this determination :*
☐	Individuals engaged in the research will have no part in determining the viability of a neonate. *Provide protocol specific findings justifying this determination:*
☐	Vital functions of the neonate will not be artificially maintained. *Provide protocol specific findings justifying this determination:*
☐	The research will not terminate the heartbeat or respiration of the neonate. *Provide protocol specific findings justifying this determination:*
☐	There will be no added risk to the neonate resulting from the research. *Provide protocol specific findings justifying this determination:*
☐	The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means. *Provide protocol specific findings justifying this determination:*
☐	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 non-pregnant biological parent need not be obtained if the pregnancy resulted from rape or incest. *Provide protocol specific findings justifying this determination:*
☐	The consent of a legally authorized representative of either or both of the parents of a non-viable neonate will not be obtained. *Provide protocol specific findings justifying this determination:*

2 Research Involving Neonates that is Not Otherwise Approvable[3] (Check if **"Yes."** All must be checked)

☐	The research does **NOT** meet the requirements of 45 CFR 46.205. *Provide protocol specific findings justifying this determination:*
☐	The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant subjects, fetuses or neonates. *Provide protocol specific findings justifying this determination:*

[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.
[2] 45 CFR 46.205
[3] 45 CFR 46.207. 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.