UC San Diego
INSTITUTIONAL REVIEW BOARD ADMINISTRATION

OIA-414 CHECKLIST: Neonates of Uncertain Viability

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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 Neonates[1] of Uncertain Viability[2] (Check if **"Yes."**. All must be checked)

☐ Where scientifically appropriate, pre-clinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.
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:

☐ One of the following is true: **(Check box that is true)**
- ☐ 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.
- ☐ 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.

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. **("N/A" if the consent process is waived)**
Provide protocol specific findings justifying this determination:

☐ 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 (LAR) is obtained in accord with the regulations, except that the consent of the non-pregnant biological parent or their LAR need not be obtained if the pregnancy resulted from rape or incest. **("N/A" if the consent process is waived)**
Provide protocol specific findings justifying this determination:

2 Research Involving Neonates of Uncertain Viability 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:

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[1] 45 CFR 46.205
[2] "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.
[3] 45 CFR 46.207. For Department of Health and Human Services-regulated research, the research may proceed only after Office for Human Research Protections 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.