RUTGERS UNIVERSITY
Office for Research

WORKSHEET: Neonates of Uncertain Viability		
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7.203 (HRP-414)	5/1/2024	1 of 2

The purpose of this checklist is to provide support for IRB members or the Designated Reviewer following the 4.202 (HRP-314) WORKSHEET: Criteria for Approval when research involves neonates of uncertain viability as subjects. This checklist may be used for all reviews (initial, continuing, modification, review by the convened IRB, and review using the expedited procedure.)

- For initial review using the expedited procedure and modifications and continuing reviews where the determinations relevant to this worksheet made on the previous review have changed, the Designated Reviewer may utilize this worksheet to make determinations required by the regulations along with protocol-specific findings justifying those determinations. The Designated Reviewer attaches this checklist to "Submit Designated Review" activity. The IRB Office retains this checklist in the protocol file.

- For initial review using the convened IRB and for modifications and continuing reviews where the determinations relevant to this worksheet made on the previous review have changed, the convened IRB completes the corresponding section of the meeting minutes to document determinations required by the regulations along with protocol-specific findings justifying those determinations, in which case this checklist does not need to be completed or retained.

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

1 Research Involving Neonates[i] of Uncertain Viability[ii] (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 father or his 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[iii] (Check if **"Yes"**. All must be checked)

☐	The research does **NOT** meet the requirements of §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 women, fetuses or neonates. *Provide protocol-specific findings justifying this determination:*

[i] "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.

[ii] 45 CFR §46.205

[iii] 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. For all other research, the research may proceed only after the Institutional Official has conducted a review in accordance with 3.008 (HRP-044) - SOP: Not Otherwise Approvable Research and approved the research.