



HRP-413 | 1/1/2024

## CHECKLIST: Non-Viable Neonates

The purpose of this checklist is to provide support for IRB members or the Designated Reviewer following HRP-314 - WORKSHEET - Criteria for Approval when research involves non-viable neonates as subjects. This checklist must be used for all reviews (initial, continuing, modification, review by the convened IRB, and review using the expedited procedure.)<sup>i</sup>

- For initial review using the expedited procedure and modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, the Designated Reviewer completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations. The Designated Reviewer attaches this checklist to “Submit Non-Committee 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 checklist made on the previous review have changed, one of the following two options may be used:
  1. 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.
  2. The convened IRB completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations and the IRB Office uploads this checklist in the “Submit Committee Review” activity and retains this checklist in the protocol file.

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

### 1. Research Involving Non-Viable<sup>ii</sup> Neonates<sup>iii</sup> (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: Click or tap here to enter text.*

- 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: Click or tap here to enter text.*

- Individuals engaged in the research will have no part in determining the viability of a neonate.

*Provide protocol specific findings justifying this determination: Click or tap here to enter text.*

- Vital functions of the neonate will not be artificially maintained.

*Provide protocol specific findings justifying this determination: Click or tap here to enter text.*

- The research will not terminate the heartbeat or respiration of the neonate.

*Provide protocol specific findings justifying this determination: Click or tap here to enter text.*

There will be no added risk to the neonate resulting from the research.

*Provide protocol specific findings justifying this determination: Click or tap here to enter text.*

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: Click or tap here to enter text.*

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.

*Provide protocol specific findings justifying this determination: Click or tap here to enter text.*

The consent of a Legally Authorized Representative (LAR) of either or both of the parents of a nonviable neonate will not be obtained.

*Provide protocol specific findings justifying this determination: Click or tap here to enter text.*

**2. Research Involving Neonates that is Not Otherwise Approvable<sup>iv</sup> (Check if “Yes.” All must be checked)**

The research does **NOT** meet the requirements of §46.205.

*Provide protocol specific findings justifying this determination: Click or tap here to enter text.*

The research presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates.

*Provide protocol specific findings justifying this determination: Click or tap here to enter text.*

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<sup>i</sup> This document satisfies AAHRPP elements I-9, II.4.A, II.4.B, II.5.A, II.5.B

<sup>ii</sup> “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.

<sup>iii</sup> 45 CFR §46.205

<sup>iv</sup> 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 when the DoD institutions demonstrate to the Senior Designated Official (SDO) that the IRB has fulfilled its duties in accordance with Subpart B or Part 45CFR46; the SDO must receive explicit written approval from the DoD Office of Human Research Protections (DOHRP). For all other research, the research may proceed only after the Institutional Official/Organizational Official (IO/OO) has conducted a review in accordance with HRP-044 - SOP - Not Otherwise Approvable Research and approved the research.