|  |  |
| --- | --- |
| University of Washington Human Subjects DIvision | **SOP Neonates** |

1. **PURPOSE and APPLICABILITY**
   1. This document describes the requirements and procedures for obtaining IRB approval of research involving nonviable neonates (NN) or neonates of uncertain viability (NUV).
   2. Viable neonates are considered children. Research involving viable neonates is therefore governed by the regulations and procedures for research involving children.
2. **POLICY**
   1. **NN/NUV: targeted or incidental inclusion.** Identify whether NN/NUV are encountered coincidentally or as a target population in order to determine how to apply the regulations.
   2. **Applicable regulations.** Different federal funding agencies have different regulations concerning the involvement of NN/NUV.
      1. **Health and Human Services (HHS):** The HHS regulations (45 CFR 46 Subpart B) apply to all research targeting NN/NUV that is supported by HHS or other federal agencies that have agreed to adopt Subpart B:
         * + Department of Homeland Security
           + Central Intelligence Agency
      2. **Department of Defense (DoD).** Though the DoD applies HHS Subpart B, it replaces the phrase “biomedical research” with “generalizable knowledge” throughout Subpart B.
      3. **Environmental Protection Agency (EPA).** EPA has its own sets of regulations which are more restrictive than the HHS regulations. The requirements are described in the **SOP Environmental Protection Agency** and the **WORKSHEET Environmental Protection Agency** rather than in this document.
      4. **All other research.** As part of its Flexibility Policy (**GUIDANCE Authority and Responsibilities of HSD and UW IRBs**), the UW applies the HHS Subpart B regulations to research that is not described in Sections 2.2.1 through 2.2.3 as follows:
         * + The research meets both of the following criteria:

NN/NUV are a specific target population;

The research involves more than minimal physical risk to the NN/NUV

* + - * + The phrase “biological knowledge” in Subpart B is replaced by the phrase “generalizable knowledge”.

1. **DEFINITIONS** 
   1. **Delivery –** complete separation of the fetus from the women by expulsion or extraction or any other means.
   2. **Neonate** – a newborn.
   3. **Nonviable neonate** – a neonate after delivery that, although living, is not viable.
   4. **Viability of a neonate** – being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration.
2. **PROCEDURES**
   1. NN/NUV may be involved in research only if the IRB determines that all the requirements and conditions described in applicable regulations are met. The IRB uses the **WORKSHEET Neonates** to ensure that the applicable requirements and conditions are addressed, and to document its decisions. The requirements are documented by using the **CHECKLIST Regulatory**.
3. **RELATED MATERIALS**
   1. CHECKLIST Regulatory
   2. [GUIDANCE Authority and Responsibilities of HSD and UW IRB](https://www.washington.edu/research/policies/guidance-authority-and-responsibilities-of-hsd-and-uw-irb/)
   3. [SOP Environmental Protection Agency](https://www.washington.edu/research/policies/sop-environmental-protection-agency-research-2/)
   4. [WORKSHEET Environmental Protection Agency](https://www.washington.edu/research/forms-and-templates/worksheet-environmental-protection-agency/)
   5. [WORKSHEET Neonates](https://www.washington.edu/research/forms-and-templates/worksheet-neonates/)
4. **REFERENCES**
   1. 45 CFR 46 Subpart B “Additional Protections for Pregnant Women, Human Fetuses, and Neonates Involved in Research”
   2. Department of Defense Instruction 3216.02, November 8, 2011: “Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research”

|  |  |  |  |
| --- | --- | --- | --- |
| **Version Number** | **Posted Date** | **Implementation Date** | **Summary of Changes** |
| 1.4 | 05.01.2025 | 05.01.2025 | Move to current template; minor updates |
| 1.3 | 06.25.2024 | 06.25.2024 | Revise reference from CHECKLIST Master to CHECKLIST Regulatory |
| 1.2 | 09.07.2017 | 09.07.2017 | Updated links |
| 1.1 | 08.28.2015 | 08.28.2015 | Clarifications regarding NN/NUV as incidental populations |
| Previous versions |  |  | For older versions: HSD staff refer to the SharePoint Document Library; Others – contact [hsdinfo@uw.edu](mailto:hsdinfo@uw.edu). |

**Keywords:** Flexibility policy; Pregnant women; Vulnerable populations