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

|  |  |
| --- | --- |
|  |  |

|  |
| --- |
| **PURPOSE AND APPLICABILITY** |

This worksheet is used as guidance to make required determinations about research involving **nonviable neonates** or **neonates of uncertain viability**. Final documentation of research involving neonates is found in the CHECKLIST Regulatory. It is not required that you complete or retain this worksheet.

Research involving viable neonates is considered research involving children and should be reviewed using the **WORKSHEET Children**.

|  |
| --- |
| **DEFINITIONS** |

**Neonate.** A newborn.

**Viable (neonate).** Being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration.

**Nonviable neonate.** A neonate after delivery that, although living, is not viable.

|  |
| --- |
| **REQUIREMENTS** |

Use the tables below to identify the regulatory requirements that apply to the study.

|  |  |
| --- | --- |
| **T****ABLE 1 - Environmental Protection Agency (EPA)** |  |
| * 1. Does the research have both of the following characteristics? * Supported by the EPA * Nonviable neonates **or** neonates of uncertain viability may be subjects, even if they are not a target population of the research | **No →** Skip to [Table 2](#table2)  **Yes →** Use **WORKSHEET EPA** to complete the review instead of this worksheet. |

|  |  |
| --- | --- |
| **T****ABLE 2 - Target Population** |  |
| 1. Are nonviable neonates or neonates of uncertain viability a **target study population**? | **No →** You are done with this worksheet. These regulations do not apply to the research.  **Yes →** Continue to [Table 3](#table3) |

|  |  |
| --- | --- |
| **T****ABLE 3 - Health and Human Services, Subpart B and Department of Defense**  **NOTE –** for DoD supported research replace the phrase “biomedical research” with “generalizable knowledge” in the criteria below. |  |
| 1. Does the research involve funding or any other type of support or involvement from any of the following federal agencies?  * Health and Human Services * Department of Homeland Security * Central Intelligence Agency * Department of Defense | **No →** Skip to [Table 4](#table4)  **Yes →** Continue to 3.2 |
| 1. Does the research involve **nonviable neonates**? | **No →** Skip to [3.3](#hhsuncertain)  **Yes →** Confirm the **all of the requirements listed below have been met** (except where indicated). |
| * + Where **scientifically appropriate** preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates [45 CFR 46.205(a)(1)]. | **Confirmed**  **Not appropriate** (explain below)   |  | | --- | | 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 (45 CFR 46.205(a)(2)]. | **Confirmed** |
| * + Individuals engaged in the research will have no part in determining the viability of the neonate [45 CFR 46.205(a)(3)]. | **Confirmed** |
| * + The vital functions of the neonate will not be artificially maintained [45 CFR 46.205(c)(1)]. | **Confirmed** |
| * + The research will not terminate the heartbeat or respiration of the neonate [45 CFR 46.205(c)(2)]. | **Confirmed** |
| * + There will be no added risk to the neonate resulting from the research [45 CFR 46.205(c)(3)]. | **Confirmed** |
| * + The purpose of the research is the development of important biomedical knowledge (generalizable knowledge for DoD) that cannot be obtained by other means [45 CFR 46.205(c)(4)]. | **Confirmed** |
| * + The legally effective informed consent of both parents of the neonate is obtained in accord with the pre-2018 Requirements or the 2018 requirements, as applicable, except that the waiver and alteration provisions of 45 CFR.116 of the pre-2018 Requirements or the 2018 Requirements do not apply. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent is sufficient, except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest. The consent of a legally authorized representative of either or both of the parents of a nonviable neonate will not suffice [45 CFR 46.205(c)(5)]. | **Confirmed** |
| 1. Does the research involve **neonates of uncertain viability**? | **No →** Skip to [Table 4](#table4)  **Yes →** Confirm the **all of the requirements listed below have been met** (except where indicated). |
| * Where **scientifically appropriate** preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates [45 CFR 46.205(a)(1)]. | **Confirmed**  **Not appropriate** (explain below)   |  | | --- | | 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 (45 CFR 46.205(a)(2)]. | **Confirmed** |
| * Individuals engaged in the research will have no part in determining the viability of the neonate [45 CFR 46.205(a)(3)]. | **Confirmed** |
| * The IRB determines that [45 CFR 46.205(b)(1)]:   + 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 **OR**   + The purpose of the research is the development of important biomedical knowledge (generalizable knowledge for DoD) which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research. | **Confirmed** |
| * 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 is obtained in accord with the pre-2018 Requirements or the 2018 Requirements, as applicable, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest [45 CFR 46.205(b)(2)]. | **Confirmed** |

|  |  |
| --- | --- |
| **T****ABLE 4– All Other Research** |  |
| * 1. For research that is not supported by EPA, HHS or DoD, **are the risks entirely non-physical?** | **Yes →** You are done with this worksheet. These regulations do not apply to the research.  **No →** Continue to 4.2 |
| * 1. Does the research involve **nonviable neonates**? | **No →** Skip to [4.3](#otheruncertain)  **Yes →** Confirm the **all of the requirements listed below have been met** (except where indicated). |
| * + Where **scientifically appropriate** preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates [45 CFR 46.205(a)(1)]. | **Confirmed**  **Not appropriate** (explain below)   |  | | --- | | Click or tap here to enter text. | |
| * + Each individual providing consent is fully informed regarding the **reasonably foreseeable** impact, if any, of the research on the neonate (45 CFR 46.205(a)(2)]. | **Confirmed**  **Not applicable** (no foreseeable impact)   |  | | --- | | Click or tap here to enter text. | |
| * + Individuals engaged in the research will have no part in determining viability of the neonate [45 CFR 46.205(a)(3)]. | **Confirmed** |
| * + The vital functions of the neonate will not be artificially maintained [45 CFR 46.205(c)(1)]. | **Confirmed** |
| * + The research will not terminate the heartbeat or respiration of the neonate [45 CFR 46.205(c)(2)]. | **Confirmed** |
| * + There will be no added risk to the neonate resulting from the research [45 CFR 46.205(c)(3)]. | **Confirmed** |
| * + The purpose of the research is the development of important generalizable knowledge that cannot be obtained by other means [45 CFR 46.205(c)(4)]. | **Confirmed** |
| * + The legally effective informed consent of both parent of the neonate is obtained in accord with the pre-2018 Requirements or the 2018 requirements, as applicable, except that the waiver and alteration provisions of 45 CFR.116 of the pre-2018 Requirements or the 2018 Requirements do not apply. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent is sufficient, except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest. The consent of a legally authorized representative of either or both of the parents of a nonviable neonate will not suffice [45 CFR 46.205(c)(5)]. | **Confirmed** |
| * 1. Does the research involve **neonates of uncertain viability**? | **No →** You are done with this worksheet.  **Yes →** Confirm the **all of the requirements listed below have been met** (except where indicated). |
| * + Where **scientifically appropriate** preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates [45 CFR 46.205(a)(1)]. | **Confirmed**  **Not appropriate** (explain below)   |  | | --- | | 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 (45 CFR 46.205(a)(2)]. | **Confirmed**  **Not applicable** (no foreseeable impact)   |  | | --- | | Click or tap here to enter text. | |
| * + Individuals engaged in the research will have no part in determining the viability of the neonate [45 CFR 46.205(a)(3)]. | **Confirmed** |
| * The IRB determines that [45 CFR 46.205(b)(1)]:   + 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 **OR**     - The purpose of the research is the development of important generalizable knowledge which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research. | **Confirmed** |
| * + 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 is obtained in accord with the pre-2018 Requirements or the 2018 Requirements, as applicable, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest [45 CFR 46.205(b)(2)]. | **Confirmed** |

|  |
| --- |
| **RELATED MATERIALS** |

[WORKSHEET Children](https://www.washington.edu/research/forms-and-templates/worksheet-children/)

[WORKSHEET Environmental Protection Agency](https://www.washington.edu/research/forms-and-templates/worksheet-environmental-protection-agency/)

|  |
| --- |
| **REFERENCES** |

45 CFR 46 Subpart B “Additional Protections for Pregnant Women, Human Fetuses, and Neonates Involved in Research”

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** |
| 3.0 | 05.01.2025 | 05.01.2025 | Transfer content from PDF to Word; significant reorganization of worksheet structure; update HHS Subpart A references |
| 2.3 | 05.27.2021 | 05.27.2021 | Remove references to paper process |
| 2.2 | 05.15.2017 | 05.15.2017 | Updated links; submission and committee drop down menus |
| 2.1 | 08.28.2015 | 08.28.2015 | Clarifications regarding neonates and neonates of uncertain viability as incidental populations |
| Previous versions |  |  | Older versions are beyond records retention requirements |

**Keywords:** Pregnant women; Vulnerable populations