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| University of Washington Human Subjects DIvision | **WORKSHEET Pregnant Women** |

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| **PURPOSE AND APPLICABILITY** |

The purpose of this worksheet is to provide guidance for HSD staff and IRB members to make required determinations about research specifically involving pregnant women and fetuses. It is also intended as a reference for investigators. It is not required to be completed or retained.

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| **INSTRUCTIONS** |

Use Table 1 to identify the regulatory and/or policy requirements based on federal agency support and UW policy. Once the applicable regulations and/or policies are identified, use the documents referenced in Table 1 and/or the regulatory criteria laid out in Table 2 to verify that an application meets those requirements.

**NOTE –** multiple regulatory and policy requirements may apply to a single study.

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| **TABLE 1 – IDENTIFICATION OF REGULATORY OVERSIGHT** |

Consider every row in Table 1.

If the “Regulations Apply”, follow instructions for ensuring compliance.

If the research does not fit any of the criteria in Table 1, there are no additional requirements or conditions for the involvement of pregnant women and/or fetuses for the research.

| **Regulatory Body** | **Applicability of Regulations** | **Regulations Apply** |
| --- | --- | --- |
| 1. **Environmental Protection Agency (EPA)** [40 CFR 26 Subparts B, C, L]
 | * The study is funded/supported by EPA; **and**
* Pregnant women and fetuses are subjects, regardless of whether they are a target or incidental population
 | [ ]  **No →** Skip to [Question 2](#table2)[ ]  **Yes →** Use **WORKSHEET EPA** to complete the review instead of this worksheet |
| 1. **Signatories of HHS Subpart B** [45 CFR 46.201-207; CIA Executive Order 12333, paragraph 2.10; DHS 6 U.S.C. section 112; DoE Order 443.1B; SSA 42 U.S.C. section 112]
 | * The study is funded/supported by HHS, CIA, Department of Homeland Security, Department of Energy, or Social Security Administration; **and**
* Pregnant women and fetuses are a target population for the research.
 | [ ]  **No →** Skip to [Question](#table2) 3[ ]  **Yes →** Use Table 2 or Table 3 to confirm the research meets the criteria in either 45 CFR 46.204 or 45 CFR 46.207 |
| 1. **Department of Defense (DoD)** [DoD Directive 3216.02]
 | * The study is funded/supported by DoD; **and**
* Pregnant women and fetuses are a target population for the research; **and**
* The research involves greater than minimal risk interventions or invasive procedures to the woman or fetus.
 | [ ]  **No →** Skip to [Question](#table2) 4[ ]  **Yes →** Use Table 2 and Table 3 to confirm the research meets the criteria in either 45 CFR 46.204 or 45 CFR 46.207 |
| 1. **National Institutes of Health (NIH)** [NIH Notice NOT-OD-19-128)
 | * The study is funded/supported by NIH; **and**
* The study involves research use of human fetal tissue obtained from elective abortion.
 | [ ]  **No →** Skip to [Question](#table2) 5[ ]  **Yes →** Confirm the NIH consent requirements described in the [**Designing Consent Guidance**](https://www.washington.edu/research/hsd/guidance/consent/design/#fetal) |
| 1. **National Institutes of Health** [Public Health Service ActSections 498A & 498B, U.S.C. 289g-1, 289g-2]

[Full UW Flexibility Policy described in **GUIDANCE Authority and Responsibilities of HSD and UW IRB**] | * The research involves transplantation of fetal tissue

**NOTE** it is UW policy to apply the NIH requirements to **all research** regardless of NIH funding/support. | [ ]  **No →** Skip to Question 6[ ]  **Yes →** Refer to **CHECKLIST Transplantation of Fetal Tissue** and consult with TOL or HSD leadership |
| 1. **University of Washington Policy**

[Full UW Flexibility Policy described in **GUIDANCE Authority and Responsibilities of HSD and UW IRB**] | * The research does not fit any of the criteria in Table 1, questions 1-3; **and**
* Pregnant women and fetuses are a target population for the research; **and**
* The research involves more than minimal physical risks to the woman and/or fetus.
 | [ ]  **No →** You are done with Table 1[ ]  **Yes →** Use Table 2 to confirm the research meets the criteria in 45 CFR 46.204 |

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| **TABLE 2 – 45 CFR 46.204 Research Involving Pregnant Women or Fetuses** |

Pregnant women and/or fetuses may be involved in research if **all the following criteria are met**.

| **Regulatory Criteria** | **Criteria Met** |
| --- | --- |
| 1. Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses.
 | [ ]  **Yes** |
| 1. The risk to the fetus is caused solely by interventions or procedures that hold out the [prospect of direct benefit](https://www.washington.edu/research/glossary/prospect-direct-benefit/) for the woman or the fetus **-OR-**

If there is no prospect of direct benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical1 (generalizable2\*) knowledge which cannot be obtained by other means. | [ ]  **Yes** |
| 1. Any risk is the least possible for achieving the objectives of the research.
 | [ ]  **Yes** |
| 1. The consent of the mother will be obtained in accord with the informed consent provisions in subpart A if **both** of the following conditions apply:
	* The research holds the [prospect of direct benefit](https://www.washington.edu/research/glossary/prospect-direct-benefit/) to the pregnant woman **or** the research holds out the prospect of direct benefit both to the pregnant woman and the fetus **or** the research holds no prospect of benefit for the woman nor the fetus and the risk to the fetus is not greater than minimal
	* The purpose of the research is the development of important biomedical1 (generalizable2\*) knowledge which cannot be obtained by other means3.
 | [ ]  **Yes** |
| 1. If the research holds out the [prospect of direct benefit](https://www.washington.edu/research/glossary/prospect-direct-benefit/) solely to the fetus when the consent of the pregnant women and the father is obtained in accord with the informed consent provisions of subpart A of this part, except that the father’s consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.
 | [ ]  **Yes** |
| 1. Each individual providing consent under rows 4 and 5 of this section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate.
 | [ ]  **Yes** |
| 1. For children who are pregnant, assent and permission are obtained in accord with the provisions of subpart D.
 | [ ]  **Yes** |
| 1. No inducements, monetary or otherwise, will be offered to terminate a pregnancy.
 | [ ]  **Yes** |
| 1. Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy.
 | [ ]  **Yes** |
| 1. Individuals engaged in research will have no part in determining the viability of a neonate.
 | [ ]  **Yes** |

1. **Biomedical knowledge** includes knowledge gained through social and behavioral research, if it has a biomedical component.
2. **Generalizable knowledge** means the information is expected to expand the knowledge base of a scientific discipline or other scholarly field or study and yield one or both of the following: **(a)** results that are applicable to a larger population beyond the site of data collection or the specific subjects studied; **(b)** results that are intended to be used to develop, test, or support theories, principles, and statements of relationships or to inform policy beyond the study.
3. **Obtained by other means** indicates that the inclusion of pregnant women in the research is necessary to obtain data required to pursue the objective.
4. \* - The term “biomedical knowledge” in the HHS regulations should be replaced with “generalizable knowledge” for research on pregnant women that is regulated by the DoD or UW Policy.

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| **TABLE 3 – 45 CFR 46.207 Research otherwise not approvable which presents an opportunity to understand, prevent, or alleviate a serious health problem affecting the health or welfare of pregnant women, fetuses, or neonates.** |

The Secretary will conduct or fund research that the IRB does not believe meets the requirements at 46.204 **only if all the following criteria are met**.

| **Regulatory Criteria** | **Criteria Met** |
| --- | --- |
| 1. The IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of serious problem affecting the health or welfare of pregnant women, fetuses, or neonates.
 | [ ]  **Yes** |
| 1. The Secretary, after consultation with a panel of experts in pertinent disciplines and following opportunity for public review and comment, including a public meeting announced in the Federal Register, has determined either:
	* The research in fact satisfies the conditions at 46.204; **or**
	* The following:
		+ 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; **and**
		+ The research will be conducted in accord with sound ethical principles; **and**
		+ Informed consent will be obtained in accord with the informed consent provisions of Subpart A and other applicable subparts.
 | [ ]  **Yes** |

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| **RELATED MATERIALS** |

[GLOSSARY Prospect of Direct Benefit](https://www.washington.edu/research/glossary/prospect-direct-benefit/)

[GUIDANCE Authority and Responsibilities of HSD and UW IRB](https://www.washington.edu/research/policies/guidance-authority-and-responsibilities-of-hsd-and-uw-irb/)

[WEBPAGE Designing the Consent Process Guidance](https://www.washington.edu/research/hsd/guidance/consent/design/)

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

WORKSHEET Transplantation of Fetal Tissue [HSD staff access in Published Document Library]

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| **REFERENCES** |

## NIH Notice NOT-OD-19-128, “Changes to NIH Requirements Regarding Proposed Human Fetal Tissue Research”. July 26, 2019

NIH Notice NOT-OD-19-137, “Clarifying Competing Application Instructions and Notice of Publication of Frequently Asked Questions (FAQs) Regarding Proposed Human Fetal Tissue Research”. August 23, 2019

NIH Office of Extramural Research, Grants and Funding. “Frequently Asked Question: Human Fetal Tissue Research”. Posted August 23, 2019 https://grants.nih.gov/grants/human-fetal-tissue-research-faqs.htm

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| **Version Number** | **Posted Date** | **Implementation Date** | **Summary of Changes** |
| 3.3 | 05.01.2025 | 05.01.2025 | Move content to current TEMPLATE Worksheet; moderate revisions to organization of information |
| 3.2 | 08.31.2023 | 08.31.2023 | Add link to glossary term “prospect of direct benefit” |
| 3.1 | 06.01.2023 | 06.01.2023 | Replaced Standard Template reference to landing page for UW consent templates |
| 3.0 | 12.13.2019 | 12.13.2019 | Changed format from PDF to Word; added NIH Human Fetal Tissue and Fetal Tissue Transplantation policies; significantly revised organziation |
| 2.3 | 02.29.2016 | 02.29.2016 | Updated link, submission type and committee drop down menus |
| Previous versions |  |  | For older versions: HSD Staff – refer to the SharePoint Document Library; Others - contact hsdinfo@uw.edu. |

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