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| Logo  University of Washington Human Subjects Division | **WORKSHEET Pregnant Women** |

**PURPOSE**

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.

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.

**TABLE 1: Identification of Regulatory Oversight**

Use this table to identify the applicable federal regulations and UW policies related to research involving pregnant women and fetuses.

Note: multiple regulatory and policy requirements may apply to a single study.

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| **A. 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.  | Use **WORKSHEET Environmental Protection Agency** to identify the regulatory requirements for this population. |
| **B. Signatories of the Common Rule, 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 Health and Human Services, Central Intelligence Agency, Department of Homeland Security, Department of Energy, or Social Security Administration; **-and-**Pregnant women and fetuses are a target population for the research. | The research must meet all the criteria listed in one of the following citations (see **Table 2**):* 45 CFR 46.204
* 45 CFR 46.207
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| **C. 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. | The research must meet all the criteria listed in one of the following citations (see **Table 2**):* 45 CFR 46.204 **but** replace “biomedical knowledge” with “generalizable knowledge”
* 45 CFR 46.207
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| **D. National Institutes of Health (NIH)** |
| The study involves the research use of human fetal tissue obtained from elective abortion. (NIH Notice NOT-OD-19-128) | National Institutes of Health (NIH) dictate specific requirements for the consent process and consent form for this type of research. Use the following documents to verify the application complies with these requirements:* **WORKSHEET Consent Requirements and Waivers**
* **UW Consent Templates**
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| The research involves transplantation of fetal tissue. (Public Health Service Act, Sections 498A & 498B, U.S.C. 289g-1, 289g-2) | There are specific criteria that must be met for this type of research:* **See CHECKLIST Transplantation of Fetal Tissue**
* **Consult TOL or HSD Management**
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| **E. University of Washington Policy**\* |
| The research does not fit any of the criteria in Table 1 sections A-C; **-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 the fetus. | It is UW policy to require that this type of research meet all the criteria listed in the following citation (see **Table 2**):* 45 CFR 46.204 **but** replace “biomedical knowledge” with “generalizable knowledge”
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| The study involves the research use of human fetal tissue obtained from elective abortion. | It is UW policy to apply NIH requirements for the consent form and consent process to all research of this kind, regardless of NIH support. Use the following documents to verify the application complies with these requirements:* **WORKSHEET Consent Requirements and Waivers**
* **UW Consent Templates**
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| The research does not fit any of the criteria in this table. | There are no additional requirements or conditions for the involvement of pregnant women and/or fetuses in this type of research. |

\* See “Flexibility” section below.

**TABLE 2: Regulatory Criteria Checklist**

Use this table to verify the regulatory criteria are met for studies that are subject to these regulations. See Table 1 to identify whether these regulatory criteria apply.

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| **45 CFR 46.204 - Research involving pregnant women or fetuses**Pregnant women and fetus may be in may be involved in research if **all** the following conditions are 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.
 |
|  | 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 purpose of the research is the development of important biomedical knowledge**1,2,\*** which cannot be obtained by other means. |
|  | 1. Any risk is the least possible for achieving the objectives of the research.
 |
|  | 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:
	1. 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* 1. The purpose of the research is the development of biomedical knowledge**1,2,\*** that cannot be obtained by any other means**3**.
 |
|  | 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.
 |
|  | 1. Each individual providing consent under paragraph (d) or (e) of this section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate.
 |
|  | 1. For children who are pregnant, assent and permission are obtained in accord with the provisions of subpart D.
 |
|  | 1. No inducements, monetary or otherwise, will be offered to terminate a pregnancy.
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|  | 1. Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate and pregnancy.
 |
|  | 1. Individuals engaged in research will have no part in determining the viability of a neonate.
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| **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 **both** of the following conditions are 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.
 |
|  | 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;
	1. The research in fact satisfies the conditions at 46.204 **-or-**
	2. 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.
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1. **Biomedical knowledge: includes knowledge gained though social and behavioral research, if it has a biomedical component.**
2. **Generalizable knowledge: 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: this means that the inclusion of pregnant women in the research is necessary to obtain data required to pursue the objective.**

**\* The term “biomedical knowledge” should be replaced with “generalizable knowledge” for research on pregnant women that is regulated by the Department of Defense or UW policy.**

**FLEXIBILITY**

UW applies its Flexibility Policy by choosing to:

1. Apply the requirements at 45 CFR 46.204 for research that: a) is not supported by EPA, HHS, CIA, DHS, DOE, SSA, DoD; b) includes pregnant women and fetuses as a target population; and c) involves more than minimal physical risks to the woman and/or the fetus.
2. Apply NIH consent requirements at NOT-OD-19-128 to all research involving the use of human fetal tissue obtained from elective abortions, regardless of NIH support.

**RELATED MATERIALS**

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

[LANDING PAGE UW Consent Templates](https://www.washington.edu/research/hsd/guidance/consent/templates/)

[SOP Pregnant Women](https://www.washington.edu/research/policies/sop-pregnant-women-2/)

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

[WORKSHEET Consent Requirements and Waivers](https://www.washington.edu/research/forms-and-templates/worksheet-consent/)

**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** |
| 3.2 | 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 organization |
| 2.3 | 05.15.2017 | 05.15.2017 | Updated links, submission type and committee drop down menus |
| 2.2 | 02.29.2016 | 02.29.2016 | Fixed typo |
| Previous versions |  |  | Previous version are beyond records retention  |

**Keywords:** Pregnant women