PI WORKSHEET: Pregnant Women

This worksheet is required for the following submission types when the research involves pregnant women: Expedited research or Full Committee research.

The purpose of this worksheet is to provide support for IRB members or the Designated Reviewer following HRP-314 - WORKSHEET - Criteria for Approval when research involves pregnant women as subjects. The PI completes this worksheet to document determinations required by the regulations along with protocol specific findings justifying those determinations. For more information about research involving pregnant women, visit: [Vulnerable Populations](https://research.uci.edu/human-research-protections/subject-enrollment/vulnerable-populations/).

Attach this worksheet to the “Local Site Documents” section of the ZOT IRB application.

1. Submission Information

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| **1.1 Basic Information** | **Submission Details** |
| **1.1.1 IRB Number:** | ​​ Click or tap here to enter text. |
| **1.1.2 Short Title:** | ​​ Click or tap here to enter text. |

1. Research Must Meet One of the Following Sets of Criteria (Complete 2.1 or 2.2.)
   1. Research Involving Pregnant[[1]](#endnote-2) Women[[2]](#endnote-3) (Check if “Yes”. All must be checked.)

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.  **NA** **if not scientifically appropriate.**

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

One of the following is true: **(Check box that is true)**

The risk to the fetus[[3]](#endnote-4) is caused solely by Interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus.

There is no prospect of benefit to the fetus, the risk to the fetus is **NOT** greater than Minimal Risk, and the purpose of the research is the development of important biomedical[[4]](#endnote-5) knowledge which cannot be obtained by any other means.

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

Any risk is the least possible for achieving the objectives of the research.

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

If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is NOT greater than Minimal Risk and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, consent of the mother is obtained.  **NA** **if research does not hold out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus.**

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

If the research holds out the prospect of direct benefit solely to the fetus, the consent of the pregnant woman and the father is obtained, 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.  **NA** **if research does not hold out the prospect of direct benefit to the fetus.**

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| 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 fetus or neonate.

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

For children who are pregnant, assent and permission[[5]](#endnote-6) are obtained in accord with the provisions of subpart D.  **NA** **if research does not enroll children who are pregnant.**

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

No inducements, monetary or otherwise, will be offered to terminate a pregnancy.

Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy.

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

* 1. Research Involving Pregnant Women that is NOT Otherwise Approvable (Check if “Yes”. All must be checked.) Follow HRP-044 - SOP - Not Otherwise Approvable Research

The research does **NOT** meet the requirements of §46.204.

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| 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.

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

1. Research Involving Pregnant Women – Additional Considerations (Check if “Yes”.)

Prior to obtaining informed consent from a subject for assisted oocyte production (AOP) or any alternative method of ovarian retrieval on a subject for the purpose of procuring oocytes for research or the development of medical therapies, a physician and surgeon shall provide to the subject a standardized medically accurate written summary of health and consumer issues associated with AOP and any alternative methods of oocyte retrieval.

Per California Law, pregnancy test results may be provided to a minor’s parent(s) or guardian only with the minor’s permission.

For research reviewed by Committee, the Investigator states whether study procedures may involve risks to the subject (embryo or fetus if subject is or may become pregnant) that are currently unforeseeable.

1. “Pregnancy” encompasses the period of time from implantation until delivery. A woman shall be assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery. [↑](#endnote-ref-2)
2. 45 CFR §46.204 [↑](#endnote-ref-3)
3. “Fetus” means the product of conception from implantation until delivery. [↑](#endnote-ref-4)
4. For Department of Defense (DOD) research, the phrase “biomedical knowledge” can be replaced with “generalizable knowledge.” [↑](#endnote-ref-5)
5. American Academy of Pediatrics v. Lungren (1997) 16 Cal.4th 307. **A minor may consent to an abortion without parental consent and without court permission.** California Health and Safety Code remains unchanged (California Family Code Section 6925; Health and Safety Code Section 123450 for abortion). [↑](#endnote-ref-6)