COOK COUNTY HEALTH

HRP-412 | 9/25/2023

# CHECKLIST: Pregnant Women

The purpose of this checklist 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. This checklist must be used for all reviews (initial, continuing, modification, review by the convened IRB, and review using the expedited procedure.) [i]

- For initial review using the expedited procedure and modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, the Designated Reviewer completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations. The Designated Reviewer attaches this checklist to HRP-402 - CHECKLIST- Non-Committee Review. The IRB Office retains this checklist in the protocol file.
- For initial review using the convened IRB and for modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, one of the following two options may be used:
  1. The convened IRB completes the corresponding section of HRP-501 - TEMPLATE - MINUTES to document determinations required by the regulations along with protocol specific findings justifying those determinations, in which case this checklist does not need to be completed or retained.
  2. The convened IRB completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations and the IRB Office retains this checklist in the protocol file.

## Submission Information

| Basic Information | Submission Details |
|---|---|
| IRB Number: | Click or tap here to enter text. |
| Study Title: | Click or tap here to enter text. |
| Short Title: | Click or tap here to enter text. |
| Investigator: | Click or tap here to enter text. |

## Research must meet one of the following three sets of criteria in Section 1-3.

### 1. Non-Federally Regulated Minimal Risk Research (Check if "Yes". All must be checked)

☐ The research is **NOT** conducted, funded, or otherwise subject to regulation by DHHS or the Environmental Protection Agency (EPA).

☐ The research involves no more than Minimal Risk to pregnant women and fetuses.

☐ The research is not funded by Department of Defense, or does not involve interventions/invasive procedures to the woman or fetus and does not involve fetuses or neonates as subjects.

### 2. Research Involving Pregnant[ii] Women[iii] (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.) ☐ NA**

*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[iv] 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[v] knowledge which cannot be obtained by any other means.

*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.

*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.) ☐ NA**

*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.) ☐ NA**

*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.

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

☐ For children who are pregnant, assent and permission are obtained in accord with the provisions of subpart D. **(NA if research does not enroll children who are pregnant.) ☐ NA**

*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.

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

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

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

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

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

3. **Research Involving Pregnant Women that is NOT Otherwise Approvable**[vi](All must be "**Yes**")

☐ The research does **NOT** meet the requirements of 45 CFR §46.204.

*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.

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

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[i] This document satisfies AAHRPP elements I.1.D, I-9, II.4.A, II.4.B, II.5.A, II.5.B

[ii] "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.

[iii] 45 CFR §46.204

[iv] "Fetus" means the product of conception from implantation until delivery.

[v] For Department of Defense (DOD) research, the phrase "biomedical knowledge" can be replaced with "generalizable knowledge."

[vi] 45 CFR §46.207. For DHHS-regulated research, the research may proceed only after OHRP has reviewed and approved the research. For research conducted or funded by the Department of Defense (DOD), the research may proceed when the DoD institutions demonstrate to the Senior Designated Official (SDO) that the IRB has fulfilled its duties in accordance with Subpart B of 45 CFR §46 and the SDO must receive explicit written approval from the DoD Office of Human Research Protections (DOHRP). For all other research, the research may proceed only after the Organizational Official has conducted a review in accordance with HRP-044 - SOP - Not Otherwise Approvable Research and approved the research.