TEXAS A&M UNIVERSITY	**CHECKLIST:** Pregnant Women		
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The purpose of this checklist is to provide support for IRB members or the Designated Reviewer when Reviewer following HRP-314 - WORKSHEET - Criteria for Approval when research involves pregnant women as subjects. This checklist or its , equivalent form or electronic equivalent must be used for all reviews (initial, continuing, modification, review by the convened IRB, and review using the expedited procedure.)[1]

- For initial review using the expedited procedure and modifications and continuing reviews where the determinations relevant to the criteria for approval have changed, the Designated Reviewer completes this checklist or equivalent to document determinations required by the regulations along with protocol specific findings justifying those determinations. The Designated Reviewer or IRB staff attaches this checklist or equivalent to the protocol file. 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 the criteria for approval have changed, one of the following two options may be used:
  1. The convened IRB completes the corresponding section of the meeting minutes to document determinations required by the regulations along with protocol specific findings justifying those determinations, in which case this checklist or equivalent form does not need to be completed or retained.
  2. The convened IRB completes this checklist or equivalent form to document determinations required by the regulations along with protocol specific findings justifying those determinations and the IRB Office uploads this checklist or equivalent form to the protocol file or uses the electronic equivalent.

IRB Number:	
Study Title:	
Short Title:	
Investigator:	

Research must meet one of the following sets of criteria in Sections 1-2.

	1 Minimal Risk Research (Check if **"Yes"**. All must be checked)
☐	The research is **NOT** conducted, funded, or otherwise subject to regulation by DHHS, Environmental Protection Agency (EPA), or Veterans Administration (VA).
☐	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[i] Women[ii] (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. **(N/A if not scientifically appropriate.)** ☐ **N/A** *Provide protocol specific findings justifying this determination:*
☐	One of the following is true**: (Check box that is true)** ☐ The risk to the fetus[iii] 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[iv] knowledge which cannot be obtained by any other means *Provide protocol specific findings justifying this determination:*
☐	Any risk is the least possible for achieving the objectives of the research. *Provide protocol specific findings justifying this determination:*
☐	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. **(N/A 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.)** ☐ **N/A** *Provide protocol specific findings justifying this determination:*

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

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☐	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. **(N/A if research does not hold out the prospect of direct benefit to the fetus.)** ☐ **N/A** *Provide protocol specific findings justifying this determination:*
☐	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:*
☐	For children who are pregnant, assent and permission are obtained in accord with the provisions of subpart D. **(N/A if research does not enroll children who are pregnant.)** ☐ **N/A** *Provide protocol specific findings justifying this determination:*
☐	No inducements, monetary or otherwise, will be offered to terminate a pregnancy. *Provide protocol specific findings justifying this determination:*
☐	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:*
☐	Individuals engaged in the research will have no part in determining the viability of a neonate. *Provide protocol specific findings justifying this determination:*

[i] "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.
[ii] 45 CFR §46.204
[iii] "Fetus" means the product of conception from implantation until delivery
[iv] For Department of Defense (DOD) research, the phrase "biomedical knowledge" can be replaced with "generalizable knowledge."