The purpose of this checklist is to provide support for IRB members or the Designated Reviewer when reviewing research involving pregnant women as subjects. This checklist must be used.

- For review using the expedited procedure this checklist is to be completed by the Designated Reviewer to document determinations required by the regulations and protocol specific findings justifying those determinations.
- For review using the convened IRB this checklist is to be completed by the convened IRB to document determinations required by the regulations and protocol specific findings justifying those determinations and retained in the protocol file.

1 Non-Federally Regulated Minimal Risk[1] Research (All must be **Yes**)

☐ **Yes** ☐ **No**	The research is **NOT** funded or conducted by DHHS[2] and the research is **NOT** funded or conducted by or have resulted intended to be submitted to the Environmental Protection Agency (EPA).
☐ **Yes** ☐ **No**	The research involves no more than minimal risk to pregnant women and fetuses.

2 Research Involving Pregnant Women (45 CFR §46.204) (All items in the left most columns must be **"Yes"**)

☐ **Yes** ☐ **No**	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. *Provide protocol specific findings justifying this determination:*
☐ **Yes** ☐ **No**	One of the following is true**: (Check box that is true)** ☐ The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus. ☐ If there is no such prospect of benefit to the fetus, the risk to the fetus is **NOT** greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means *Provide protocol specific findings justifying this determination:*
☐ **Yes** ☐ **No**	Any risk is the least possible for achieving the objectives of the research. *Provide protocol specific findings justifying this determination:*

[1] *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life of normal persons or during the performance of routine physical or psychological examinations or tests in normal persons.

[2] If the research is subject to a federalwide assurance, it is subject to DHHS regulations regardless of whether the research is conducted or funded by DHHS.

☐ **Yes** ☐ **No**	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 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. *Provide protocol specific findings justifying this determination:*
☐ **Yes** ☐ **No**	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. *Provide protocol specific findings justifying this determination:*
☐ **Yes** ☐ **No**	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:*
☐ **Yes** ☐ **No**	For children who are pregnant, assent and permission are obtained in accord with the provisions of subpart D. *Provide protocol specific findings justifying this determination:*
☐ **Yes** ☐ **No**	No inducements, monetary or otherwise, will be offered to terminate a pregnancy. *Provide protocol specific findings justifying this determination:*
☐ **Yes** ☐ **No**	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:*
☐ **Yes** ☐ **No**	Individuals engaged in the research will have no part in determining the viability of a neonate. *Provide protocol specific findings justifying this determination:*

3 **Research Involving Pregnant Women that is NOT Otherwise Approvable (45 CFR §46.207)**[3] (All must be **"Yes"**)	
☐ **Yes** ☐ **No**	The research does meets the requirements of 45 CFR §46.204 or §46.205. *Provide protocol specific findings justifying this determination:*
☐ **Yes** ☐ **No**	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. *Provide protocol specific findings justifying this determination:*

[3] For DHHS-regulated research, the research may proceed only after OHRP has reviewed and approved the research. For all other research, the research may proceed only after Organizational Officials have conducted a review in accordance with the SOP – Not Otherwise Approval Research and approved the research.