UC San Diego INSTITUTIONAL REVIEW BOARD ADMINISTRATION	**OIA-412 CHECKLIST:** Pregnant Subjects		
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The purpose of this checklist is to provide support for IRB members or the designated reviewer following the *OIA-314 WORKSHEET: Criteria for Approval and Additional Considerations*, or equivalent, when research involves pregnant[1] individuals as subjects.[2] This checklist, or equivalent, may be used for all reviews (initial, continuing, amendment, review by the convened IRB, and review using the expedited procedure) when the research is funded or supported by the Department of Health and Human Services (DHHS), the Department of Defense (DOD), or the Department of Homeland Security (DHS). Research involving the intentional exposure of pregnant human subjects to insecticides will not be approved. For DOD studies, the applicability of this checklist is limited to research involving pregnant individuals as participants in research that is more than minimal risk and includes interventions or invasive procedures in the pregnant individual or the fetus,[3] or involves fetuses or neonates as participants. It does not need to be completed or retained.

If research includes pregnant subjects solely to obtain data and involves no research interventions, UCSD Office of IRB Administration's (OIA) determination is that the research involves no more than minimal risk to the pregnant subject and no risk to the fetus except risk to privacy, then this checklist does not need to be used. In these cases, the only requirement of the designated reviewer or IRB is to ensure the investigator and research staff will not discuss or participate in termination of a pregnancy or determination of the infant(s)' viability. This determination can be made by looking at protocol procedures and, if one exists, the consent document.

IRB Number:	
Investigator:	

Research must meet one of the following three sets of criteria in Sections 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, DHS, or the Environmental Protection Agency (EPA).	
☐	The research involves no more than minimal risk to pregnant subjects and fetuses.	
☐	If the research is conducted or funded by DOD, it involves no interventions or invasive procedures to the pregnant subject or the fetus, and does not involve fetuses or neonates as subjects.	
2	**Research Involving Pregnant Subjects** (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 subjects, have been conducted and provide data for assessing potential risks to pregnant subjects and fetuses. *Provide protocol specific findings justifying this determination:*	
☐	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 pregnant subject 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] 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 subject, the prospect of a direct benefit both to the pregnant subject and the fetus, or no prospect of benefit for the pregnant subject or 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 pregnant subject is obtained. *Provide protocol specific findings justifying this determination:*	
☐	If the research holds out the prospect of direct benefit solely to the fetus, the consent of the pregnant subject and the other biological parent is obtained, except that the other biological parent's consent need **NOT** be obtained if they are 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:*	
☐	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 45 CFR Part 46 subpart D.[5] *Provide protocol specific findings justifying this determination:*	

[1] "Pregnancy" encompasses the period of time from implantation until delivery. An individual shall be assumed to be pregnant if they exhibit any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery.
[2] 45 CFR 46.204
[3] "Fetus" means the product of conception from implantation until delivery.
[4] For DOD research, the phrase "biomedical knowledge" can be replaced with "generalizable knowledge."
[5] 45 CFR Part 46, Subpart D Additional Protections for Children Involved as Subjects in Research

☐	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:*
3	**Research Involving Pregnant Subjects that is NOT Otherwise Approvable**[6] (All must be **"Yes"**)
☐	The research does **NOT** meet the requirements of 45 CFR 46.204. *Provide protocol specific findings justifying this determination:*
☐	The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant individuals, fetuses or neonates. *Provide protocol specific findings justifying this determination:*

[6] 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 DOD, the research may proceed only after the Director, Defense, Research and Engineering has reviewed and approved the research.