Annexure 2

AX 02/ SOP 20/V5

Checklist – Requirements for Research Involving Pregnant Women & Fetuses

Investigator: ***IEC #:***

Study Title: _____

_____

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_____

SECTION 1

☐ **THIS RESEARCH INVOLVES PREGNANT WOMEN OR FETUSES PRIOR TO DELIVERY**

	Yes	No	NA
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;	☐	☐	☐
The risk to the fetus is not greater than minimal, or any risk to the fetus which is greater than minimal is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus;	☐	☐	☐
Any risk is the least possible for achieving the objectives of the research;	☐	☐	☐
The woman's consent or the consent of her legally authorized representative is obtained in accord with the informed consent provisions, unless altered or waived.	☐	☐	☐
The woman or her legally authorized representative, as appropriate, is fully informed regarding the reasonably foreseeable impact of the research on the fetus	☐	☐	☐
No inducements, monetary or otherwise, will be offered to terminate a pregnancy;	☐	☐	☐
Women's participation in the research will not have an effect on the decisions by investigator with respect to the timing, method or procedures used to terminate a pregnancy; and	☐	☐	☐
The decision of investigator determining the viability of a fetus will not have an effect if the women participates in the research	☐	☐	☐

If the response to any of the above is No, the research is not approvable by the IEC at this time. See section 3

SECTION 2

☐ **THIS RESEARCH INVOLVES FETUSES AFTER DELIVERY**

	Yes	No	NA
1. Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to fetuses	☐	☐	☐
2. The individual(s) providing consent is fully informed regarding the reasonably foreseeable impact of the **research** on the fetus	☐	☐	☐
3. No inducements, monetary or otherwise, will be offered to terminate a pregnancy;	☐	☐	☐
4. Women's participation in the research will not have an effect on the decisions by investigator with respect to the timing, method or procedures used to terminate a pregnancy; and	☐	☐	☐
5. The decision of investigator determining the viability of a fetus will not have an effect if the women participates in the research	☐	☐	☐

AND

A. Fetuses of uncertain viability	**Yes**	**No**	**NA**
1. Does the **research** hold out the prospect of enhancing the probability of survival of the particular fetus to the point of viability, and any risk is the least possible for achieving the objectives of the **research;**	☐	☐	☐
OR			
The purpose of the **research** is the development of important biomedical knowledge which cannot be obtained by other means and there will be no risk to the fetus resulting from the **research**;	☐	☐	☐
2. The legally effective informed consent of either parent of the fetus or , if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained.	☐	☐	☐

And/or

B. Nonviable fetuses	Yes	No	NA
1. Vital functions of the fetus will not be artificially maintained;	☐	☐	☐
2. There will be no risk to the fetus resulting from the research;	☐	☐	☐
3. The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and	☐	☐	☐

4. The legally effective informed consent of both parents of the fetus will be obtained except that the waiver and alteration provisions do not apply. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable fetus will suffice to meet the requirements of this paragraph. The consent of a legally authorized representative of either or both of the parents of a nonviable fetus will not suffice to meet the requirements of this paragraph.	☐	☐	☐

If the response to any of above is **No,** the research is not approvable by the IEC at this time. See section 3.

SECTION 3

THIS RESEARCH CAN BE CONDUCTED ONLY AFTER:

(a) The IEC finds that 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 or fetuses **and,**

(b) The secretary, after consultation with a panel of experts in pertinent disciplines (for examples: science, medicine, ethics, law) to determine either:

(1) That the research in fact satisfies the conditions of Schedule Y , as applicable, or

(2) The following:

(i) 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 or fetuses;

(ii) The research will be conducted in accord in sound ethical principles; and

(iii) Informed consent will be obtained in accord with informed consent provisions of Schedule Y and other applicable subparts, unless altered or waived in accord.

Signature of Principal Investigator: _____ Date _____

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