**FORM 5.1C CHECKLIST** – **REQUIREMENTS FOR RESEARCH INVOLVING PREGNANT WOMEN AND FETUSES**

**INVESTIGATOR: IDI REC #**

**STUDY TITLE**

**SECTION 1**

[ ]  **THIS RESEARCH INVOLVES PREGNANT WOMEN OR FETUSES PRIOR TO DELIVERY**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Yes** | **No** | **N/A** |
| 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, unless altered or waived by the IDI REC; | [ ]  | [ ]  | [ ]  |
| The woman or her legally authorized representative, as appropriate, is fully informed regarding the reasonably foreseeable impact of the research on the fetus or resultant child; | [ ]  | [ ]  |  |
| If the research involves children aged 17 years or younger who are pregnant, assent and permission will be obtained; | [ ]  | [ ]  | [ ]  |
| No inducements, monetary or otherwise, will be offered to terminate a pregnancy; |[ ] [ ] [ ]
| Individuals engaged in the **research** will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and |[ ] [ ] [ ]
| Individuals engaged in the **research** will have no part in determining the viability of a fetus. |[ ] [ ] [ ]

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

**SECTION 2**

[ ] **THIS RESEARCH INVOLVES FETUSES AFTER DELIVERY**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Yes** | **No** | **N/A** |
| 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 or resultant child; |[ ] [ ] [ ]
| 3. No inducements, monetary or otherwise, will be offered to terminate a pregnancy; |[ ] [ ] [ ]
| 4. Individuals engaged in the **research** will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; |[ ] [ ] [ ]
| 5. Individuals engaged in the **research** will have no part in determining the viability of a fetus. |[ ] [ ] [ ]

**AND**

|  |  |  |  |
| --- | --- | --- | --- |
| **A. Fetuses of uncertain viability** [ ]  | **Yes** | **No** | **NA** |
| 1. Does the **research** holds out the prospect of enhancing the probability of survival of the particular fetus to the point of viability, and any risk is the leastpossible 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'slegally authorized representative is obtained. | [ ]  | [ ]  | [ ]  |

**And/or**

|  |  |  |  |
| --- | --- | --- | --- |
| **B. Nonviable fetuses** [ ]  | **Yes** | **No** | **NA** |
| 1. Vital functions of the fetus will not be artificially maintained; |[ ] [ ] [ ]
| 2. The research will not terminate the heartbeat or respiration of the fetus; |[ ] [ ] [ ]
| 3. There will be no risk to the fetus resulting from the research; |[ ] [ ] [ ]
| 44. The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and |[ ] [ ] [ ]
| 55. The legally effective informed consent of both parents of the fetus will be obtained in accord with Section 6 of the National Guidelines for Research Involving Humans as Research Participants, except when the waiver provisions of Section 6.5 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. 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 the above is **No,** the research is not approvable by the IDI REC at this time. See Section 3

**SECTION 3**

[ ]  **THIS RESEARCH CAN BE CONDUCTED ONLY AFTER:**

1. The IDI REC 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**
2. The Secretary of the UNSCT, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, ethics, law) and following opportunity for public review and comment, including a public meeting, has determined either:
	1. That the research in fact satisfies the conditions of Section 9.9 of the National Guidelines for Research Involving Humans as Research Participants, as applicable, or
	2. The following:
		1. 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;
		2. The research will be conducted in accord with sound ethical principles; and
		3. Informed consent will be obtained in accord with the informed consent provisions of National Guidelines for Research Involving Humans as Research Participants, Section 6 and other applicable subparts, unless altered or waived in accord with Section 6.5.

Comments:

Primary Reviewer Date