

CHECKLIST – REQUIREMENTS FOR RESEARCH INVOLVING PREGNANT WOMEN AND FETUSES

SC 501-B

01/01/07

Investigator:

IRB #:

Study Title:

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 nonpregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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;	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Any risk is the least possible for achieving the objectives of the research;	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
The woman's consent or the consent of her legally authorized representative is obtained in accord with the informed consent provisions of subpart A of this part, unless altered or waived in accord with 45 CFR §46.101(i) or §46.116(c) or (d);	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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;	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If the research involves children as defined in 45 CFR 46.402(a) who are pregnant, assent and permission will be obtained in accord with the provisions of subpart D of that part;	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
No inducements, monetary or otherwise, will be offered to terminate a pregnancy;	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Individuals engaged in the research will have no part in determining the viability of a fetus.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

If the response to any of the above is **No**, the research is not approvable by the IRB 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;	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. The individual(s) providing consent is fully informed regarding the reasonably foreseeable impact of the research on the fetus or resultant child;	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. No inducements, monetary or otherwise, will be offered to terminate a pregnancy;	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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;	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Individuals engaged in the research will have no part in determining the viability of a fetus.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

AND

A. Fetuses of uncertain viability <input type="checkbox"/>	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 least possible for achieving the objectives of the research ;	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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 ;	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

And/or

B. Nonviable fetuses <input type="checkbox"/>	Yes	No	NA
1. Vital functions of the fetus will not be artificially maintained;	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. The research will not terminate the heartbeat or respiration of the fetus;	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. There will be no risk to the fetus resulting from the research;	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

<p>5. The legally effective informed consent of both parents of the fetus will be obtained in accord with subpart A of 45 CFR 46, except that the waiver and alteration provisions of §46.116(c) and (d) 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.</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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If the response to any of the above is **No**, the research is not approvable by the IRB at this time. See Section 3

SECTION 3

THIS RESEARCH CAN BE CONDUCTED ONLY AFTER:

(a) The IRB 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 example: science, medicine, ethics, law) and following opportunity for public review and comment, including a public meeting announced in the Federal Register, has determined either:

(1) That the research in fact satisfies the conditions of 45 CFR §46.204, 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 with sound ethical principles; and

(iii) Informed consent will be obtained in accord with the informed consent provisions of 45 CFR 46 subpart A and other applicable subparts, unless altered or waived in accord with 45 CFR §46.101(i) or §46.116(c) or (d).

Comments:

Primary Reviewer

Date