TANEY COUNTY HEALTH DEPARTMENT

IRB CHECKLIST – PREGNANT WOMEN, FETUSES, & NEONATES

HRPP # _____

Pregnant Women, Fetuses and Neonates: Please note that the exemptions set forth in 45 CFR 46.101(b)(1)-(6)) may be applied to research involving these vulnerable populations.

For research involving pregnant women, fetuses or neonates that is not otherwise approvable under the provisions below, (1) the IRB must determine that the research has the reasonable probability of providing important biomedical knowledge; **AND** (2) the IRB must forward its determination to the Director of the TCHD who will consult with experts and determine whether the research may go forward. Please consult with ORA for further details.

Please select all that apply:

☐ **Research directed at Pregnant Women and Fetuses** (complete Part A below)

☐ **Research directed at Neonates** (complete Part B below)

PART A – PREGNANT WOMEN AND FETUSES PRIOR TO DELIVERY

Pregnancy encompasses the period of time from implantation until delivery. A woman shall be assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery. **Delivery** means complete separation of the fetus from the woman by expulsion or extraction or any other means. **Fetus** means the product of conception from implantation until delivery.

1. If the research is directed at pregnant women or fetuses prior to delivery, the research may be approved if the following conditions are met. Please verify that the following criteria have been satisfied:	Yes	No
a. Where scientifically appropriate, pre-clinical studies and data are available, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risk to pregnant women and fetuses.	☐	☐
b. Risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the women or the fetus; **OR** If there is no such prospect of benefit, 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.	☐ ☐	 ☐
c. Any risk is the least possible for achieving the research objectives.	☐	☐
d. No inducements will be offered to terminate the pregnancy.	☐	☐
e. Researchers will have no part in determining viability or the timing, methods, or procedures for terminating the pregnancy.	☐	☐

Comments or Concerns:

2. If the research is directed at pregnant women or fetuses prior to delivery, the following conditions regarding informed consent must be satisfied:	Yes	No	N/A
a. The fully informed consent of **the pregnant woman** is obtained because 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 where 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.	☐ ☐ ☐	☐	☐
b. If the research holds out the prospect of direct benefit solely to the fetus, informed consent will be obtained from: ▪ both the **pregnant woman** and the **father** **OR** ▪ only the **pregnant women** because the father is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.	☐ ☐	☐	☐
c. Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate.	☐	☐	☐
d. For **pregnant children**, assent of the pregnant child and parental permission are both obtained in accordance with Subpart D (*see Reviewer Checklist Attachment 1 – Children*).	☐	☐	☐
Comments or Concerns:			

PART B – NEONATES (FETUSES AFTER DELIVERY)

Neonates are newborns (i.e., delivered fetuses). A **nonviable neonate** means a neonate after delivery that although living, is not viable. **Viable**, as it pertains to the neonate, means being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration. If the neonate is viable, it is considered a child under the regulations and Subpart D of 45 CFR Part 45 applies (see Reviewer Checklist Attachment 1 – Children).

A **legally authorized representative** means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

3. If the research is directed at neonates, the following conditions must be satisfied:	Yes	No
a. Is the research directed at **neonates of uncertain viability?** (*If no, skip to question 3.b. below.)* If yes, all of the following conditions must be met:		
1) Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risk to neonates.	☐	☐
2) Individuals engaged in the research will have no part in determining the viability of a neonate.	☐	☐
3) Research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, **and** any risk is the least possible for achieving that objective. **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 added risk to the neonate resulting from the research.	☐	☐

	Yes	No
4) The legally informed consent of **either parent** (or **either parent's legally authorized representative** if neither parent is available to consent because of unavailability, incompetence, or temporary incapacity) is obtained, because the research holds out the prospect of direct benefit solely to the fetus. **OR** The legally informed consent of the **mother** or **mother's legally authorized representative** is obtained because the pregnancy resulted from rape or incest.	☐ ☐	☐
5) Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate.	☐	☐
b. Is the research directed at **nonviable neonates?** (*If no, skip to question 3.c. below.)* If yes, all of the following conditions must be met:	☐	☐
1) Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risk to neonates.	☐	☐
2) Individuals engaged in the research will have no part in determining the viability of a neonate.	☐	☐
3) Vital functions of the neonate will not be artificially maintained.	☐	☐
4) The research will not terminate the heartbeat or respiration of the neonate.	☐	☐
5) There will be no added risk to the neonate resulting from the research.	☐	☐
6) The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means.	☐	☐
7) The legally informed consent of **both parents** is obtained; and the informed consent of a legally authorized representative is not permitted). **OR** The legally informed consent of **one parent** is obtained because the other parent is unable to consent because of unavailability, incompetence, or temporary incapacity. **OR** The legally informed consent of the **mother** is obtained because the pregnancy resulted from rape or incest.	☐ ☐	☐
8) Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate.	☐	☐
c. Is the research directed at **viable neonates?** (*If yes, Subpart D of 45 CFR Part 46 applies, complete reviewer checklist Attachment 1)*	☐	☐
Comments or Concerns:		
Signature of Reviewer:	Date:	

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