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Type of Policy:	***PROTECTION OF HUMAN RESEARCH PARTICIPANTS***	Category:	**Orlando Health Institutional Review Board (IRB)**

Title:	***Research involving Pregnant Women, Fetuses and Neonates***	Policy #:	**0330-1016**
		Replaces #:	6000-402
Page:	1 of 4	Developed By:	Orlando Health Institutional Review Board (IRB)
Issue Date:	**7/19/95**	Approved By:	Philip Giordano, MD Institutional Official **SIGNATURE ON FILE**
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I. PURPOSE:

To impose additional safeguards to protect pregnant women, fetuses, and/or neonates in human subjects research and to also maintain ethical and legal standards when reviewing human subjects research.

II. DEFINITIONS:

When used in this policy these terms have the following meanings:

A. Delivery: complete separation of the fetus from the woman by expulsion or extraction or any other means.
B. Fetus: the product of conception from implantation until delivery
C. Dead fetus: a fetus that exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord.
D. 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.
E. Neonate: a newborn, from time of birth to thirty days.
F. Viable neonate: a neonate that is able, after delivery, to survive (given the benefit of medical therapy) to the point of independently maintaining heartbeat and respiration.
G. Non-viable neonate: a neonate after delivery that, although living, is not viable.

III. POLICY:

It is the policy of Orlando Health to require additional safeguards in research involving fetuses, pregnant women, and/or neonates.

IV. PROCEDURE:

A. In order to enroll pregnant women or fetuses in research, all of the following ten (10) conditions must be met:
   1. 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;
   2. The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman 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;
   3. Any risk is the least possible for achieving the objectives of the research;
   4. The informed consent of the pregnant woman shall be obtained in accord with the standard regulatory provisions for informed consent if 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 when 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;
   5. The informed consent of the pregnant woman and the father shall be obtained in accord with the standard regulatory provisions for informed consent if the research holds out the prospect of direct benefit solely to the fetus; except the father's consent need not be obtained if he is unable to consent

because of unavailability, incompetence, or temporary incapacity, or if the pregnancy resulted from rape or incest;

6. Each individual providing consent under 4 or 5 of this section (Section A of this policy) is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;
7. For children who are pregnant, assent and permission are obtained in accord with the requirements outlined in IRB Policy#0330-1011 "Children in Research…";
8. No inducements, monetary or otherwise, will be offered to terminate a pregnancy;
9. 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
10. Individuals engaged in the research will have no part in determining the viability of a neonate.

B. Requirements for research involving neonates of uncertain viability or nonviable neonates: Neonates of uncertain viability and nonviable neonates may be involved in research only if the IRB finds that all four (4) of the following conditions are met and the IRB documents the protocol-specific findings supporting that conclusion for each condition:

1. Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates
2. Each individual providing consent under Section C(2) or Section D(5) of this policy is fully informed regarding the reasonably foreseeable impact of the research on the neonate.
3. Individuals engaged in the research will have no part in determining the viability of a neonate.
4. The requirements of Section C or Section D of this policy have been met, as applicable.

C. Research involving neonates of uncertain viability: In addition to the requirements set in Section B of this policy, until it has been ascertained whether or not a neonate is viable, a neonate may not be involved in research unless the IRB finds that the following two (2) additional conditions are met and documents the protocol-specific findings supporting that conclusion for each condition:

1. The IRB determines that:
   a) The 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
   b) 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; and
2. The legally effective informed consent of either parent of the neonate 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 in accord with subpart A of 45 CFR 46, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.

D. Research involving nonviable neonates: In addition to the requirements set in Section B of this policy, after delivery, a nonviable neonate may not be involved in research unless the IRB finds that all of the following five (5) additional conditions are met and documents the protocol-specific findings supporting that conclusion for each condition:

1. Vital functions of the neonate will not be artificially maintained;
2. The research will not terminate the heartbeat or respiration of the neonate;

3. There will be no added risk to the neonate resulting from the research;
4. The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and
5. The legally effective informed consent of both parents of the neonate is obtained in accord with the standard regulatory provisions for informed consent. Note: the IRB is not permitted to grant a waiver or alteration of such informed consent for research involving nonviable neonates. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable neonate will suffice to meet the requirements of this paragraph, except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest. The consent of a legally authorized representative of either or both of the parents of a nonviable neonate will not suffice to meet the requirements of this paragraph.

E. Research involving viable neonates : A neonate, after delivery, that has been determined to be viable is a child and may be included in research only to the extent permitted by and in accord with the requirements outlined in IRB Policy#0330-1011 “Children in Research…”.

F. Research involving, after delivery, the placenta, the dead fetus, or fetal material (including the umbilical cord and/or cord blood)
1. Research involving, after delivery, the placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus (including the umbilical cord and/or cord blood) does not constitute “human subject” research in accordance with the Federal Policy definition of “human subject” and shall be conducted only in accord with any applicable federal, state, or local laws and regulations regarding such activities.
2. If information associated with the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus is recorded in such a manner that living individuals (e.g., the parents(s)) can be identified, directly or through identifiers linked to such individuals, those individuals are “human subjects” of the research study and the requirement for their informed consent applies.

G. Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates; research the IRB does not believe meets the requirements of research involving pregnant women, fetuses, and neonates above may be approved only if:
1. 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, fetuses or neonates; and
2. 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:
   a) The research in fact satisfies the conditions of research involving pregnant women or fetuses listed above, as applicable; or
   b) All of the following:

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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, fetuses or neonates;
ii. The research will be conducted in accord with sound ethical principles; and
iii. Informed consent will be obtained in accord with the standard regulatory provisions for informed consent unless the IRB has approved a waiver or alteration of the standard informed consent requirements.

V. DOCUMENTATION:

A. Research involving Pediatrics, Pregnant Women, and/or Fetuses Form

VI. REFERENCES:

A. 45 CFR 46 Subpart B – Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research

VII. ATTACHMENTS:

A. None