**Dartmouth College**

**COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS**

**CPHS@Dartmouth.edu** **• 603-646-6482**

**CPHS – RESEARCH INVOLVING NEONATES**

**Please complete: CPHS# PI:**

Regulatory Definitions:

**Neonate** means a newborn.

**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.

Have the neonates eligible for participation in this study been determined to be viable?

[ ]  **No** [ ]  **Yes** [ ]  **Uncertain**

If yes, the neonates are subject to the regulations for the involvement of children in research studies. Please complete the[**Research Involving Children**](http://www.dartmouth.edu/~cphs/tosubmit/forms/) form**.**

If uncertain or no, please answer the following questions:

a. Where scientifically appropriate, have preclinical and clinical studies been conducted to provide data for assessing potential risks to neonates?

[ ]  **No** [ ]  **Yes**

Explain:

b. The Principal Investigator assures that individuals engaged in the research will have no part in determining the viability of the neonate:

[ ]  **No** [ ]  **Yes**

Explain:

c. Is the purpose of the research the development of important biomedical knowledge that cannot be obtained by other means and will there be no added risk to the neonate as a result of the research?

[ ]  **No** [ ]  **Yes**

Explain:

d. Will there be any added risk to the neonate resulting from the research?

[ ]  **No** [ ]  **Yes**

Explain:

e. Does the research hold out the prospect of enhancing the probability of survival of the neonate to the point of viability, and is any risk the least possible for achieving that objective?

[ ]  **No** [ ]  **Yes**

Explain:

f. Will legally effective informed consent from either parent\* be obtained in the case of a neonate of uncertain viability?

[ ]  **No** [ ]  **Yes**

Explain:

**Respond to g through i only if the study involves neonates that have been determined to be nonviable independently from the investigator.**

g. Will legally effective informed consent from both parents\* be obtained in the case of nonviable neonates?

[ ]  **No** [ ]  **Yes**

Explain:

h. Will vital functions of the neonate be artificially maintained?

[ ]  **No** [ ]  **Yes**

Explain:

i. Will the research terminate the heartbeat or respiration of the neonate?

[ ]  **No** [ ]  **Yes**

Explain:

\*The legally effective informed consent of either parent may be waived because of unavailability, incompetence, or temporary incapacity, in which case the legally effective informed consent of either parent's legally authorized representative is obtained in accord with subpart A of CFR 45 part 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.