1 PURPOSE

1.1. The purpose of this guidance is to describe the processes for conducting non-exempt research with pregnant women, fetuses, and neonates.

2 BACKGROUND

2.1. “Fetus” means:

2.1.1. the product of conception from implantation until delivery.

2.2. “Neonate” means:

2.2.1. a newborn.

2.3. “Nonviable neonate” means:

2.3.1. A neonate after delivery that, although living, is not viable.

2.4. “Pregnancy”

2.4.1. 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.

2.5. “Viable” means:

2.5.1. Being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration.

2.6. The guidance provided is reflective of Federal regulations, Title 45, part 46, Subpart B. The state of Florida may have additional regulations when conducting research with this

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3.2.4.2.5. The legally effective consent of both parents of the neonate is obtained in accordance with Subpart A 45CFR46, except that the waiver and alteration provisions for consent do not apply. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the consent of one parent o. t41.76 691.44 Tm ( )Tj ETy incapow be