Consent of Pregnant Women and Neonates

Pregnant women, fetuses, and neonates involved in research are identified as ‘special populations.’ The federal regulations [45 CFR 46 (Subpart B)] governing human subjects research provide additional protections to those groups, and make additional requirements on investigators. These requirements may vary, depending on (a) the expected risks and benefits to the pregnant woman and/or her fetus or neonate, (b) the age of the pregnant woman, (c) the study timeframe, and (d) the expected viability of the neonate.

General principles for research that involves the pregnant woman alone, or the pregnant woman and her fetus or neonate:

When the pregnant woman is an adult (18 years of age or older):

- Consent of only the adult pregnant woman is required when the following conditions are met:
  - Either: the risk to the pregnant woman and/or the fetus is not greater than minimal [45 CFR 46.102.i] and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means [45 CFR 46.204.d]
  - Or: the research is more than minimal risk but holds out the possibility of direct benefit to the pregnant woman, or to both the pregnant woman and her fetus.

  Note: For either of these two conditions, identifiable private information about the neonate during this hospitalization (i.e., birth) may be collected using this consent process (i.e., a single consent form signed by the adult mother). If identifiable private follow-up information about the neonate will be collected over time, an additional separate consent form will be required because the child now becomes a research subject in his or her own right. Based on the follow-up study’s level of risk, the IRB can determine whether the permission of one parent is sufficient, or whether the permission of both parents are required [45 CFR 46.408.b]. Usually, research that is minimal risk will require the signature of only one parent.

- When the possibility of direct benefit is limited solely to the fetus, consent of both the pregnant woman (regardless of her age) and the father (if available) is required [45 CFR 46.204.e].

  Note: 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.
When the pregnant woman is less than 18 years of age:

- If the pregnant woman is a ‘minor’ according to the Commonwealth of Pennsylvania and the research activity focuses solely on her, she cannot consent for her own participation in research; consent from her parent or legally authorized guardian is required, as is her permission and assent. Note that under Pennsylvania law, a minor is not considered ‘emancipated’ for purposes of consenting to research activities unless there is a court order that specifically permits this.

- If the research includes both the pregnant minor and her neonate or infant, she can consent for the research procedures involving her infant, but if she is also a participant in the research, her parent(s) are still required to provide consent for her participation, as noted above. In this instance, the consent form would be signed by her (for the research participation of her fetus or neonate) and by one or both parents (for her own research participation). Both the protocol and consent form must describe the research activities for both the mother and the neonate or infant.

General principles for research that involves the neonate alone:

If the neonate is of uncertain viability, the neonate cannot be included in research until the IRB determines the following:

- Either (a) the research holds out the possibility of enhancing the probability of survival to the point of viability (and any risk associated with that is the least possible for achieving that goal), 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.

- The legally effective informed consent of either parent is obtained (for greater elaboration, see [45 CFR 46.205.b.2].

If the neonate is non-viable, the neonate cannot be included in research until the IRB determines the following:

- Vital functions of the neonate will not be artificially maintained, the research will not terminate the heartbeat or respiration of the neonate, there will be no added risk to the neonate resulting from the research, the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means.

- The legally effective informed consent of both parents of the neonate is obtained; if either parent is unable to consent because of unavailability, incompetence or temporary incapacity, the informed consent of one parent will suffice. Note that the consent of the father is not required if the pregnancy resulted from rape or incest.