Sharrissa Cook
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2. What factors should an IRB consider in determining that the research-related risks of standard of care interventions, provided to research subjects in the research context, are reasonably foreseeable and therefore required to be disclosed to subjects? a. What criteria should be used by the IRB to evaluate whether the risks to subjects are reasonably foreseeable?

--Health care professionals know what constitutes an oxygen level that is too high or too low. They are also aware of the health ramifications of an oxygen level that may be too high or too low. Therefore, I believe that they should have conveyed to me the effect of my son's oxygen level being too high or too low. That information should have been given to me at the time I was asked to put him in the study. Had I known the full extent of the study, I would not have given my consent .The medical personnel who approached me were not forthcoming with information in their possession, therefore taking away my ability to truly make an informed decision. However, due to the lack of information provided regarding the potential risks involved I unknowingly place my son in harm's way. I trusted them with my baby's life. First, the IRB should be aware that women who have just given birth to a premature baby with serious difficulties is in a very vulnerable state. The only thing a mother wants is for her baby to be well and she will trust the doctors have that same interest at heart. In that state, we are not thinking about medical research or what is good for some baby in the future, only what is best for my baby now.

--The criteria should include any data that is all ready available. If you are aware of health risks, those risks should be made known during the initial consulation.

3. How should randomization be considered in research studying one or more interventions within the standards of care? Should the randomization procedure itself be considered to present a risk to the subjects? Why or why not? If so, is the risk presented by randomization more than minimal risk? Should an IRB be allowed to waive informed consent for research involving randomization of subjects to one or more standard of care interventions? Why or why not?

I believe the randomization process should be fully disclosed. No matter which group you are placed in, the consenting adult should be fully informed of the risks that are associated with each group, prior to giving consent. Yes, because if you do not present the risks associated with participation in a study, you take away my ability to make an informed decision. The known standards of care should be fully explained to potential participants. Additionally, the information should be presented in such a way that a person with any level of education can understand what is being asked and the potential ramifications associated with participation regardless of the group assignment.

Informed consent should not be waived at anytime. I don't understand how anyone can ask, in good conscience, someone to participate in a program that may be detrimental to their loved one's life when they are aware of the potential risks involved.

5. Under what circumstances do potential risks qualify as reasonably foreseeable risks? For example, is it sufficient that there be a documented belief in the medical community that a particular intervention within the standard of care increases the risk of harm, or is it necessary that there be published studies identifying the risk?

In a study that involves human life, any potential risk should qualify as a foreseeable risk. If there is documented belief in the medical community that an intervention within the standard of care increases the risk of harm that information alone should be enough to cause trial facilitators to tread with caution and take care to make certain that participants are informed regarding information that is all ready available.