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Precluding Consent by Clinicians Who are Both the Attending and the Investigator: An Outdated Shibboleth?

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The question raised by this case about who should obtain parental permission can be clarified by considering four general requirements for informed consent: 1) individuals must have the capacity to give consent; 2) the information must be disclosed; 3) the information must be understood; and 4) the decision must be voluntary (Faden and Beauchamp 1986).

This case highlights challenges related to two of these concepts: understanding and voluntariness. Specifically, does a parent's ability to comprehend and give voluntary permission differ depending on whether such permission is obtained by the attending physician, a researcher, or a study coordinator?

This research protocol utilized a standard approach of having a researcher not involved in the infant's care obtain permission. The rationale for this approach is that parents can more readily distinguish trial participation from regular clinical care when approached about participation by a researcher who is not directly responsible for their infant's clinical care. Additionally, a researcher has a thorough understanding of the study and is therefore better suited to convey accurate information about the research. Furthermore, there is the potential concern that the attending physician in charge of the infant's clinical care might exert undue influence on a parent's decision, perhaps stemming from the possibility of the parents' belief that the attending physician would suggest participation only if it was clearly in the best interest of their child. These are speculative concerns for which there are limited empirical data.

However, there is an alternative perspective, also speculative, that it is preferable for the attending physician responsible for the infant's clinical care and not involved in the research to obtain permission. First is the concern that a researcher has so much personal investment in a trial that he or she will be overly enthusiastic, overstate the benefits, and thereby unduly influence a parent to grant permission for the child to participate. An attending physician

will be better suited to present the trial, including its risks and benefits, in the context of the child's ongoing medical issues. The attending physician also might be better positioned to be aware of multiple clinical trials underway in the ICU for which the infant may be eligible and perhaps be more balanced in presenting all of these options to the parents.

An even more complicated scenario arises when the researcher is also the attending physician. In those cases, attempts to keep the roles separate can lead to additional logistical complexities. Of course, it is possible that either the attending physician or the researcher role can complicate understanding and voluntariness, but it is not clear that these concerns should preclude those in either role from obtaining parental permission. For both ethical, as well as pragmatic reasons, however, study coordinators often are viewed as the happy medium, as they stand at a distance from clinical care while also presumably having the ability to be more balanced about presenting the research in which they are engaged (Davis et al. 2002).

IRBs have a range of practices and may specify or exclude individuals in these roles from obtaining the parental permission. For example, one IRB might determine that study coordinators cannot obtain parental permission because they might not have as deep an understanding of the trial (or of the clinical condition), while another IRB might prohibit the researcher or the attending physician from obtaining permission. In this case, it is clear that the IRBs for the different sites came to differing conclusions. In large part, this is because the common rule does not specify who can obtain parental permission (45 CFR 46, Subpart D). Rather, each IRB sifts through the considerations addressed above regarding the advantages and disadvantages of individuals in different roles obtaining parental permission. Therefore, a range of possible solutions are ethically and practically acceptable.

Two points require further consideration. First, what exactly is meant by "obtaining parental permission?" If a particular IRB determines the researcher must be the one to "obtain permission," this probably means, in its most simplified form, that the researcher must be the person sitting with the parent when he or she signs the permission form. However, signing the permission form is but the final step in the consent process as a whole. Numerous people in various roles might have conversations with the parents about the study during the time the parents are making their decision. If a problem exists with individuals in a certain role pressuring parents, designating an individual of a different role to "obtain permission" by simply obtaining a signature will not solve the underlying problem because the pressure may already have been exerted. Conversely, if a parent is giving permission with true understanding and voluntariness, then the specific role of the person handing the parents the pen should not make a difference.

Second, just as normative arguments can be made for every side of this issue, parents who find themselves in this situation also have varying opinions. While the literature fails to provide clarity on parental preferences for these different options (Hoberman et al. 2013; Singhal et al. 2002; Tait et al. 2003), anecdotes from the clinical and research experiences of the authors reveal a wide range of preferences. Some parents are more comfortable talking with their attending physician regardless of that person's role in research, while others prefer to talk with a researcher who is not involved in their child's clinical care.

Study recruitment for neonatal research requires a very delicate balance. Facilitating trial enrollment is itself an important ethical goal, and exploring approaches that improve recruitment are desirable. Nevertheless, the primary goal in recruitment should be to promote the parents' understanding and their ability to give voluntary permission. What is of critical importance is that the attending physician, researcher, or study coordinator establishes a trusting relationship with the infant's family. This requires that whoever is charged with obtaining permission should be explicitly aware of his or her own potential to unduly influence the parent. Two simple strategies include 1) offering three reasons some parents choose to participate and three reasons some do not; and 2) offering parents the opportunity to talk with another person about the study before making a decision. With further empirical research, additional strategies to promote ethical recruitment can be developed.

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