Research with vulnerable persons such as children and prisoners

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Complex regional pain syndromes (CRPS) are increasingly recognized in children, and treatment is unsatisfactory in many cases. An anesthesiologist designs a clinical research project to study the efficacy of lumbar sympathetic blockade (LSB) with lidocaine compared to intravenous (IV) lidocaine in pediatric patients with CRPS who have not responded to traditional therapy. The study is a double-blind placebo-controlled study, involving 40 children between the ages of 7 and 12. All will receive general anesthesia and placement of a lumbar sympathetic catheter. Patients will then be randomized to receive either IV lidocaine plus saline via lumbar sympathetic catheter, or LSB with lidocaine plus IV saline. In obtaining informed consent, the researcher explains to parents and children (to the degree that the children can understand) the risks of general anesthesia and lumbar sympathetic catheter placement. In answer to the expressed desires and expectations from patients and parents of pain relief, the researcher informs them that the “real” drug may be effective (in fact, he thinks it will be), but that it is equally important that researchers determine if LSB lidocaine is ineffective in relieving the pain. Several parents express concerns that their children may be subjected to the risks of general anesthesia and of lumbar catheter placement, but not receive the benefit of pain relief. They want assurances that their children will receive lidocaine and not placebo. What are the ethical considerations in human subjects research when the patients who are being studied belong to vulnerable groups, such as children? Should human subjects research be conducted in vulnerable populations?

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