Challenges in Review of Pediatric Transplantation Research

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Challenges in the IRB Review of First-in-Pediatrics Hand Transplantation Research: In February 2012, the IRB of a pediatric, academic institution began the review process of a first in pediatrics research protocol to study the safety and efficacy of bilateral hand transplantation in pediatric subjects. The IRB struggled with making risk benefit determinations, as there were a number of ethical concerns, including the balance of serious risk (surgical risks, host-graft disease) against the subjective benefit of increased quality of life. As this was controversial research that stretched across multiple departments in the hospital, the IRB had to develop a more customized procedure for the review of this study. Rather than review at standing IRB meetings, a quorum was often convened to discuss only this protocol. After this first IRB meeting, it was determined that an action letter to the research team may not accurately reflect the issues raised by Members. Many concerns raised by the Committee were communicated to the Principal Investigator at the specialized meetings, and responded to in person, with supporting documentation submitted after the meeting. Coincidentally, one of the IRB Members reviewing the protocol has a congenital lower limb deficiency, and was uniquely able to offer insight from the subjects’ perspective.

Methods: Throughout the review process, several different departments were involved in the review and approval of the research. The IRB’s Administrative Office had to develop procedures for coordinating these different departments and their feedback. Throughout this review process, many lessons were learned that can be applied to future review of complex and controversial research. Throughout the review process and after approval, IRB members were often asked to provide feedback on how to convey their concerns to the research team and how the IRB administrative staff could better ascertain information from the research team. Additionally, the research team was asked to provide feedback on the clarity and relevance of the IRB’s comments, communication between departments in the hospital, and overall impression of the hospital-wide review process.

Next Steps: Going forward, the IRB will prioritize administrative flexibility, in both IRB review and hospital-wide coordination. Having separate meetings to convey concerns and responses was instrumental in efficiently and accurately addressing the Committee’s concerns and obtaining IRB approval. Additionally, this IRB will continue to value the subjects’ perspective in the review of research and seek out these more expert opinions on a protocol-by-protocol basis.