Shifting Responsibilities: Transitioning from Signed Assent to Attestation of Affirmative Assent
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Purpose: Only 50% of IRB’s in the United States have a standardized procedure for obtaining assent. Even within centers that require signed assent, documentation can vary from simply adding a signature line to the parental permission form to providing a simplified assent form for the minor’s signature. Children’s oncology trials often require enrollment at the time of diagnosis and before treatment – a time when the opportunities for engagement and discussion is compressed. Given that children mature at different rates, respond differently to stressors, and have had different life experiences, the assent process can be challenging. Three years ago, our IRB approved a proposal transitioning from a signed assent to an attestation of affirmative assent by the investigator, thus shifting responsibility for documentation from the child to the investigator. This project was undertaken to evaluate the experiences of investigators in Pediatric Oncology.

Method: A 60-minute focus group was conducted with a multidisciplinary group of clinical investigators using a semi-structured interview. Textual data was categorized by the first author using directed qualitative analysis techniques. Major themes and subthemes were identified.

Results: Major themes: I. Provision of minor child with freedom to participate in decision making to the extent that they are capable (Grow model): Engagement; support of developing autonomy. II. Provision of resources to facilitate age appropriate understanding: Enlist parent(s) as resource; informational resources, websites, printed materials; key information sheets composed or highlighted during the discussion. III. Provision of an interactive and informative discussion: Alignment with patient/family values; provision of internal locus of control; communication of key points; breaking larger components into smaller, easier to understand parts; signed assent. IV. Investigator attestation level of understanding: Freedom to ask questions; anxiety increased decreased; ability to divide large protocol into manageable parts decreased increased.

Conclusions: Investigators felt that the transition from “signed assent” to “investigator attestation” provided a less stressful experience for children. While the level of understanding and the freedom to ask questions were felt to be equivalent, encounters ending with investigator attestation were felt to be more flexible. Investigators felt that minor children wanted to be involved in the discussion and have the freedom to express their views and ask questions. Minors who had prior experience with oncology treatment and trials were more likely to take a more active role in the discussions.