Introduction

The Belmont Report highlights 3 fundamental ethical principles that form the foundation of clinical trials research. These principles include respect for persons, beneficence and justice. The first 2 principles are core to the informed consent process during which researchers discuss a clinical trial with a competent adult participant.

Minors on the other hand are considered a vulnerable population because they may not have achieved the required competency. Competency requires that the individual understand the information relevant to their decision and foresee the consequences of that decision.

In deference to respect for persons and the developing autonomy of the minor child, parental permission and informed assent have replaced the informed consent. This allows the assent to take place according to the child’s capacity to understand.

Practices regarding the determination of capacity and the assent process are very variable. A U.S. survey by Whillte et al on assent practices found that only 50 % of the 188 IRBs chairs had a procedure in place to obtain assent and 50 % relied on investigator judgement.

In 2010 at the request of the Pediatric Oncologists, the Winthrop IRB granted permission to transition from signed assent to investigator attestation.

The purpose of this study was two fold:
1. to assess whether our researchers in pediatric oncology felt that the transition improved the assent process
2. To explore current practice to determine capacity and to maximize the quality of the assent process.

Methods & Materials

A one hour focus group was held with 7 members of pediatric oncology research team - 5 pediatric oncologists and 2 certified oncology nurses. Six of the seven participants had personal experience with both the signed assent and the investigator attestation process.

Comments & opinions were collated and summarized in to the themes listed below.

Themes

Question 1.

Value of the Investigator Attestation

1. Given that the minor signature is not legally binding, the addition of their signature to a lengthy document adds unnecessary stress.
2. Using a one on one discussion allows the minor to ask questions with the reassurance that they will be answered in a manner they can understand and that their assent is a voluntary choice. For an assent to be valid the child must affirm their choice to participate. It is not sufficient to “not object”.
3. This process allows the child to bring his parent(s) into the discussion.

Question 2.

Techniques to maximize the quality of the assent process & Current practice for determining capacity

1. Establish rapport with child at time of initial referral & evaluation in Pediatric Oncology
2. Provide each child access to members of the multidisciplinary team in Pediatric Oncology
3. As members become familiar with the child they can better assess the child’s capacity to understand the disease process and the information about the clinical trial
4. This multidisciplinary team meets on a regular and ad hoc basis to discuss each individual child.
5. Feedback to the physician researchers is provided by the team, at these meetings and individually, by parents, referring pediatricians and direct interactions with the child.
6. Both formal and informal feedback loops contribute to a more accurate determination of capacity.

Key Findings

Investigator attestation (IA) vs signed assent (SA)
1. IA allows for an individualized informed assent discussion
2. IA is less stressful as a one on one discussion
3. IA shifts the burden of responsibility to the investigator

Assent:
1. Acuity of the presenting illness often mandates a compressed time frame in which to establish rapport and have important discussions with the child and family.
2. The team approach helps to facilitate the process by allowing children access to additional support systems to help them understand the key elements of their assent.
3. Information and support is also available through the websites, social media and resources of the Children’s Oncology Group.

References


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