Shifting Responsibilities: A Single Center Experience with Transitioning from Signed Assent to Attestation of Affirmation & Assent

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The process of obtaining affirmation & assent to participate in clinical trials is often challenging in Pediatrics. In fact a survey of US IRB’s reported only 50% with a standardized procedure for obtaining assent. There is a high degree of variability in assent practices within centers that require signed assent – varying from simply adding a signature line to the parental permission form to providing a simplified assent form for the minor’s signature. Others do not require a minor’s signature. The consistent feature is that minor must provide affirmative and assent. Children mature at different rates and come with varying experiences, coping styles and desires to participate in decision making. 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. Approximately three years ago, the Winthrop University Hospital IRB approved a proposal to move from a signed assent from a minor to an attestation of affirmation & assent by the investigator.

Methods:

A 60 minute focus group was conducted with a group of clinical investigators including both oncology nurses and physicians using a semistructured interview guide. The session was audiotaped for accuracy and completeness and an onsite transcription was also performed to address nuances in responses. Textual data was categorized by the first author using directed qualitative analysis techniques. Major themes and subthemes were identified and representative quotes were selected.

Major themes

I. Provision of the minor child with the freedom to participate in decision making to the extent that they are capable (Grow model)

• Engagement of minor child
  * Support developing autonomy of child
  * Minor signature is not legally binding

II. Provision of resources to facilitate age appropriate understanding

• Enlist parent(s) as resource
  * COG informational resources, websites, printed materials
  * Information sheets composed during the discussion highlighting important points
  * Alternately one investigator used the informed consent document to highlight important components of the trials (this was done with older teens)

III. Provision of an Interactive and Informative Discussion

* Culturally sensitive
* Aligned with patient/family values
* Help provide a sense of control (internal locus of control)
* Communicate key points of the trial
* Align discussion with child’s values
* Communicate key points of clinical trial
* Break larger components into smaller, more easy to understand parts

Signed Assent Investigator Attestation
Level of understanding same same
Freedom to ask questions same same
Anxiety increased decreased
Ability to divide manageable parts decreased increased
Large protocol into

Other comments Witnessed discussions have same impact as signing – anxiety provoking

Conclusions:

Shifting the responsibility for documenting the informed assent from the minor to the clinical investigator was preferred by our group of investigators based on three major themes which included provision of the minor child with the freedom to participate in decision making to the extent that they are able, provision of resources to improve their understanding and provision of an interactive and informative discussion in a less stressful manner. Witnessed discussions and signing a document were both felt to be anxiety-provoking for the child.