Communicating with Parents: Approaches to Informed Consent

Breck Gamel

April 5, 2016
Disclaimer

The views and opinions expressed in this presentation are those of the individual presenter and do not necessarily reflect the views of the Clinical Trials Transformation Initiative.
Approach & Consent: Of Critical Importance

**Who**
- Should be a trusted source
- Someone familiar with, and involved in, the child’s care

**When**
- Especially in situations of critical illness or medical fragility
- When immediacy is not a factor, consider a participant-facing website to introduce studies to parents
- When immediate decisions are needed, provide parents with a 1-page summary to review and return later to discuss at length

**How**
- With sensitivity, compassion, empathy, concern & familiarity with child’s care and family situation
  - Provide sensitivity training in med/nursing schools,
  - Include sensitivity training at Investigator meetings; require study staff to provide documentation of completion
Questions for Discussion

- How should site staff be trained to approach parents about study participation, especially in the unique environment of a critically ill/medically fragile child?
  - Who should be responsible for providing that training?
  - How should such training be maintained?
  - Should there be a specialty certification for conducting research with very ill/fragile children?

- What tools are needed?
Protocol & Logistical Concerns

- Engage parents and primary care when designing the study to ensure they will be willing to support/champion the study.

- Consider the age and perspective of the child when designing the schedule of events and procedures:
  - What may not be scary to a teenager may be terrifying to a preschooler.

- Minimize scary, invasive or painful procedures to only those necessary to answer the primary study question and maintain safety.

- Incorporate age-appropriate motivators to participation and retention.

- Be flexible in scheduling appointments (to minimize missed work hours (parents) or school hours (children)):
  - Consider the use of digital technology and/or remote visits to reduce the burden of participation.
Questions for Discussion

How can we better engage primary care providers (e.g., family medicine, general pediatricians) and parents in study design and development?

- How can studies be designed to be more child- and family-friendly?

Who needs to be convinced to reduce the burden of participation (fewer blood draws, fewer invasive procedures, fewer on-site visits, etc.), greater use of digital and/or mobile technology?

How should the use of alternative visit types and data collection methods (remote (digital) visits, telemedicine, phone visits, electronic PROs, diaries, etc.) be encouraged/facilitated?

How motivators that aren’t coercive be standardized?

What tools are needed?
Communication Needs

- Describe current uses of study drug (if any) as well as if the drug is FDA approved for other uses
- Use the drug’s trade name (when possible)
- Always use lay language
- Create an advocate or champion in the child’s own doctor
- Create a mechanism for parents to engage with other parents about CTs in general or specific studies (Parent Advocate Team)
  - Create parent advocates of research
Communication Needs (2)

Always clearly convey

- How the child will benefit from participation
- That well-being and safety are of primary importance to all involved
- Risks based on parent’s desired level of knowledge
- The potential for furthering the common good
- Appreciation
- Study results (in a timely fashion)
Questions for Discussion

How can trial champions be made of community providers (pediatricians, family practitioners, etc.) and parents?

Should someone develop a standard glossary of procedures and tests, described in lay language, which can be used in pediatric study consent and other informational documents?
- If so, who?

What is the best mechanism for rapidly sharing study results with parents of participants?

What tools are needed?
Thank you.