Communicating with Parents: Approaches to Informed Consent

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Disclaimer

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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.

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