Communicating with Parents: Approaches to Informed Consent

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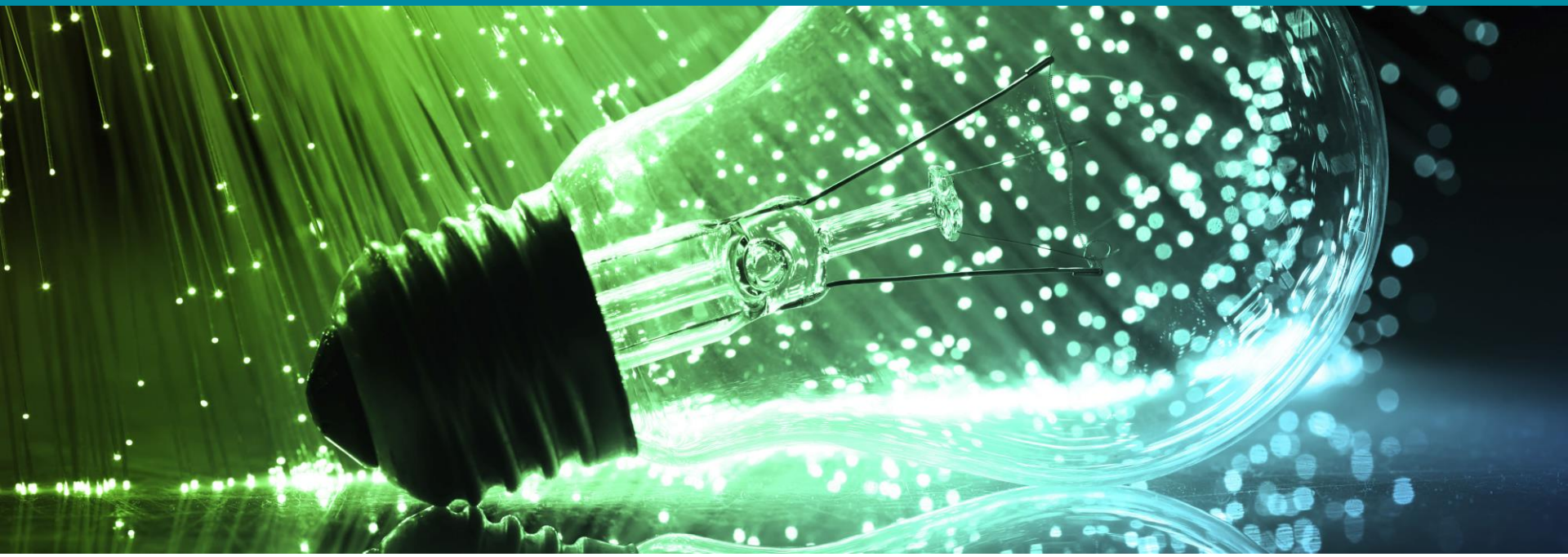

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Approach & Consent: Of Critical Importance

- ***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 pre-schooler
- 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 can 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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