Informed Consent: Perspectives from a Pediatric Emergency Room

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Course Title: History and Bioethics of Informed Consent  •  Faculty Advisor: Dr. Karen Greif, Biology
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What did I do?

For my fieldwork, I participated in the Academic Associates program at CHOP’s Emergency Department (ED). Along with other volunteers, I screened patients in the ED to see whether they were eligible for any clinical research studies. These studies included testing a device designed to tell if a shunt is malfunctioning without the need for a CT scan, seeing if certain genes are turned on when someone is fighting a bad infection, and conducting surveys designed to gather information and improve care. When there was an eligible patient, I either approached the family directly to ask if they were interested and get consent (usually for the survey-based studies), or handed it off to a research coordinator or other practitioner (for most of the studies involving medical interventions).

Clinical Research Basics:

- Clinical research is used for, among other things, investigating new medications, determining if older medications can be used for new purposes, and evaluating the efficacy of surgeries or other procedures.
- In order to participate in research, a patient must agree by providing informed consent.

Informed Consent

- involves complete information...including risks, benefits, and alternatives.
- is voluntary...without coercion.
- requires comprehension and decision making ability
- Does the patient understand the information being presented?
- Do they have the capacity to decide whether or not to consent?

My Learning Questions/Goals:

- How does informed consent change when the research subject is a minor?
- How are children involved in the informed consent process?
- How does the age of the child affect what that process looks like, and how they can participate in it?

What I Found Out:

- Since children cannot legally provide consent, informed consent is replaced by a combination of parental permission and child assent.
- Parental permission is the agreement of one or both parents (depending on the type of study) for their child to participate in research.
- Child assent is when the child actively agrees to participate in research.
- Assent is generally required for any child above age 7, unless they are incapable of assenting.
- Assent must be tailored to the child’s maturity and level of understanding, which doesn’t necessarily conform to their age.
- Ultimately, the person obtaining permission and assent must be sensitive, and tailor the information to the needs and understanding of the parents and child.