

Research Consent: Determining Capacity and “Getting” Consent

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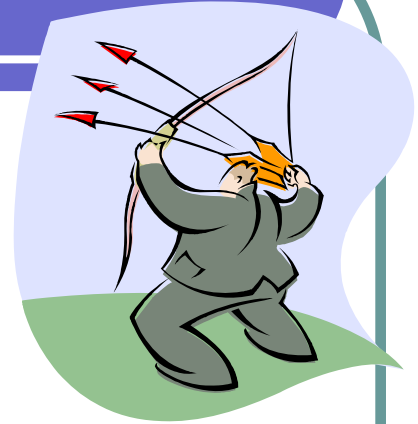
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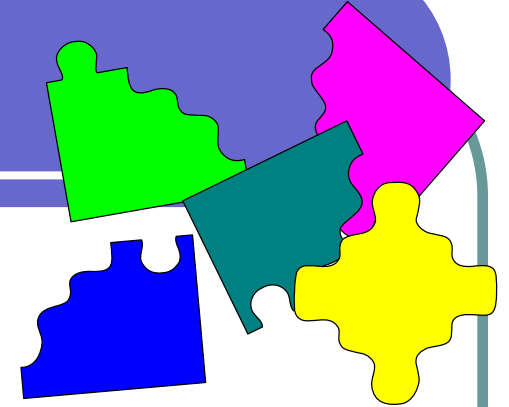


Objectives

- Appreciate requirements for a valid research consent
- Appreciate the ethical and legal principles grounded in consent to research requirements
- Appreciate the ethical and logistical challenges associated with “getting” a valid consent – i.e. capacity.



Outline



- Research Ethics
- Consent
- Relevant Policy & Law
- Getting Down to the Nitty Gritty
- Discussion
- Take-Away Messages.

Modern Research Ethics

- Premised on a dynamic relationship between ethical principles and procedures.

Tri-Council Policy Statement



- TCPS is a source for procedures & research ethics principles
- All research funded by CIHR, NSERC & SSHRC must be approved follow procedures and requirements set out in the TCPS
- Based on the belief that all research should meet TCPS's ethical standards, all research conducted at SickKids or by SickKids staff must follow the TCPS and receive REB approval.

Ethical Principles

- Ethical principles seek to ensure that subjects are not merely used, but are protected, and treated respectfully as an essential part of research
- In their best uses, principles serve as shorthand reminders of more complex & context specific moral reflection.

Ethical Principles

- **Respect for Human Dignity** – cardinal principle in research ethics - respect for the developing autonomy of potential research participants
- **Respect for Vulnerable Persons** – special protection of their rights
- **Respect for Justice & Inclusiveness** – procedural justice as well as substantive distribution of burdens and benefits.
- **Subject Centeredness** – implications of the research for the individual subjects.

Research Ethics



- Gift Analogy
- When consenting to treatment, consenting to something that is being proposed for patient's benefit
- Research may not have direct benefits to participant
 - Need even higher standards re consent process, assurance of capacity, transparency.

Consent

- Consent process refers to the dialogue, information sharing and general process through which prospective subjects choose to whether or not to participate in research
- Law related to competence & capacity varies between jurisdictions and over time
- For our purposes both are ability centered notions.

Consent - Historical



- In Ontario up until 1996, the ability to consent for a health care treatment was tied to one's age
- Idea that upon reaching a specific age, a person was considered globally able to understand and appreciate
- Even today there are some jurisdictions where, “competence” or “capacity” to consent to a treatment or research is tied to age i.e. 16, 18.

Consent

- Ontario does not have an age of consent to treatment or research
- Where the TCPS is either vague, we can look to Ontario's Health Care Consent Act (HCCA) for guidance re consent and competence
- The HCCA addresses consent for treatment
 - Much treatment children receive at SickKids is in the context of research
 - HCCA should be the minimum standard.



Competence - TCPS

- The ability of prospective subjects to give informed consent in accordance with their own values
- Involves ability to understand info presented and appreciate potential consequences of a decision.

Competence

- Ability may vary according to the choice being made, the circumstances surrounding the decision, the time in question
- Competence is not an all-or-nothing condition
- Does not require that prospective subjects be able to make every kind of decision.



Policy & Law – To Consent:

- Research subject must be competent
- Research subject must be informed
 - All info relevant to a free & informed consent
- Consent must be voluntary
 - Without manipulation, undue influence or coercion
- There is no age of consent to treatment – follow this for research as well
- A 3rd party may give permission where subject not legally competent
- Most of the time in writing

Confidentiality

- One's participation in research is confidential
- Child competent to consent to participate in research has right to not have others know that s/he participating in a research study
- Implications for parents?

Assessing “Capacity”

- Does the potential research participant have the ability to understand the information and appreciate the consequences of making a decision (to participate or not)?

Ability to Understand

- Does the potential participant have the factual knowledge about his/her own health or medical problems in the context of what is being asked of him/her in the research?
- Does the potential research participant understand the available options?
- Is the potential participant able to communicate thoughts and wishes in a reliable way?

Appreciate

- Does the potential participant have a realistic appraisal of the risks and benefits (if any) associated with participation in the research?
- Is the potential participant able to link the general facts relating to the proposed research with his/her own situation?
- Is the potential participant able to communicate these in a reliable way?

Who Assesses Capacity?

- Generally, the person who proposes the “treatment” that is the focus of the research
- A person:
 - with knowledge of the procedures and
 - who can assess the potential subject’s understanding and appreciation of what is being asked.



When is Capacity Assessed?

- An evaluation of the ability to understand and appreciate should only follow a discussion that is developmentally appropriate to the potential subject.

Who Can Assess Capacity?

- When the research is the treatment or intervention:
 - Follow guidance of TCPS & HCCA
 - List of persons who can assess capacity: professions under Regulated Health Professions Act and social workers.

Who Can Assess Capacity?

- For research that is not treatment or an intervention:
 - Guided by principle of proportionality
 - The amount of necessary proof grows with the risk associated with the research
 - Lower risk
 - Individuals knowledgeable in child development and the research in question may be able to assess capacity in this context.

Role of the Guardian

- When potential participant is incapable:
 - Guardian can give permission for child to participate in the research
- When potential participant is capable:
 - With permission of the participant, guardian may be given information about the study
 - In many cases will need support of guardian to ensure participant able to get to hospital for components of the research.

Case 1 – Quality of Life Follow-Up

- Follow-up study that includes a research quality of life measure for a 13 year old. The filling out of forms will add about 60 minutes to a scheduled clinic visit. No information is being asked of the parent.
- **Who do you ask for consent?**
- **What kinds of questions would you ask of the child to assess capacity?**
- **Do you inform the parent if the child is capable and agrees to participate?**

Case 2 – Genetics Follow-Up

- A child received a treatment many years ago and returns to a clinic every two years for follow-up. She is now 14 years old. A research protocol has been developed and approved to look at genetic markers that might predict outcomes to specific treatments. The research asks for an extra 5ml of blood during routine blood draw to look for potential genetic traits that might be helpful to children and their treating physicians in the future.

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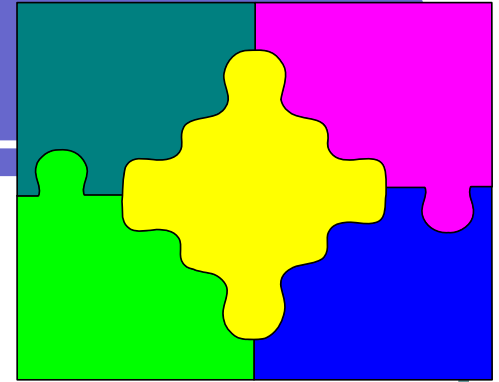
Case 3 – Clinical Trial with Potential Harmful Effects

- An 11 year old child has a progressive illness that has not responded to standard treatments over a number of years. The child has taken a turn for the worse. There is an experimental treatment that has been developed and a research protocol has been approved of this drug that may target the causes of this disease. It is unknown whether the drug will offer any relief or additional quality of life. In fact there are some serious side effects of this treatment.

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- **Who do you ask for consent to participate in this research protocol?**
- **What kinds of questions do you ask to assess the ability to understand and appreciate the consequences?**
- **Do you inform the parent of the child is capable and agrees to participate?**

Take-Away Message



- There is no age of consent to research in Ontario
- Requirements of a free & informed consent:
 - Competence / Capacity
 - Informed
 - Voluntariness
- Competence is decision and time specific.



Thank you.