ETHICAL RESEARCH INVOLVING CHILDREN

Centre for Children and Young People
research, education, advocacy

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HARMS AND BENEFITS

Facilitating future benefit when a participant has a degenerative illness and cannot give consent

Background context:

Very often a child with a severe fixed, or an evolving, neurodegenerative condition cannot give meaningful consent to research. The child's age and the profundity of their evolving neurological condition make consent impossible. Neurodegenerative conditions are extremely rare, are still very poorly understood and require tertiary/quaternary centre management for appropriate diagnosis and subsequent management. Such management is often highly complex and is at the very frontiers of understanding.

Health care professionals involved in managing such children are faced with accepting the status quo or endeavouring to effect a change that will benefit other such cases in the future through increasing knowledge of the condition by conducting research.

The ethical challenge:

There is a fundamental necessity to develop a knowledge base about the causes of and the evolving clinical pathology of degenerative conditions in order to assist future case management.

The ethical challenge is whether:

a) Such a journey should be undertaken at all, as the medical management is challenging in itself without this additional role.

b) Tempering understandable expectations against realism, that such discoveries generally occur unexpectedly, but usually after a great deal of time and background effort has been put in place.

c) Any answers generally will have a very limited role, if any, for that particular child.

d) Whether to proceed with the research when consent from the child has not been, and is unable to be, obtained.

Choices made:

- Limit the investigations to clinical and research necessity and where there is a realistic chance of a result based on previous empirical literature or strong clinical evidence, rather than pure exploration. That is, the research should have a robust scientific and/or clinical rationale.

- Maintain meticulous medical records over many years including medical imaging and photography.

- Take sufficient DNA, after appropriate signed consent, and store it for future, presently unknown, diagnostic tests. Consider also skin and muscle biopsies to allow cell cultures.

- Obtain full consent from the child's parents or guardians for discussion of cases and presentation at relevant regional, national and international meetings.

- Even when consent is impossible, explain to the child, using verbal, pictorial (i.e., drawings, photographs or videos), dramatic or other appropriate methods about all aspects of his/her care including investigations and storage of DNA or other material for potential future testing. Do this in the parents' presence.

- During their lifetime and afterwards, keep these children in your own and other clinicians' memories, so that their contribution to research is acknowledged and their humanity emphasised. For example (using real life examples in which the decision was made by parents to waive anonymity), if parents give consent, the children can be used on a national television broadcast,[i] photographs of the child could be displayed in medical offices or children's wards; a prize, scholarship or charity could be named after them,[ii] parents may be included as co-authors on conference abstracts and individual children named.[iii]

Reflexive questions/considerations:

- Are you going to just do your job or, as well, put in extra time, over years, to improve knowledge and provide future benefit?

- Ask yourself what is motivating you. Are you doing this to benefit the child and his/her parents, future patients and their families, or yourself?

- How are you going to balance the need to find an answer against the possibility of unrealistic family expectations of the timeframe for delivery and what such an answer will realistically mean, when it eventually arrives?

- When the child's condition makes it unlikely that they can provide consent, how will you meet the requirements for them and their parents to be informed?

- The child's interests must always be first and foremost - and never the family's or your own.

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[i] http://www.youtube.com/watch?v=y_w_ltD7UhQ Children in Need Appeal 2012, introduced by Dame Helen Mirren accessed December 27th 2012.

[ii] http://www.thomassfund.org.uk/ accessed September 10th 2012 Thomas' Fund in Northamptonshire, United Kingdom. This provides in-patient music therapy on paediatric and neonatal wards in Northamptonshire as well as at home for children and young people with life- limiting illnesses or a disability which, for medical reason, means they are too ill to attend school for extended periods.

[iii] Alzoubidi R., Price S., Smith L., Baas F., & Williams A.N. (2010). A New Subtype of Pontocerebellar Hypoplasia. Dev Med Child Neurol., Volume 52, Issue s1, p. 31.