Young People Consenting to Medical Research

Felicity Davies[1,2,*], Harriet Fisher[3], Giles Birchley[1,*]

1. Bristol Medical School (Population Health Sciences), University of Bristol
2. University Hospitals Bristol and Weston
3. National Institute for Health Research Health Protection Research Unit (NIHR HPRU) in Behavioural Science and Evaluation (BSE), Bristol Medical School, University of Bristol, Bristol, UK.

*Corresponding authors

Introduction: Age-based consent for research

The regulations and guidance regarding young people's consent to participate in medical research are complex.[1] Current regulations divide medical research into two types: research that involves the trial of a medication and research that does not (Fig.1). Trials of medications are governed by the Medicines for Human Use (Clinical Trials) Regulations 2004,[2] whereas other forms of medical research operate without statutory guidance. The statute states that anyone aged 16 years or older can consent to participate in a clinical trial. Those under the age of 16 cannot consent, and consent must be provided by a parent or guardian. This age-based approach is in keeping with other legislation surrounding a young person's decision-making, such as age limits on learning to drive or buying a lottery ticket. This approach is pragmatic, as it is straightforward to identify which young people can consent for themselves.

Competence-based consent for research

Rather than using age, research not involving trials of medications identifies which young people are able to consent based on an assessment of their competence. The Health Research Authority (HRA) guidance for England, Wales and Northern Ireland suggests that competent young people, aged under 18 years, should be able to consent to research without additional input from their parents.[3] Guidance from Council for International Organisations of Medical Sciences (CIOMs) states that parents should *always* be involved in the consent process.[4] This more cautious stance has been adopted by the Republic of Ireland, where it is a legal requirement to obtain parental consent for any research participant under the age of 18.[5] Ethics committees in England may diverge in their adherence to national and international guidance, resulting in researchers receiving disparate advice for similar research studies.

Identifying young people who can consent for themselves based on competence protects any over-15-year-old who would struggle with decision-making and enables self-directed decision making for a competent 14-year-old. The criterion of competence is harder to apply in practice than an age-based delimiter. The concept of competence comes from case law guiding medical treatment. Case law follows a system of precedent, where it is assumed that rulings in cases taken to court are likely to apply to similar scenarios. To date, no case has specifically considered the law guiding a young person's consent to medical research. Whether a young person can consent for their own medical *treatment* is guided by the concept of Gillick competence.[6] Gillick competence holds that a person under 16 can consent to medical treatment if they have sufficient maturity and intelligence to use and weigh this information in reaching a decision. It is unclear from current case law whether 16–17-year-olds need to be assessed as being competent to consent, or whether this can be presumed. There is a statutory presumption that 16 and 17 year olds have capacity to consent.[7] Recent case law has suggested that the concept of Gillick competence might apply to a young person aged 17-years.[8]

This would mean that 16 and 17 year olds require both capacity and competence to consent. Although a 16 or 17 year old may have the capacity to consent, they may not be competent.[9] This lack of clarity in case law for medical treatment also extends to research and further confuses existing guidance.

Refusing consent

Although competent young people can consent for their own medical treatment and in everyday practice may have their refusal respected, it is not legally the case that they are able to refuse treatment that is in their best interests. If a young person refused consent for treatment that a doctor believed was in their best interests, then consent could potentially still be obtained from their parents or the courts instead of the young person.[8,10] Unlike medical treatment, most medical research is not intended to be in the best interests of a young person. A young person entering an experimental study which evaluated the effect of a novel physiotherapy might subsequently find that their therapy improved their outcome, but it would not have been possible to know this when the study commenced. It is not clear that participation of a healthy control in a research study is in a young person's best interests, and there may be a real risk of harm. In such situations, a researcher who receives the consent of a Gillick competent 15 year-old to participate in a research study without the consent of their parent could theoretically be taken to court by that parent for battery.[1] Given the lack of clarity regarding the legal position in this scenario, many research ethics committees stipulate that consent is obtained from parents. Despite HRA guidance that a competent young person should be able to consent for themselves, it is not clear that this position is adequately supported by current law.

Assent: a solution?

Taking consent from a young person's parent and not from the young person themselves could lead to some young people feeling less involved in the process and less engaged with the research that they have been enrolled in by their parents.[11] This can mean that research is less meaningful or lead the young person to withdraw from the study prematurely. Most advisory bodies now suggest that where a young person is not able to consent for themselves, researchers should obtain parental consent and adolescent assent.[12] Unlike consent, assent is not described in law. It is used to describe the agreement of a child or young person to participate in a research project based on information provided to them. Whether a young person is doing something meaningful when assenting or simply saying what they believe their parents want them to say is difficult to establish. Researchers may not fully inform the young person about the research, and the young person may be less likely to engage with the information since they are not the decision maker.[13] Some ethicists have argued that assent is effectively meaningless, given that parents still retain the ability to consent.[14]

Joint consent

Rather than assent, the legal framework in Australia solves these concerns by requiring consent for medical research from both a young person and their parents.[15] In the event of a lack of consensus, the young person would not be enrolled in the research study. A process in which both parent and child are recognised as jointly involved in the consent process may be a more accurate representation of what takes place. Rather than either party giving consent alone, parents give permission, and the young person provides meaningful agreement. This enables a more gradual transition from parental consent, to shared consent, to consent provided by a young person themselves, providing a young person with the opportunity to develop decision making skills whilst acknowledging the need for support during a vulnerable transition period into adulthood. It is hard

to get representative samples of young people to consent to sensitive research if parental permission is always needed, so there is still a strong case for young people to be allowed to consent to sensitive research without parental permission in some circumstances. It should be sufficient for a researcher to obtain consent from a competent 15 year old, but it is not clear that this is adequately supported by current legislation. In the absence of sensitive research, the ideal scenario is one where the decision to participate in research is made as a family, with involvement of both the parents and the young person in the legal act of consent.[12]

It is increasingly recognised that young people are underrepresented in research. While this has been responded to with legal and bioethical innovations, these result in further layers of complexity that may paradoxically inhibit new research and fuel research drop out. There is an urgent need to develop an approach that can address this complexity coherently and empowers the decision making of competent young people

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Figure 1. Flowchart for obtaining consent for participation of young people under 18 in medical research