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Approaches to consent in public health research in secondary schools

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ABSTRACT

Objectives We assess different approaches to seeking consent in research in secondary schools.

Design We review evidence on seeking active versus passive parent/carer consent on participant response rates and profiles. We explore the legal and regulatory requirements governing student and parent/carer consent in the UK.

Results Evidence demonstrates that requiring parent/carer active consent reduces response rates and introduces selection biases, which impact the rigour of research and hence its usefulness for assessing young people's needs. There is no evidence on the impacts of seeking active versus passive student consent but this is likely to be marginal when researchers are directly in communication with students in schools. There is no legal requirement to seek active parent/carer consent for children's involvement in research on non-medicinal intervention or observational studies. Such research is instead covered by common law, which indicates that it is acceptable to seek students' own active consent when they are judged competent. General data protection regulation legislation does not change this. It is generally accepted that most secondary school students age 11+ are competent to provide their own consent for interventions though this should be assessed individually.

Conclusion Allowing parent/carer opt-out rights recognises their autonomy while giving primacy to student autonomy. In the case of intervention research, most interventions are delivered at the level of the school so consent can only practically be sought from head teachers. Where interventions are individually targeted, seeking student active consent for these should be considered where feasible.

INTRODUCTION

Research ethics committee and those conducting research in secondary schools are faced with choices as to whether to seek active (ie, opt-in) or passive (ie, opt-out) consent from parents/carers and/or students. Our experience as researchers is that the advent of general data protection regulation (GDPR) legislation has led some ethics committee to require parent/carer active consent. However, many researchers are reluctant to seek active parent/carer consent because of concerns about the potential impact of this on student autonomy, the quality of data and what can be learnt from it. In this paper, we present a non-systematic narrative review of the literature to consider the impact of seeking active versus passive parent/carer and student consent on participant response rates and profiles, and explore the ethical, legal and regulatory requirements governing consent for children and young people in research in secondary schools in the UK.

Impact of active versus passive consent on research participation

A recent systematic review and meta-analysis identified 15 studies which compared research participation rates among children and young people when active versus passive parent/carer consent was sought. These studies did not seek student active or passive consent. The meta-analysis included 104 074 children aged 11–18 years. Participation rates were significantly lower for studies using active compared with passive parent/carer consent. Samples using active parent/carer consent under-represented boys, as well as students who were older, from ethnic minority backgrounds or engaged in risk behaviours, such as substance use.[1] Similar findings have been reported in studies published since or otherwise not included in this review. These also report that requiring active parental/carer consent results in under-representation of students with lower educational attainment, from lone-parent and socioeconomic disadvantaged families, and engaged in violence.[2 3] Response rates using active parent/carer consent range from 29% to 60%, compared with rates of 79% to 100% using passive parent/carer consent.[4–11]

In the case of intervention studies, active parent/carer consent is therefore likely to reduce power to detect intervention effects and undermine subgroup analyses featuring disadvantaged students. Because some kinds of social disadvantage, such as living in an economically deprived area and being poor, are causes of health inequalities, the lack of wider representation in research hinders

assessment of intervention effects on health inequalities. In the case of observational research, it is likely to lead to the underestimation of the prevalence of adverse outcomes and incorrect estimation of associations between exposures and outcomes.[2] It may also be a barrier to research participation for children and young people who wish to participate in research, and who have capacity and competence to provide informed consent.[12]

We have searched for but not found any studies comparing active versus passive student consent. It is likely that, in cases where researchers directly supervise data collection, requiring student active consent will only marginally reduce participation rates in school-based research compared with passive consent. Where researchers have direct contact with students in schools, it is logistically much easier for researchers to answer questions and collect completed consent forms. This is not the case for parents/carers, with whom researchers communicate generally via schools' email, text or postal communication channels. While researchers can answer parents'/carers' questions via email, they cannot directly contact parents/carers to remind them to return forms if they wish to opt in. It is, therefore, much less likely that students will not provide active consent merely because they did not get round to submitting the consent form, as is likely with at least some parents/carers not opting their children into research. However, this will not apply to cases where researchers do not have direct involvement in data collection, as has often been the case during research undertaken during the COVID-19 pandemic.

LAW AND REGULATIONS ON CONSENT FOR PARTICIPATION OF CHILDREN UNDER 16 IN RESEARCH

It is a legal requirement to seek parent/carer consent for the participation of minors under the age of 16 years in clinical trials of medicinal products according to the Medicines for Human Use (Clinical Trials) regulations. This would encompass research involving intrusive data collection, such as blood and saliva sampling. Regarding research on other interventions, such as public health or educational interventions, or observational research, guidance[13] states:

> There is no statute in England, Wales or Northern Ireland governing a child's right to consent to take part in research other than a Clinical Trial of an Investigational Medicinal Product (CTIMP), that is, consent for non-CTIMPs.

Non-medicinal observational or intervention research is instead covered by common law and, in particular, the Gillick ruling,[14] which allows for minors to give their own informed consent for participation in non-investigational medicinal research when they are deemed competent to do so. Guidance[13] states:

> Case law suggests that if a young person has sufficient understanding and intelligence to understand fully what is proposed, and can use and weigh this information in reaching a decision (ie. they are 'Gillick competent'), he or she can give consent to treatment… When a young person is believed to be competent, consent from those with parent/carer responsibility is not legally necessary. However, the involvement of parents/carers in decision-making is encouraged in most circumstances… In the absence of law relating specifically to research, it is commonly assumed that the principle of 'Gillick competence' can be applied not only to consent for treatment, but also to consent for research… A child / young person's right to give consent is dependent upon their capacity to understand the specific circumstances and details of the research being proposed, which in turn will relate to the complexity of the research itself.

Guidance states[15] that in relation to research not involving medicinal products:

> Generally, where children have sufficient understanding and intelligence to understand what is proposed, it is their consent and not that of their parent/guardian that is required by law… No statute governs the rights of those under the age of 16 to give consent for medical treatment or research. However, case law provides the example of the Gillick case with respect to treatment. This case determined that where a young person has sufficient understanding and intelligence to understand fully what is proposed, and use and weigh this information in reaching a decision, he or she can give consent to treatment and consent from parents is not legally necessary—although parental involvement should always be encouraged. The term "Gillick competent" is used to describe a young person's ability to make a decision regarding consent. In the absence of case law dealing specifically with research, the Gillick principles might reasonably be applied here, although the threshold for understanding will vary according to the complexity of the research. (p.22–24)

Although such guidance gives no age by which children or young people are likely to be competent to provide consent, our experience suggests that researchers and teachers have generally taken the transition to secondary school at age 11–12 years as the age at which students are more likely to be competent.[16]

In our experience, GDPR legislation is sometimes given as a reason for seeking active parent/carer consent either by schools or by ethics committees. However, this legislation does not change the legal situation regarding consent. GDPR allows several legal bases for collecting and using personal information. UK Research and Innovation (UKRI) advises that 'The most likely lawful basis for research in UKRI Institutes and in universities (as public authorities) is 'task in the public interest".[17] The UKRI goes on to advise that:

> Consent as one of GDPR's lawful bases for legally processing personal data is different to, and should not be confused with, consent that researchers usually seek from people to participate in a project… Consent discussions should include all relevant aspects of the research project including any sharing of confidential information, so participants can make an informed decision about whether to take part. Therefore, it is important to continue to include the processing of personal data, if that is part of the project, in research consent discussions. However, 'consent', as defined by GDPR, is not likely to be the lawful basis for processing personal data for research purposes; therefore, the consent requirements of GDPR are unlikely to apply to research.

IMPLICATIONS FOR RESEARCH IN SECONDARY SCHOOLS

Reduced response rates and participation by those likely to be at higher risk of many adverse outcomes suggest significant adverse consequences of requiring active parent/carer consent on the quality of the data collected. It undermines the feasibility of research in secondary schools and seriously limits its ability to provide useful evidence on the impacts of interventions, particularly in relation to health inequalities.[18] This is particularly concerning given that many risk behaviours and adverse outcomes first manifest in adolescence so that schools are a key site for public health and other interventions.[19]

Our interpretation of the legal framework is that it is legally necessary to seek the full (active) consent of students to participate in non-medicinal research procedures in secondary schools where students are individually deemed by school staff to possess the understanding and intelligence to provide this. We recommend that active consent from children and young people should be sought for participation, but this should only occur when students are deemed to be competent, judged on the established combination of: students' understanding of the specific circumstances and details of the research; students' ability to use and weigh this information in reaching a decision in relation to what they are being asked to do; and students' understanding how the data will be used. To avoid biases in the selection of students for research participation in schools, and to enable as many students to participate as possible, researchers should develop tools that provide schools with guidance on determining students' competence. These include evidence-based information and measures to establish competence for research participation. Use of an adapted consent support tool, which builds understanding of the research iteratively as part of testing capacity for research (eg, explaining how the study will anonymise data then checking participants understand what this means) is one promising approach.[20]

Researchers should provide students deemed competent with written, age-appropriate information on the research some time before data collection, which will include: what is involved in data collection; why they are being approached for participation; how data will be managed and used; how their confidentiality and anonymity will be protected and the situations in which anonymity will be removed (eg, in response to safeguarding concerns); their right of withdrawal; and any benefits and risks. Ethics committees tend to require ever more information be provided, risking information becoming less understandable. We recommend information be limited to that essential to inform consent decisions. Other information, such as on GDPR, can be provided separately. Researchers should also provide verbal information and an opportunity for questions and discussion to all students before seeking their consent. Written information material for students should ideally be codesigned with young people. This can help to ensure that they effectively address children's vulnerabilities and genuinely support their rights in the research process.[20] Distress or reluctance should be assumed to indicate a withdrawal of consent from that data point, particularly among younger children who may find it hard to challenge an adult.

While the legal basis for consent indicates that parent/carer involvement is also 'encouraged', we recommend that this can generally be discharged by providing parents/carer with detailed, clear and timely information, the opportunity to ask questions and the right and means to withdraw their children from research if they wish (by contacting the school or researchers). Online or face-to-face meetings can be useful. Not providing parents with the right of withdrawal runs counter to the encouragement given it in the above legal frameworks and could cause tensions between schools and parents. However, there may sometimes be harmful consequences of allowing this, such as limiting the ability of research to explore harms caused by parents. Collaboration between teachers and researchers about parents/carer who might lack language or other capacity or need additional information is critical. As above, there are protocols that can be implemented to address these issues, such as translating parent/carer information sheets for parents/carers who do not speak English as a first language.

Research in schools often involves the evaluation of interventions. In most cases, these are universal and delivered at the school or class level. It is not then feasible to seek individual student or parent/carer consent regarding exposure to such interventions. In such cases, it is common practice to seek the (active) consent for intervention from the head-teacher. It should be noted that these processes align with schools' assigned loco parentis responsibilities. In other words, schools and teachers act on behalf of parents/carers while children are in school. However, where interventions do target specific students, it should be possible to seek students' individual active consent for this except where doing so is not feasible, for example in the case of evaluations of disciplinary

intervention where seeking individuals' consent for intervention might not align with school rules.

It may be that ethics committees sometimes require parent/carer active consent because of a desire to maintain citizens' trust in science or a recognition that some school-based interventions, such as sex education, may arouse parent/carer concerns. However, it is important that these imperatives do not result in an erosion of legally recognised student autonomy. In most cases, parent/carer concerns are likely to centre on interventions rather than research procedures and, as discussed above, these are anyway generally consented to by head teachers not parents/carers or teachers. In some cases, head teachers may decide to allow parents/carers to withdraw their children from certain lessons; this would generally require parents/carers to opt their children out rather than requiring all parents/carers to opt their children in, since secondary schools would likely deem the latter practically unworkable, as is the case, for example, with sex education in England.[21]

CONCLUSION

Seeking active parent consent can undermine secondary school students' autonomy, and limit participation, particularly among disadvantaged students, so biasing research. Our analysis suggests that active student consent and passive parent/carer consent be standard practice for most research procedures in secondary schools. More intrusive data collection, such as blood and saliva samples, would require parent/carer active consent since such procedures would be defined as diagnostic procedures so being classed as an investigational product.[13] However, we would argue that for questionnaire completion, observation or routine data, student consent and autonomy should have primacy with parents having the right and means to receive full information, ask questions and withdraw their children from research should they wish. This approach gives proper primacy to student autonomy while also respecting parent/carer autonomy. The use of student active as opposed to passive student consent is unlikely to make any more than marginal reductions in response rates when researchers directly supervise data collection.

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