

Conference presentation

Ethical issues in school-based research

HEIKE FELZMANN

Centre of Bioethical Research and Analysis, NUI, Galway, Ireland.

Email: heike.felzmann@nuigalway.ie

This paper provides an introduction to ethical issues arising in children's research that takes place in school-settings. It addresses three main areas of ethical concern: the informed consent process, confidentiality, and harm and benefit. Informed consent in school settings is characterized by the involvement of multiple stakeholders, including not just researchers, parents and individual children but also school principals, teachers and the children's peer group. The added complexity of the setting has implications for the management of the informed consent process, including the decision at what point and in which manner each stakeholder group needs to be involved in the process. The presence and divergent roles of these multiple stakeholders in the school setting also have implications for addressing issues of confidentiality, especially due to the group setting in which participants take part in the research and role expectations within school settings. Harm and benefit in school-based research are of a non-physical nature; relevant areas of concern relate primarily to the potential for psychological and social harm, realistic presentation of likely benefits from research and the issue of rewards for research participation.

Introduction

This paper aims to provide a general introduction to ethical issues in children's research that takes place in school-settings. School-based research is not a particularly prominent topic in the research ethics literature, despite the fact that the majority of children's research takes place in school settings and that all but a tiny fraction of children who participate in research do so in school-settings. The lack of interest in school-based research, and the general lack of educational representation on RECs [1,2] might be related to the perception that school-based research is practically risk-free and therefore not worthy of ethical attention. However, as will be discussed in the following, school-based research is faced with ethical challenges of considerable complexity.

Informed consent with multiple stakeholders

The ethical requirement of achieving informed consent from participants applies to research in school contexts just as to most other research settings. A significant complication in the school context is the involvement of multiple stakeholders, which adds further complexity to the management of the decision-making process. Research with children has to meet the ethical and legal requirement of obtaining assent not just from the participating children, but also from a legally recognized surrogate decision-maker. While researchers need to be careful not to underestimate children's abilities [3-7], consent practices are based on the assumption that children's decision-making capacity is not fully equivalent to adults'. Accordingly, they cannot

give binding consent, but can only give assent [8]. Assent is the informed agreement to participate in research on the basis of information that is appropriate to the child's level of cognitive and emotional development. Doing justice to the following will facilitate a more child-friendly assent process [9-14]:

- Use interviewers or facilitators with experience of or training in communicating with children
- Use flexible assent protocols that facilitate children's active engagement in the assent process
- Create age-appropriate information and assent materials with the following characteristics:
 - Simple language, adapted to required reading or oral comprehension level
 - Limited length
 - Age-appropriate explanations,
 - Illustrative pictures and visual aids
 - Appropriate font size
 - Case examples where appropriate
 - Different materials for different age groups, if several age groups are included in research.

Assent carries considerable authority, but needs to be supplemented by informed consent, usually by the child's parents, to be fully binding. Research with mature minors who are deemed to have full decision-making competence might be deemed exempt from parental consent under some circumstances [15]. In the case of disagreement between children and their parents regarding consent, the following rules apply:

- Consent trumps assent, ie parents are given more

authority than children in deciding on research participation.

- Refusal trumps acceptance, ie the party that refuses is generally given priority. Children who do not want to participate in research need not participate, regardless of whether their parents have agreed for them to participate [16], with an exception for some cases of beneficial clinical research [17].

In the case of school-based research, teachers and school principals (and in some cases school boards) enter the picture as additional stakeholders, with the effect of adding complexity especially to the informed consent process. Frequently, the principal is the primary gate-keeper that decides on the researcher's access to the school, while teachers have considerable involvement in the facilitation of children's assent.

One of the main concerns regarding consent in school-based research concerns the form that parental involvement should take. In some cases, *standing parental consent* is in place, which means that parents have agreed to transfer authority to the principal to make decisions on their children's participation in low-risk research [18]. In most cases, however, parents remain directly involved and receive information on any intended research, usually distributed via the children, and they then decide whether children can be enrolled. *Active consent* or 'opt-in' consent requires parents to state their agreement with their child's research participation by signing a parental consent form before children can be enrolled in research. In contrast, *passive consent* or 'opt-out' consent allows parents to state their disagreement with their child's research participation through an opt-out form; in the absence of this form, consent is presumed and the child is enrolled in the research if the child wishes. Not surprisingly, when expending similar resources on recruitment, a passive consent protocol generally yields comparatively higher response rates [19] and reduces selection bias which can be crucial for the validity of a study [20,21]. However, RECs are frequently hesitant to grant approval for opt-out proposals [22], due to the reduced stringency of consent requirements in such protocols: it cannot be concluded with any confidence that parents have made a well-informed decision not to raise objections if no opt-out form is submitted. However, it is important to note that in many cases the converse is also true, insofar as the absence of a consent form frequently does not mean that parents object to their child's participation in research. In favour of the opt-out approach, it might be argued that in school contexts parental consent is at least supplemented by the consent of the principal who acts in loco parentis. That extra ethical safety net might justify weakening the requirements for

parental consent at least in those cases that might otherwise be considered appropriate for standing consent.

Assuming that the ethical goal for children's participation is the facilitation of their reflective involvement in the decision-making process, what form should their engagement in the consent process take? Currently, there is no general agreement on good practice. Active involvement of children at an early stage of the process is ethically desirable if their role as active and reflective participants is to be taken seriously; however, established gate-keeping practices, the ethos of schools or limited research resources might not facilitate such an involvement [23,24]. In many cases, researchers delegate the information and assent phase to a class teacher, who uses materials provided by the researcher. Such delegation is partly due to resource constraints, but is also partly due to the assumption that a trusted teacher might be better able than an unknown researcher to communicate effectively with the children and facilitate a meaningful assent process.

This raises concerns about the potential for role conflicts. While performing a delegated function for the researcher, teachers continue to be perceived in their usual role as school teachers with authority over the students. Students may assume, often accurately, that research activities are a continuation of their ordinary educational activities [25] and that participation is expected of them in the same way as participation in other school activities is expected [24], or else they may understand but doubt the separation between the teacher's roles and assume that research-related behaviour could have implications in the school context [26]. It might seem ethically desirable for the teacher to have no role in the process and for the researcher to be fully in charge of the recruitment to avoid these elements of role confusion or subtle coercion. However, due to the multi-stage nature of the consent process, especially the requirements of parental consent, it is generally not feasible to avoid teacher involvement, and a certain degree of role conflict remains a nearly unavoidable part of the consent process.

One further ethical concern is intrinsically linked to the school setting: children in schools are generally approached as a group, and in most cases significant parts of the assent process and the research participation itself occur in a group context. The presence of others is known to influence decision-making [27]. Students may feel uncomfortable with research participation, but feel pressured into participating because their peers are participating. Also, students who could not provide parental consent but want to participate might feel singled out when being left out from their classmates' activities. Accordingly, researchers need to reflect carefully on the practicali-

ties of managing participation and non-participation and ensure that these can be implemented in the participating schools. Potential options for dealing with non-participating students may include the development of alternative activities, and if non-participating students need to be separated from the group arrangements for a break-out room and supervision. Especially in cases where research activities are perceived as comparatively attractive and participating children are young, a separation from the group and lack of attractive alternative activities might be perceived by the affected students as a punishment rather than as a facilitation of their rights as research participants. In these cases researchers may need to consider whether it is ethically appropriate to offer comparable activities in the group setting.

Confidentiality and the need to protect

Confidentiality requires the researchers not to divulge information from research activities without the express agreement of the research participant. In children's research, child protection legislation may require researchers to breach confidentiality, due to mandatory reporting requirements for suspicions of child abuse. In theory, child protection can become an issue in any research context; however, in school-based research the likelihood increases significantly. It needs to be addressed in the informed consent process with all relevant stakeholders by stating the reporting requirement and likely actions arising from abuse suspicions. Researchers need to be careful to address these matters in an appropriate manner that conveys their obligations without appearing unduly alarming or off-putting. This is particularly significant in the researcher's communications to children, where child protection requirements need to be addressed in an age-appropriate manner.

Mandatory reporting requirements are only the most extreme case of the general ethical obligation to act upon knowledge of potential danger to participants; many other situations in which children are at risk might require the researcher to take some action [28,29]. A further complication can arise if the researcher is expected by parents or teachers to communicate information relating to children's experiences or well-being. It is well established that misconceptions about the scope of confidentiality are widespread [30-33]. Those involved in research activities within the school setting might be perceived to have the same obligations as school staff, including the communication of any concerns relating children's well-being to parents and appropriate staff within the school. Active consultation with representatives of all stakeholder groups is advisable if research addresses sensitive issues or uses methods that require intense personal engagement by participants [34-36]. Researchers need to communicate their understand-

ing of their ethical responsibilities clearly, but they also need to be prepared to consider modifications of strict confidentiality practices to do justice to concerns of other stakeholders, eg by developing mechanism to allow generalised feedback on potential issues of concern to the school.

The group context in which school-based research is conducted also has implications for confidentiality. In the researcher-participant dyad, only the researchers' commitment to confidentiality needs to be ensured. However, if information is shared in a group context the number of those in possession of this information multiplies, while their commitment to confidentiality is doubtful. Researchers need to be conscious that sensitive information is often shared during the use of participatory methods or focus groups, and it is their responsibility to ensure that participating children are aware of these limitations of confidentiality.

Varieties of risk and benefit

Research in school settings is in most cases devoid of significant physical risk, but psychological and social risks are not uncommon [37]. Potential psychological risks include emotional upset or destabilization, and in exceptional settings emotional fatigue or emotional dependency. Most significant among these is the risk of emotional upset which could be triggered by:

- Confrontation with particularly emotionally evocative material
- Confrontation with age-inappropriate material
- Confrontation with sensitive topics
- Confrontation with topics related to personal difficulties or difficult life experiences
- Triggering of traumatic memories

Social risks may include:

- being singled out
- embarrassment in front of other students,
- change of image within peer group
- loss of status within the peer group.

Social risks are particularly pertinent in contexts where research takes place within an established peer group, and they are increased by a choice of research methodology that relies on intensified social interaction among a peer group.

The ethical acceptability of any research depends on a positive risk-benefit ratio; in children's research it is generally required that risks are no more than minimal, with the exception of special clinical circumstances where direct benefit to participants might outweigh the presence of more than minimal risk. Unfortunately, psychological and social risks are notoriously complex and difficult to accurately predict, assess and avoid [37,38]. Despite their best efforts,

researchers' knowledge about their research participants is too limited to identify risk accurately. One consequence of this uncertainty is that there is a danger of both overprotection and under-protection of participants. On the one hand, there is a tendency to impose restrictions on any research that addresses sensitive issues in order to avoid the risk of emotional upset. However, it can be argued that this potentially underestimates the ability and willingness of students to engage with sensitive and potentially upsetting issues [26,27] and may prevent the creation of a solid evidence base on issues that affect children's lives [20]. Topics like underage sexual activity, abortion, smoking and drug use, mental illness, death and dying are of concern to many children, but they are not always facilitated in contributing their views in research due to protective concerns [20]. On the other hand, due to the less tangible nature of these kinds of harm, such risks may also be overlooked or underestimated in the ethical reflection on such research projects. Interestingly, there is a distinct lack of studies dedicated to establishing empirically how children experience research [39], and in particular to what extent research participants experience research-related non-physical harm [40]. In order to be able to identify and address these harms, researchers have the responsibility of providing debriefing opportunities [41], especially where research activities included more intense methods of participant engagement or where research topics were of a sensitive nature. They also need to make arrangements to address negative effects after the completion of the research. For research within a school context it is often appropriate to identify a qualified staff member as contact person should support needs arise.

The significance of the burden of research participation as another aspect of potential harm is frequently not fully appreciated because it is not of a spectacular nature. Especially in seemingly non-contentious forms of research, like survey research, it is important not to ignore the burden of completing lengthy and repetitive questionnaires. Researchers should aim at achieving proportionality between research burden and the significance of expected research results. In this context, it is important to consider the contribution of unnecessary research burden to the increasingly common phenomenon of research fatigue. The amount of research that is conducted in schools has increased significantly in recent years as a consequence of increased academic research activities and mandatory student research requirements. As a result the willingness of schools to participate in further research projects diminishes. In the absence of a higher-level gate-keeping mechanism in the school system that could facilitate a more even distribution of research between schools, it is up to researchers to design research projects with a view to

capturing children's interest [42] and to minimize burden.

The perception of research as valuable depends largely on whether research participants perceive the benefits of research participation as outweighing the risk and burden of participation. Unlike much clinical research, most school-based research does not promise a potential immediate benefit to the participants unless it investigates the effectiveness of an intervention or educational programme. However, benefit does not need to be personal; children are frequently motivated by altruistic motivations in deciding on research participation [43,44]. The most likely benefit in school-based research is that knowledge gained from research might be used at some later point to underpin future policy decisions, and the possibility of such contribution is frequently stated by researchers as potential benefit. Yet, much research, including the majority of student projects, is unlikely to have any further impact, and should be presented as such.

Rewards given to participants can be considered a potential benefit of research participation, provided they are not detrimental to participants' health or otherwise inappropriate [41]. There is currently no consensus whether it is ethically appropriate to offer children incentives for taking part in research [45,46]. Those against argue that children are particularly susceptible to rewards and should make decisions on research participation without the influence of incentives. On the other hand, it can be argued that the incentivizing nature of rewards should not be overemphasized to the detriment of the aspect of acknowledgement for children's input. As long as rewards are not overly large [20,47,48] their potential to unduly sway children into participating is limited. Instead, they can be seen in a more constructive light as expression of the researcher's appreciation for the child's willingness to engage with the research tasks [36].

The appreciation of participants' contributions also extends to the courtesy of providing them with feedback after participation and further information on the results of the research after completion [41]. Feedback after participation might be of particular interest to participants where tests have been conducted as part of the research; in these cases care must be taken that feedback is delivered in a way that is sensitive to participants' feelings and information needs. Regarding the communication of final research results, participants may or may not be interested in the results, but they should at least be given the opportunity to receive information on results if they so wish; especially after longer-term research activities, a launch of results in the school setting with active involvement of participants might be appropriate.

Conclusion

Research in school settings is an ethically challenging field that deserves more attention than it usually receives. Researchers and REC members need to be aware of the specific concerns that arise in this setting in relation to the core considerations of informed consent, confidentiality and risk and benefit management. Particular attention needs to be paid to the implications of the presence of multiple stakeholders and the effect of professional roles and expectations on the ethical management of the research process.

Acknowledgements

Many thanks to my colleagues Jane Sixsmith, Siobhan O'Higgins, Saoirse NicGabhainn and Sorcha Ni Chonnachtaigh who collaborated with me on the project 'Ethics committees and ethical review of children's research in Ireland', funded by the Office of the Minister for Children, that led me to engage more thoroughly with the issue of school-based research. I'd also like to thank the children's researchers and children participants who contributed their views on ethical issues in children's research during the course of that project. And finally thanks for the interest shown in the topic by participants at the AREC conference in Birmingham 2009 which prompted me to write up this paper.

References

- Howe KR, Dougherty KC. Ethics, institutional review boards, and the changing face of educational research. *Educational Researcher* 1993; 22(9): 16-21.
- Howe KR, Moses MS. Chapter 2: Ethics in educational research. *Rev Res in Edu* 1999; 24(1): 21-59.
- Ashcroft R, Goodenough T, Kent J, Williamson, E. Children's consent to research participation: Social context and personal experience invalidate fixed cutoff rules. *Am J Bioethics* 2003; 3(4): 16-18.
- Joffe S. Rethink 'Affirmative agreement', but abandon 'assent'. *Am J Bioethics* 2003; 3(4): 9-11.
- Ladd RE. Child assent revisited. *Am J Bioethics* 2003; 3(4): 37-38.
- Miller VA, Drotar D, Kodish E. Children's competence for assent and consent: A review of empirical findings. *Ethics & Behavior* 2004; 14(3): 255-295.
- Morrow V, Richards M. The ethics of social research with children: An overview. *Children & Society* 1996; 10(2): 90-105.
- Baylis F, Downie J, Kenny N. Children and decision making in health research. *IRB: Ethics and Human Research* 1999; 21(4): 5-10.
- Bray L. Developing an activity to aid informed assent when interviewing children and young people. *J Res Nurs* 2007; 12(5): 447-457.
- Bruzzese J-M, Fisher CB. Assessing and enhancing the research consent capacity of children and youth. *Appl Devel Sci* 2003; 7(1): 13-26.
- Diekema DS. Taking children seriously: What's so important about assent? *Am J Bioethics* 2003; 3(4): 25-26.
- Ford K, Sankey J, Crisp J. Development of children's assent documents using a child-centred approach. *J Child Hlth Care* 2007; 11(1): 19-28.
- Tait A, Voepel-Lewis T, Malviya S. Presenting research information to children: a tale of two methods. *Anaesth Analg* 2007; 105(2): 358-364.
- Thomas N, O'Kane C. The ethics of participatory research with children. *Children & Society* 1998; 12(5): 336-348.
- Sanci LA, Sawyer SM, Weller, PJ, Bond LM, Patton GC. Youth health research ethics: Time for a mature-minor clause? *Med J Austral* 2004; 180: 336-338.
- Grover S. On the limits of parental proxy consent: Children's right to non-participation in non-therapeutic research. *J Acad Ethics* 2003; 1(4): 349-383.
- DHHS, Code of federal regulations, title 45 - public welfare: Department of Health and Human Services, part 46: Protection of human subjects. 2005, United States Department of Health and Human Services (DHHS): Washington.
- NHMRC, National statement on ethical conduct in research involving humans. 2007, National Health and Medical Research Council Canberra, Australia.
- O'Donnell LN, Duran RH, San Doval A, Breslin MJ, Juhn GM, Stueve A. Obtaining written parent permission for school-based health surveys of urban young adolescents. *J Adoles Hlth* 1997; 21(6): 376-383.
- Moolchan ET, Mermelstein R. Research on tobacco use among teenagers: Ethical challenges. *J Adoles Hlth* 2002; 30(6): 409-417.
- Santelli J, Smith Rogers A. Parental permission, passive consent, and 'children' in research. *J Adoles Hlth* 2002; 31(4): 303-304.
- Wagener DK, Sporer AK, Simmerling M, Flome JL, An C, Curry SJ. Human participants challenges in youth-focused research: Perspectives and practices of IRB administrators. *Ethics & Behavior* 2004; 14(4): 335-349.
- Heath S, Charles V, Crow G, Wiles R. Informed consent, gatekeepers and go-betweens: Negotiating consent in child- and youth-oriented institutions. *Br Educ Res J* 2007; 33(3): 403-417.
- Homan R. The principle of assumed consent: The ethics of gate-keeping. *J Philos Educ* 2001; 35(3): 329.
- David M, Edwards R, Alldred P. Children and school-based research: 'informed consent' or 'educated consent'? *Br Educ Res J* 2001; 27(3): 347-365.
- Denscombe M, Aubrook L. 'It's just another piece of schoolwork': The ethics of questionnaire research on pupils in schools. *Br Educ Res J* 1992; 18(2): 113.
- Cohn JM, Fein JA. Adolescent decisional autonomy regarding participation in an emergency department youth violence interview. *M J Bioethics* 2005; 5(5): 70-74.
- Santelli J, Geller G, Chen DT, Speers MA, Botkin JR, Laswell S. Recruitment of pregnant, minor adolescents and minor adolescents at risk of pregnancy into longitudinal, observational research: The case of the national children's study. In Kodish E (ed). *Ethics and research with children: A case-based approach*. New York: Oxford University Press, 2005: 100-119.
- Scarr S. Ethical problems in research on risky behaviors and risky populations. *Ethics & Behavior* 1994; 4(2): 147-155.
- Ford CA, Thomsen SL, Compton B. Adolescents' interpretations of conditional confidentiality assurances. *J Adoles Hlth* 2001; 29(3): 156-159.
- Lyren A, Kodish E, Lazebnik R. Understanding confidentiality in the adolescent patient/doctor relationship: a pilot study (phase 1). *J Adoles Hlth* 2004; 34(2): 114-115.
- Lyren A, Kodish E, Lazebnik R, O'Riordan MA. Understanding confidentiality: Perspectives of african american adolescents and their parents. *J Adoles Hlth* 2006; 39(2): 261-265.
- Pasternak RH, Cheng TL, Geller G, Parrish C. Parent and adolescent views of risk behavior research and consent. *J Adoles Hlth*, 2005; 36(2): 104-105.
- Fisher CB, Wallace SA. Through the community looking glass: re-evaluating the ethical and policy implications of research on adolescent risk and psychopathology. *Ethics & Behavior* 2000; 10(2): 99-118.

35. Fisher CB. Adolescent and parent perspectives on ethical issues in youth drug use and suicide survey research. *Ethics & Behavior* 2003; 13(4): 303-332.
36. Flicker S, Guta A. Ethical approaches to adolescent participation in sexual health research. *J Adoles Hth*, 2008; 42(1): 3-10.
37. Thompson RA. Behavioral research involving children: a developmental perspective on risk. *IRB: Ethics and Human Research* 1990; 12(2): 1-6.
38. Thompson RA. Vulnerability in research: a developmental perspective on research risk. *Child Development* 1990; 61(1): 1.
39. Goodenough T, Williamson E, Kent J, Ashcroft R. 'What did you think about that?' researching children's perceptions of participation in a longitudinal genetic epidemiological study. *Children & Society* 2003; 17(2): 113-125.
40. Mayeux L, Underwood MK, Risser SD. Perspectives on the ethics of socio-metric research with children: How children, peers, and teachers help to inform the debate *Merrill-Palmer Quarterly* 2007; 53(1): 53-78.
41. British Educational Research Association. Revised ethical guidelines for educational research, 2004. Available at <http://www.bera.ac.uk/files/2008/09/ethical1.pdf>
42. Edwards R, Alldred PAM. Children and young people's views of social research: the case of research on home-school relations. *Childhood* 1999; 6(2): 261-281.
43. McGee EM. Altruism, children, and non-beneficial research. *Am J Bioethics* 2003; 3(4): 21-23.
44. Wolthers OD. A questionnaire on factors influencing children's assent and dissent to non-therapeutic research. *J Med Ethics* 2006; 32(5): 292-297.
45. Borzekowski DLG, Rickert VI, Ipp L et al. At what price? The current state of subject payment in adolescent research. *J Adolesc Hlth* 2003; 33(5): 378-384.
46. Weise KL, Smith ML, Maschke KJ, Liesel Copeland H. National practices regarding payment to research subjects for participating in pediatric research. *Pediatrics* 2002; 110(3): 577-582.
47. Bagley SJ, Reynolds WW, Nelson RM. Is a 'wage-payment' model for research participation appropriate for children? *Pediatrics* 2007; 119(1): 46-51.
48. Scherer DG, Brody JL, Annett RD, Hetter J, Weiss Roberts L, Cofrin KMW. Financial compensation to adolescents for participation in biomedical research: adolescent and parent perspectives in seven studies. *J Pediatr* 2005; 146(4): 552-558.

FUTURE CONFERENCE PROGRAMME

Friday, 13th November 2009

AREC WINTER CONFERENCE

Ethical review: barrier or facilitator to research

To be held at the Holiday Inn, Bloomsbury, London

Speakers to include: Sharon Witherspoon, Professor Jan Pahl, Dr Ron Iphofen, Dr Trish Groves, Dr Cyril Clarke, Dr Janet Wisely, and Dr John Lamberty

The meeting will include the AREC AGM

Booking forms available on the AREC website