Ethical Standards in Research with Children

Principle 1. NON-HARMFUL PROCEDURES: The investigator should use no research procedure that may harm the child either physically or psychologically. The investigator is also obligated at all times to use the least stressful research procedure whenever possible. Psychological harm in particular instances may be difficult to define; nevertheless, its definition and means for reducing or eliminating it remain the responsibility of the investigator. When the investigator is in doubt about the possible harmful effects of the research procedures, consultation should be sought from others. When harm seems inevitable, the investigator is obligated to find other means of obtaining the information or to abandon the research. Instances may, nevertheless, rise in which exposing the child to stressful conditions may be necessary if diagnostic or therapeutic benefits to the child are associated with the research. In such instances careful deliberation by the Ethics Review Board should be sought.

Principle 2. INFORMED CONSENT: Before seeking consent or assent from the child, the investigator must obtain parental consent (see Principle 3 and additional notes on opt-out consent). As well, the investigator must inform the child of all features of the research that may affect his or her willingness to participate and should answer the child's questions in terms appropriate to the child's comprehension. The investigator should respect the child's freedom to choose to participate in the research or not by giving the child the opportunity to give or not give assent to participation as well as to choose to discontinue participation at any time. Assent means that the child shows some form of agreement to participate without necessarily comprehending the full significance of the research necessary to give informed consent. Investigators working with infants should take special effort to explain the research procedures to the parents and be especially sensitive to any indicators of discomfort in the infant. In spite of the paramount importance of obtaining consent, instances can arise in which consent or any kind of contact with the participant would make the research impossible to carry out. Non-intrusive field research is a common example. Conceivably, such research can be carried out ethically if it is conducted in public places, participants' anonymity is totally protected, and there are no foreseeable negative consequences to the participant. However, judgments on whether such research is ethical in particular circumstances should be made in consultation with an Ethics Review Board.

Principle 3. PARENTAL CONSENT: The informed consent of parents or legal guardians should be obtained in writing for persons under the age of 18 years. (See additional notes on opt-out consent.) Informed consent requires that parents/guardians be informed of all the features of the research that may affect their willingness to allow the child to participate. This information should include the professional and institutional affiliation of the investigator. Not only should the right of the responsible adults to refuse consent be respected, but also they should be informed that they may refuse to participate without incurring any penalty to them or to the child.

Principle 4. ADDITIONAL CONSENT: The informed consent of any persons, such as schoolteachers for example, whose interaction with the child is the subject of the study should also be obtained. As with the child and parents or guardians informed consent requires that the persons interacting with the child during the study be informed of all features of the research which may affect their willingness to participate. All questions posed by such persons should be answered and the persons should be free to choose to participate or not, and to discontinue participation at any time.

Principle 5. INCENTIVES: Incentives to participate in a research project must be fair and must not unduly exceed the range of incentives that the child normally experiences. Whatever incentives are used, the investigator should always keep in mind that the greater the possible effect of the investigation on the child, the greater is the obligation to protect the child's welfare and freedom.

Principle 6. DECEPTION: Although full disclosure of information during the procedure of obtaining consent is the ethical ideal, a particular study may necessitate withholding certain information or deception. Whenever withholding information or deception is judged to be essential to the conduct of the study, the investigator should satisfy research colleagues that such judgment is correct. If withholding information or deception is practiced, and there is reason to believe that the research participants will be negatively affected by it, adequate measures should be taken after the study to ensure the participant's understanding of the reasons for the deception. Investigators whose research is dependent upon deception should make an effort to employ deception methods that have no known negative effects on the child or the child's family.
Principle 7. ANONYMITY: To gain access to institutional records, the investigator should obtain permission from responsible authorities in charge of records. Anonymity of the information should be preserved and no information used other than that for which permission was obtained. It is the investigator's responsibility to ensure that responsible authorities do, in fact, have the confidence of the participant and that they bear some degree of responsibility in giving such permission. In complying with requirements for data sharing, researchers need to carefully consider whether they have provided data that, if combined, risks violating participant anonymity.

Principle 8. MUTUAL RESPONSIBILITIES: From the beginning of each research investigation, there should be clear agreement between the investigator and the parents/guardians and the child, when appropriate, that defines the responsibilities of each. The investigator has the obligation to honour all promises and commitments of the agreement.

Principle 9: JEOPARDY: When, in the course of research, information comes to the investigator's attention that may jeopardize the child's well-being, the investigator has a responsibility to discuss the information with the parents or guardians and with those expert in the field in order that they may arrange the necessary assistance for the child. Researchers need to be aware that they may obtain findings suggesting that a child's health and well-being might be in jeopardy, that these findings may include false positives, and they should be knowledgeable about current human subjects procedures and regulations for informing families of incidental findings.

Principle 10. UNFORESEEN CONSEQUENCES: When research procedures result in undesirable consequences for the participant that were previously unforeseen, the investigator should immediately employ appropriate measures to correct these consequences, and should redesign the procedures if they are to be included in subsequent studies.

Principle 11. CONFIDENTIALITY: The investigator should keep in confidence all information obtained about research participants. The participants' identity should be concealed in written and verbal reports of the results, as well as in informal discussion with students and colleagues. When a possibility exists that others may gain access to such information, this possibility, together with the plans for protecting confidentiality, should be explained to the participants as part of the procedure of obtaining informed consent.

Principle 12. INFORMING PARTICIPANTS: Immediately after the data are collected, the investigator should clarify for the research participant any misconceptions that may have arisen. The investigator also recognizes a duty to report general findings to participants in terms appropriate to their understanding. Where scientific or humane values justify withholding information, every effort should be made so that withholding the information has no damaging consequences for the participant.

Principle 13. REPORTING RESULTS: Because the investigator's words may carry unintended weight with parents and children, caution should be exercised in reporting results, making evaluative statements, or giving advice.

Principle 14. IMPLICATIONS OF FINDINGS: Investigators should be mindful of the social, political and human implications of their research and should be especially careful in the presentation of findings from the research. This principle, however, in no way denies investigators the right to pursue any area of research or the right to observe proper standards of scientific reporting.

Notes

These guidelines have been adapted from procedures recommended by the Society for Research in Child Development and are consistent with principles for conducting research contained in the Declaration of Helsinki (World Health Organisation, paras. I.9, 11), the National Children’s Bureau Guidelines for Research, and the British Psychological Society’s Code of Conduct.

Legal consent can usually only be obtained from individuals who are 18 years of age and over. However, young people aged 16-18 with sufficient understanding are able to give their full consent to participate in research independently of their parents and guardians. Children under 16 are able to give their full consent providing they have been counseled and do not wish to involve their parents and they have sufficient maturity to understand the nature, purpose and likely outcome of the proposed research.
Use of opt-out consent with children

What is opt-out consent?

Opt-out consent is where participants are informed about a piece of research and are automatically included in that research unless they indicate that they are unwilling to participate.

Why is opt-out consent problematic?

Ethical guidelines state that research participants must participate in research in a voluntary way, free from any coercion. This may be difficult to ensure with opt-out consent; the individual may not have received or understood the information, they may forget to withdraw consent, or they may feel uncomfortable about withdrawing consent.

What does the BPS say about opt-out consent with children?

BPS guidelines state:

‘In relation to the gaining of consent from children and young people in school or other institutional settings, where the research procedures are judged by a senior member of staff or other appropriate professional within the institution to fall within the range of usual curriculum or other institutional activities, and where a risk assessment has identified no significant risks, consent from the participants and the granting of approval and access from a senior member of school staff legally responsible for such approval can be considered sufficient. Where these criteria are not met, it will be a matter of judgment as to the extent to which the difference between these criteria and the data gathering activities of the specific project warrants the seeking of parental consent from children under 16 years of age and young people of limited competence.’ (p.17.)

They also state:

‘In research with children under the age of 16... researchers should ensure that parents or guardians are informed about the nature of the study and given the option to withdraw their child from the study if they so wish.’ (p.32.)

Thus although the BPS allow for opt-out consent in certain circumstances, there is still an obligation on the researcher to ensure that every parent receives information about the research and has the opportunity to withdraw their child. In practice this may be difficult, thus the potential benefits of the research would need to outweigh this risk.
Can headteachers legally provide consent for children in their care, in place of their parents?

Whilst there does not seem to be a definitive answer to this question, legal advice provided to the Psychology Department REC is that opt-in parental consent should be obtained.

What is the position of the Psychology Department REC on use of opt-out consent with children?

Given the legal advice provided to the REC, and the difficulties of ensuring that all parents have received study information with opt-out procedures, the committee’s position is that all research with children should normally require that parents provide opt-in consent.

In exceptional circumstances the committee may consider the use of opt-out consent with children. This may be deemed acceptable for instances in which (a) the research procedures and measures are in line with activities normally conducted by the institution (which would typically mean that children are not tested individually), and (b) no children are disadvantaged by taking part in the study.