



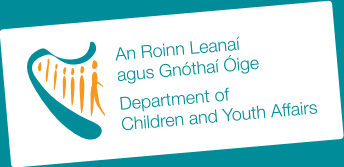
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Guidance for developing ethical research projects involving children



Guidance for developing ethical research projects involving children

APRIL 2012

DEPARTMENT OF CHILDREN AND YOUTH AFFAIRS

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Foreword

by Minister for Children and Youth Affairs

The decision to establish the Department of Children and Youth Affairs demonstrates the vision of Government: that growing up in Ireland means you have the best start in life.

To realise this vision, we need to understand our children - their lives, their circumstances, their needs and the services and supports required to meet their needs. Research is crucial.

The type of research being conducted by the Research Unit in my Department, and by other institutions, is providing us with a wealth of valuable data to understand our children better.

Clearly, such research has the potential to improve children's lives by strengthening the evidence base for policy development and service delivery. It can also, however, carry some risk. It is critical that our pursuits to better understand our children should never compromise them.

For this reason, it gives me great pleasure to be associated with this very important document, which sets out guidance for undertaking ethical research projects with children in Ireland to ensure that the involvement and participation of children in research projects is safe, respectful, meaningful and beneficial.

I am grateful to the Working Group, established by my Department, and the range of other stakeholders, including the Office of the Data Protection Commissioner, the Ombudsman for Children's Office and the Department of Health, for the time and effort they contributed to bring this guidance document to completion. I am particularly grateful to Dr. Anne Cleary, Chair of the Working Group.

Given that this document is underpinned by earlier research commissioned by my Department, by the United Nations Convention on the Rights of the Child, by legal and policy precedent, and by best practice principles, including *Children First: National Guidance for the Protection and Welfare of Children* (2011), it provides a very useful guidance for researchers on the complex web of ethical issues that can arise at each stage of the research journey, each requiring careful consideration.

Frances Fitzgerald, TD
Minister for Children and Youth Affairs

Introduction

by Chairperson of Working Group

The need to protect children when they are involved in research is self-evident, but it has taken a relatively long time to translate this notion into policy and practice. The history of research endeavour includes many unethical practices involving children - from intrusive and invasive procedures, to the over-investigation of some populations. Organisations caring for children sometimes regarded them as a ready source of research data with little regard to the ethical issues involved. The voices of children were rarely heard in research and their potential to contribute to its development ignored.

The objective of this document is to provide ethical guidance for developing research projects involving children across a range of disciplines, from medicine to the social sciences. The impetus came firstly from a Department of Children and Youth Affairs' commissioned report on ethical issues and children's research, which identified a lack of standardisation in this area (Felzmann *et al*, 2010). Another incentive was to use the knowledge developed from ethical deliberations relating to the *Growing Up in Ireland* study. Part of this project has been the development of rigorous ethical procedures to both protect children and facilitate their participation in the research process.

The Working Group was largely formed from the GUI Research Ethics Committee and, as with the latter, participants came from a variety of disciplinary backgrounds - research, clinical, ethical/legal, as well as representatives from agencies serving children. It also included DCYA officials Dr. Sinéad Hanafin and Bairbre Meaney. Each committee member brought specific skills, but the success of the Working Group was due to the exceptional commitment they gave to the work, including the drafting of this guidance. The objective of the group, and this national guidance, is to safeguard children within research and to assist researchers to do better, more creative investigations with and for children.

Dr. Anne Cleary
Chairperson

Working Group on Ethics in Children's Research

WHY WE NEED ETHICAL GUIDANCE FOR CHILDREN'S RESEARCH

Research with, and for, children is necessary because knowing about children and their lives and understanding the child's perspective are key to protecting, promoting, and supporting their health and well-being (Department of Health and Children, 2000). There are specific issues arising from children's and young people's legal status, their knowledge and experience of the world, their differing levels of cognition and their relative lack of independence and autonomy, all of which require particular attention in order to ensure appropriate and ethical research practice.

AIM OF ETHICAL GUIDANCE

The aim of this guidance paper, produced by a working group on behalf of the Department of Children and Youth Affairs (DCYA), is to advise on good practice principles for undertaking research with children (defined in Ireland as people below the age of 18). Members of the working group are listed in the Appendix.

This guidance, which builds on a report by Felzmann *et al* (2010), is based on legal or policy precedent and/or best practice principles. It is also driven by the principles of the United Nations Convention on the Rights of the Child, in particular Articles 2, 3, 4 and 6 (UN, 1989). The guidance is intended for all those who carry out research with, and for, children in Ireland.

There is currently no single regulatory system and no body responsible for research ethics in Ireland. The most clearly regulated area of research is clinical trials, which must operate under the aegis of the EU Directive on Clinical Trials (Department of Health and Children, 2004) and which require review by a research ethics committee recognised by the Department of Health. Ethics relating to research outside this remit is covered primarily by research ethics committees (RECs) in health and social care organisations and in universities. The experience and competence of these RECs in relation to, for example, examining diverse methodologies vary greatly, as do their requirements and review procedures (Felzmann *et al*, 2010). The proposed Health Information Bill¹ includes a regulatory framework for the collection, use, management and storage of personal health information, as well as provision for a new national structure for research ethics. The Health Information and Quality Authority (HIQA) will soon become the supervisory body under the EU Clinical Trials Regulations and has already established a national research advisory body. The Health Information Bill will make the HIQA the supervisory body for approved RECs for all other types of health research.

CORE ETHICAL PRINCIPLES AND CONCEPTS IN CHILD-RELATED RESEARCH

There are basic ethical principles that apply to all research. These include:

- a commitment to the well-being, protection and safety of participants;
- a duty to respect the rights and wishes of those involved;
- an obligation to address the issue of who ought to receive the benefits of research and bear its burdens;
- a responsibility to conduct high-quality scientific research;
- a commitment to communicate the results of research to relevant stakeholders and policy-makers.

Based on these principles, a number of core ethical concepts arise in research. These are:

1. minimising risk of harm;
2. informed consent and assent;
3. confidentiality and anonymity.

In relation to children's research, a number of additional issues need to be addressed, namely:

4. child protection principles;
5. legal obligations and policy commitments in relation to children;
6. a child-centred, inclusive approach to research.

¹ The powers set out in the Health Information Bill will apply to all health research that is not otherwise governed by EU law. See legislative proposals at www.dohc.ie/issues/hib/

1. Minimising risk of harm

One of the main concerns in research ethics is the protection of participants from harm or the limitation of risk of harm. A key ethical consideration in research involving children is the level of risk to which children may be exposed. Risk refers to potential harm (physical, psychological or social) that may arise from the research. Some research, such as early phase clinical trials, poses a more identifiable risk of harm. But perceived low-risk research could result in different types of harm, for example, mental distress or the stigmatising of certain social, cultural, racial or religious groups.

International research guidelines advocate a 'minimal risk' standard, which implies that the anticipated probability and magnitude of harm or discomfort are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. The degree of risk may vary based on the level of physical, psychological or social vulnerability in the study population or sample. Risk can be both overestimated and underestimated. Guides to assessing the risk-benefit balance in health-related research have been produced by the Irish Medical Council (2009), the Medical Research Council (2004) and the Royal College of Paediatrics and Child Health (2000) in the United Kingdom, and the US Department of Health and Human Services (2009). In addition, the Data Protection Commissioners in Ireland have published guidelines on research in the health sector (2007).

Research on sensitive topics should not automatically be considered high risk. Provided adequate protection measures are in place, such research is often valuable and could, in fact, be comparatively low risk. Conversely, social science research with children is not necessarily low risk and could pose significant psychological or social risks. In relation to these issues, research ethics committees, investigators and reviewers of research protocols need to:

- evaluate the potential risk or discomfort posed for children, interpreting minimal risk in relation to the normal experiences of average healthy children;
- ensure measures are in place to mitigate potential harm arising from the research process, including suspension of the research project if a child's safety or well-being is negatively affected.

2. Informed consent and assent

For consent to be valid, it has to be informed (Shaw *et al*, 2011) and the onus is on the researcher to show that he or she has taken the steps necessary to ensure that the person whose consent is being sought has been given the requisite information and has been supported in developing an adequate understanding of the research. In addition, consent for access to contact information by researchers is generally required under the Data Protection Acts (*see Section 3 below*). Parental and/or guardian (informed) consent is required for a child (defined in Ireland as a person below the age of 18) to participate in research. Where a child is in the care of the State, additional requirements may be necessary. Good practice also requires the child's agreement to participate (informed assent) and this should be sought independently (*see below*). The nature of the child's involvement in the decision-making process will be dependent on their age and maturity, as well as on an evaluation of their ability to understand the nature, purpose and implications of what is involved and to make a decision about this.

In the United States of America, the National Commission for the Protection of Human Subjects (1977) recommends that children over the age of 7 should be asked for their assent to participate in research and that the objection of a child at any age should be adhered to unless the intervention being tested were to offer an important direct benefit to the child's health. In Ireland, young people over the age of 16 can exercise rights in relation to medical and dental decisions concerning themselves, but the general law in this country is that parental rights remain intact until the child reaches 18 years of age (Irish Council for Bioethics, 2005).² The ability of children to understand the consequences of taking part in the research is influenced by the type and context of the research, but if information is presented in a child-appropriate manner and children are supported throughout the decision-making process, then many children will be competent to assent to participate (Medical Research Council, 2004). Adequate information about the project's aims, methods and potential outcomes must be provided in a child-accessible form and children

² It should be noted, however, that the EU Clinical Trials Regulations define an adult as someone who has attained the age of 16.

should be given time to assimilate the information, ask questions and consult with others as necessary before deciding whether to assent. Children should also be made aware that their participation is entirely voluntary and that they are free to withdraw at any time without any negative consequences attached to this decision. If, at any time, a child withdraws assent, parental consent should not override this wish.

Complex or long-running projects may require confirmation of consent and assent at various points to take account of children's increased level of understanding. In research that straddles the age of consent, once the research participants reach the age of 18 the previously acquired parental consent is negated and not seeking the young adult's consent at this stage could be deemed akin to proceeding without consent (Spriggs, 2010).

3. Confidentiality and anonymity

Confidentiality implies that research data that include identifiable information on participants should not be disclosed to others without the explicit consent of the participants (except in the case of a child protection concern, see *Section 4 below*). The data should be collected with the consent of the participant and the researcher should also explain who will have access to the data and why. The principle of anonymity is that individual participants should not be identifiable in research documentation, unless agreed to by the participant.³

In Ireland, the Data Protection Acts 1988 and 2003 (Government of Ireland, 1988 and 2003) cover a wide range of research-related activities, including the collection, storing, accessing and disclosing of personal data held in either electronic or manual filing systems by individuals or in general organisational records. In terms of this legislation, which does not expressly specify a particular age threshold for consent, the agreement to allow disclosure of identifiable information on a child research participant must be sought from the child's parent or guardian. However, good practice principles require that the child, depending on age and competence, be fully informed of these issues and provides assent where applicable.

Key points of the data protection legislation include:

- Where consent is relied on for processing, including disclosure, of sensitive data, then the consent must be explicit, unless it is necessary for medical purposes⁴ in which case implied consent can be relied on.
- Only the minimum amount of personal data required should be sought and retained.
- Personal data may not be used for any other purpose other than that specified at the point of collection - unless this is agreed to by the participant - and cannot be retained once the initial purpose has ceased.
- Access to research data by others (e.g. colleagues, research staff) is contingent on prior consent for this being obtained from the research participants. Guarantees of confidentiality and anonymity given to participants must be honoured, unless there are clear overriding reasons to do otherwise (most importantly, when there is a child protection issue) and any limitation in relation to confidentiality must be explained to participants when consent is sought.
- Appropriate security measures must be taken and the degree of security depends on the level of sensitivity and the harm that might result from an unauthorised disclosure. Methods for preserving the anonymity of data include the removal of direct identifiers, the use of pseudonyms or the use of technical means to break the link between data and identifiable individuals. In qualitative research, additional protective measures may be needed, for example, changing or omitting certain characteristics (e.g. age, gender, geographic location, distinctive details) to disguise participants' identities. All research outputs and publications must be checked carefully to ensure confidentiality and anonymity. Where there is a need to store personal data for the purpose of the research, it must be kept in a safe and secure environment, i.e. system and physical security safeguards must be in place.
- Research participants have a right of access to personal data, but this does not apply to personal data kept only for the purpose of preparing statistics.

³ The HIQA website (www.hiqa.ie) contains guidelines to assess privacy risks to individuals before and during a project involving personal information.

⁴ Medical purposes as defined by Section 2B(4) of the Data Protection (Amendment) Act 2003 includes medical research. The full list of criteria for the processing of personal data is set out in Sections 2A and 2B of the Act.

4. Child protection and well-being

To ensure research procedure is in keeping with current best practice standards of child protection, researchers must carry out their work in accordance with *Children First: National Guidance for the Protection and Welfare of Children*, published by the Department of Children and Youth Affairs (DCYA, 2011). *Children First* provides information on protecting and promoting child welfare and the best practice response to personal evidence or reports that children are being harmed or at risk of harm. *Children First* requires that concerns about children be reported to the Children and Family Services of the HSE, which has statutory responsibility to protect children, or in an emergency to the Gardaí (*ibid*, p. 3), and outlines the standard reporting procedure to be used in passing this information to the statutory authorities. *Children First* also recommends that effective child protection is best achieved where the national and local guidelines are supported by comprehensive training, supervision and support services for children and families. The national guidance recommends that every organisation in regular direct contact with children should develop policies and procedures for staff and/or volunteers relating to child protection and well-being. Such organisations are also required to appoint a designated liaison person within the organisation to take responsibility for this and for reporting allegations or suspicions of child abuse. Research organisations should have a child protection policy in place that ensures that children's welfare is the primary concern and that research staff are clear about their role and responsibility. Factors that should be implemented to ensure the child is protected include:

- developing a risk assessment before starting the research;
- ensuring that Garda-vetting and employment checks are carried out on study personnel;
- ensuring that all researchers have adequate skills, training and access to relevant expertise in relation to child protection issues;
- having a trusted adult, or third party, present, recording interviews on video or conducting interviews in an environment where there is passive surveillance by a third party.

The researcher's competence in working with children, and access to relevant expertise where necessary, is a prerequisite for ensuring child safety and well-being in the research process. Researchers should have access to a designated liaison person within the research team or organisation who holds a senior position and has expertise and/or knowledge of child protection best practice principles. This person should be a source of advice and information, and be responsible for ensuring that the standard reporting procedure is followed. The designated liaison person themselves should ensure that they are knowledgeable about child protection and undertake any training considered necessary to keep themselves updated on new developments (DCYA, 2011, p. 14).

Research that involves the participation of children may, in rare circumstances, have adverse effects on the children who are participating. If at any time during the research process there is an indication that a child's safety or well-being is being negatively affected, the research must be suspended until the issue has been addressed. If through the course of the research the child appears to be negatively affected by the research, the parent or guardian must be informed and the child and family offered appropriate support.

Child protection best practice principles and legislation may alter the usual rules and conditions of research. An example of this relates to the area of confidentiality. Where a child or young person discloses that they or others are at risk of significant harm, or where the researcher observes or receives evidence of incidents likely to cause serious harm to the child, the researcher has a duty to take steps to protect the child and/or other children (DCYA, 2011, p. 16). However, while the consent or the assent of the child need not be sought to report a serious risk, it is important that the researcher does this after discussion with the child, ensuring that they are fully aware of the situation and the steps that are going to be taken in order to protect them and/or other children. If the researcher decides they need to inform others of any situation in line with the *Children First* national guidance, then they must ensure that the child has immediate support and is kept fully informed. This potential situation requires that children and young people should be told at the outset, and as necessary during the course of an interview, that confidentiality cannot be guaranteed if information of this type emerges. In reporting these concerns, the researcher is protected in law by the Protections for Persons Reporting Child Abuse Act 1998 (Government of Ireland, 1998). If during the course of research it becomes necessary to report a child protection concern in line with the *Children First* national guidance, it is important that every possible effort is made to keep the child's parents/carers informed of the situation, except in circumstances where doing so might place the child at further risk.

Protective considerations for the researcher

Providing a place where information can be disclosed to researchers in private has been seen as important, especially in qualitative research with children. However, in recent years concerns about risks to the researcher in a one-to-one research situation have arisen in the context of child protection legislation. The potential of allegations of infringements of such legislation have led to changing research practices. Researchers can engage one-to-one with children provided they are always in sight of others. Protective factors in relation to child protection also ensure the protection of the researcher. When making decisions about implementing protective factors, it is necessary to produce a set of procedures to address potential allegations against a researcher/interviewer. These procedures should include measures that:

- protect children, including reporting as per *Children First* national guidance where appropriate;
- allow internal investigation into the allegation (which must not interfere with any statutory inquiry);
- provide appropriate support for the researcher during the investigation process.

5. Legal requirements and policy commitments

The rights of children in Ireland in relation to their participation in research are covered in the *United Nations Convention on the Rights of the Child* (UN, 1989), which Ireland has ratified. This provides for free expression for children who are capable of forming their own views (Articles 12 and 13) and the right to access appropriate information (Article 17). Although parental rights are given predominance in the 1937 Constitution of Ireland (Article 42), young people also have rights under Article 40.3.1, which include a right to dignity, privacy, bodily integrity and a right to autonomy or self-determination.⁵ Children as participants in research projects also have rights under the Data Protection Acts, as do their parents (Government of Ireland, 2003). Under the *European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004* (Department of Health and Children, 2004), parental or guardian consent is required for clinical trials involving minors, who are defined in this case as persons under the age of 16 years.⁶ All research in Ireland involving children should, as stated above, be carried out within the framework of *Children First: National Guidance for the Protection and Welfare of Children* (DCYA, 2011).

6. Children's participation in the research process

Participation of children

Children have a right to be involved in many aspects of the research process and their participation can enhance the quality of the research (Shaw *et al*, 2011; Williams, 2011). Successful participation of children in research is associated with:

- their understanding of the process;
- making informed decisions to become involved and the ability to do this develops over time;
- having the opportunity, where feasible, to become actively involved in different stages of the research endeavour.

Researchers have a responsibility to provide whatever assistance is required to ensure successful participation. This can include:

- design of an appropriate methodology;
- inclusion of children, when appropriate, in key decision-making aspects, including ethical issues and the interpretation of results;
- consideration of the use of rewards for participation; however, the risk of inducement needs to be carefully balanced against the wish to provide recompense and/or thanks;
- dissemination of research findings to children in appropriate formats;
- making every effort to ensure that positive change for children is an outcome of the research.

⁵ These rights are not expressly mentioned in the text of the Constitution, but have been interpreted by the Irish Supreme Court as falling within the meaning of personal rights in Article 40.3.

⁶ The age requirement for research other than clinical trials is generally 18 years.

Participation and protection of children in specific contexts and settings

Researchers adopting a participatory approach to research with children should have appropriate training and employ high methodological standards to ensure that the children's right to protection is balanced with their right to participate in the research process. Particular care is required in relation to some groups of children who have distinct needs, as well as all children in specific settings. Researchers should have adequate knowledge of, and acceptable attitudes in relation to, children with specific needs, such as children from minority ethnic backgrounds. Similarly, researchers should be aware of issues that arise in studying children in specific contexts, as in the school or in a care environment.

In the past, children's research has often been problem-focused, i.e. investigating the perceived problems of children or problems caused by children (Carroll and Gutmann, 2011). Arising from this concept, some groups of children have been over-researched. It is important to protect children from being over-investigated and this is now enshrined in international ethical guidelines (see, for example, US Department of Health and Human Services, 2005). Providing safeguards are in place, particularly in relation to obtaining consent and assent, participation in research can be very positive for all children (McLaughlin, 2006).

More specific ethical issues arise in relation to particular groups of children and settings. For example, schools, hospitals, care homes, early-years facilities and youth clubs are settings that can provide relatively easy access to representative samples of children for research projects. Similarly, children who have particular illnesses, or disabilities, and/or come from various ethnic and socio-economic groupings can also provide a sampling frame for research studies. Yet, while investigating children in specific settings can provide increased understanding of such children, additional ethical issues must be considered to ensure that their rights are protected.

Power relationships

Researchers need to be conscious of factors that could lead children to agree to activities that they might otherwise reject. In this way, Morrow and Richards (1996) cite the disparities in power and status between adults and children as the greatest ethical challenge for researchers working with children. An example of this type of research are teacher-led studies, where the teacher has a personal stake in achieving student participation; such research often takes place in a group or whole class setting, and the social consequences of opting out of the research can have an effect on children's decisions. In such situations, the fact that a student is not participating will be known to peers and may cause embarrassment. This type of research, therefore, requires alternative arrangements for those who are not participating in the research.

This disparity in power and status is even more of an issue in social care situations, where children may be accustomed to adults making decisions on their behalf and these power relationships may unduly influence the child's decision to participate in a research study (Meaux and Bell, 2001; NHMRC, 2007; Carroll and Gutmann, 2011). Appointing an individual from outside the organisation to act as an intermediary between the children and the internal researchers will help to ameliorate this problem. Children who are in State-appointed care settings may have experienced negative adult relationships in the past and they may also have experienced the involvement of a wide range of professionals in decisions relating to their lives. This may make it difficult for the researchers to convince the participants of their objectivity and independence from the care institutions and their personnel. Equally, researchers should be clear about boundaries and if a trust relationship is built up over time, great care should be given to how that relationship is ended.

Sensitivity to specific needs

Research should not unjustly single out or overburden any group of children for increased exposure to research risk on the basis of their particular medical condition, disability, ethnic or social circumstance. Minimising distress and disruption for the children and avoiding unwanted intrusion into their privacy require consideration if children are, for example, in residential care or in hospital. Researchers should be sensitive to the diversity and individuality of children, and be scrupulously non-judgmental with regard to the children's care experience and family circumstances. One of the best ways of ensuring an ethical approach to research in these environments is to discuss the specific ethical issues with people who work with the children on a daily basis and, if possible, with representative groups of the children to be studied.

Clinical research will require researchers to pay particular attention to potential risk or discomfort for the children in relation to:

- the duration of the testing period;
- whether the research procedures or interventions are reasonably comparable to past tests or treatments undergone by the children and their knowledge and understanding of the treatments that they might undergo in the future;
- evaluation of the contribution to knowledge about a particular disorder or condition, especially if the study child has the disorder or condition.

Research with children with disabilities should be carried out in line with guidelines produced by the National Disability Authority for research among children with disabilities (Good, 2010). In addition to the issues raised above, extra time and support should be built into the research process to allow for the needs of children with disabilities. Similarly, dissemination of findings will need to be informed by an understanding of the specific communication needs of the children and their families.

Consent and assent in context-specific settings

Settings play a major part in the consent process. For example, parents and pupils can usually only be contacted through the school and researchers depend on the cooperation of schools and teachers to access participants and conduct their research. There are often policies in place in schools, and in other child and youth settings, that affect the seeking of consent. Schools sometimes operate a policy of seeking general parental/guardian consent for a variety of activities (e.g. educational testing, short trips to library), but strict caution is advised in relation to this approach to consent. All schools must ensure that any consent obtained is specific enough to ensure that no one is surprised subsequently to learn how their children's data were used. Larger educational research projects increasingly have advisory committees on which parents (through the National Parents' Councils), as well as school management bodies and teacher unions, are represented and procedures for seeking consent are among the matters dealt with by these committees.

In relation to negotiating assent with children, they should be clear that their assent is voluntary and that refusal to participate, or any criticism they may disclose to the researcher about the care or service received in the particular setting, will not have any adverse impact on the future service they receive.

While parents devolve some degree of decision-making power to the management and/or staff of such bodies as schools, hospitals, youth clubs or crèches, this devolution cannot be considered to be absolute and parents still retain the ultimate say regarding their children's welfare. Factors that may be relevant in addressing the issue of consent include:

- the extent to which the research is an extension of what normally happens in the setting (e.g. in the classroom, the care centre);
- the extent to which anonymity can be guaranteed given the context in which the research is being carried out;
- the nature of the contact, if any, between the researcher and the child;
- number of participants and feasibility of researcher's direct contact with parents and children.

Confidentiality in context-specific settings

For some research projects, basic personal information (name, gender and date of birth) is compiled on potential participants and these data are also subject to ethical and legal conditions. In general, data protection legislation precludes schools and other organisations from releasing personal information about children without parental permission.

Another ethical issue in relation to group settings is the risk of limited confidentiality and social harm based on a child's participation in research which others are witness to. Children might inadvertently make contributions that carry social risks (for example, communicating sensitive information), with the danger of being ridiculed by their peers later. Researchers need to be aware of that risk, especially when choosing research methodologies that allow for unpredictable interaction between participants or when potentially sensitive topics are being investigated.

CONCLUDING POINTS

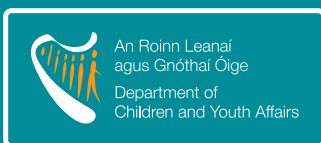
- Research with, and for, children (defined in Ireland as people below the age of 18) is necessary and beneficial, but particular ethical concerns arise in relation to children's involvement in research and these must be addressed.
- Basic ethical principles apply to all research and these include a commitment to the well-being, protection and safety of participants; a duty to respect the rights and wishes of those involved; a responsibility to conduct high-quality scientific research; and a commitment to disseminate and communicate the results to stakeholders.
- In addition to core ethical principles, research with children requires that legal and policy commitments in relation to children, especially national and international child protection policies and guidelines, are adhered to and that a child-centred, inclusive approach to research is adopted.
- Parental/guardian consent is required for a child to participate in research, but good practice also requires the child's agreement or assent.
- Confidentiality is key to research practice, but a limitation exists in child-related research if a child protection issue arises and this restriction in relation to confidentiality must be explained when obtaining consent.
- To ensure child protection, research with children should be carried out in accordance with *Children First: National Guidance for the Protection and Welfare of Children* (DCYA, 2011) and research organisations should have a child protection policy in place, as well as a designated liaison person or member of staff responsible for the implementation of this policy.
- Every effort should be made to actively involve children as participants in the research process and care must be taken to protect the rights of all children, as well as specific groups of children, in research activity.

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Mr. Laurence Bond	Equality Authority
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Dr. Celia Keenaghan	(formerly) Health Service Executive
Ms. Aine Lynch	National Parents' Council
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