

## RCSI Information & Guidelines for Research involving children<sup>1</sup>

### Fundamental ethical concepts arise in research concerning children:

- 1) Maximising potential benefit and **minimising risk of harm**;
- 2) **Informed consent**: where individuals are under the age of 18 years, written consent must be obtained from parents or legal guardians. All consent should be **informed** and **voluntary**. Appropriate Information Leaflets (researcher should adapt PIL from RCSI templates) should accompany the consent forms. Records should be kept of all steps taken with regard to consent.
- 3) **Informed assent**; and information leaflets should be developed for children and adolescents.
- 4) Confidentiality and anonymity.

#### 1) **To minimise the risk of harm researchers need to:**

- Evaluate the potential risk(s) posed for children, interpreting minimal risk in relation to the normal experiences of average healthy children;
- Ensure measures are in place to lessen potential harm arising from the research process, including suspension of the research project if a child's safety is negatively affected.

#### 2) **Informed consent:**

- For consent to be valid it has to be informed: [Click to view the National Consent Policy 2014](#) and the onus is on the researcher to show they have taken the steps necessary to ensure this and participants are supported in developing an adequate understanding of the research. The researcher must show that participation was not influenced by external factors such as incentives or pressures. 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.
- **Informed parental and/or legal guardian consent is required for a child (a person under the age of 18) to participate in research.**
- **Parent information and consent:** Written information provided to parents before they consent to their child taking part, should include:
  1. Information on access to the data collected on children is available here: <http://staff.rcsi.ie/wp-content/uploads/20151110-Data-Protection-in-RCSI.pdf>
  2. Information with respect to the limits of confidentiality (*described below*)
- Evidence of parental consent must be provided for research with children before proceeding with data collection. Parents should be given a copy of the consent form to retain. If parents are separated consent from both parents should be obtained where possible.
- In the case of studies which take place over a prolonged period of time i.e. longitudinal studies, the researcher must re-consent the participants once they reach the age of 18.

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<sup>1</sup> Children are defined in Ireland as any person under the age of 18

### 3) Informed assent:

- The child's agreement to participate (informed assent which is graduated with age from 0 to 17 and therefore is a continuous, on-going process as opposed to just an initial agreement) should also be sought independently.
- Prior to data collection, children should be informed as fully as possible, given their age and competency, about the nature of the study and the methods to be used.
- Information for children should be written in clear and simple language. It should be read to children by the researcher. Children should also receive a written copy to keep.
- A child's right to refuse to take part should be respected. This applies even if parents and/or legal guardians have given consent. It should be explained to children that they may choose to discontinue the session if they are not comfortable with their participation. (Child friendly/age appropriate PIL adapted by researcher from RCSI template).
- Whether children aged 16-18 should be asked to provide written consent is unclear. Under the EU directive, the age of consent for clinical trials is 16, but for human related research it is 18. In all cases, it is advisable to obtain written assent from children aged 16 and 17. However where sensitive personal data is processed, you will always need explicit written consent provided by parent or legal guardian-[http://www.dcy.gov.ie/documents/Publications/Ethics\\_Guidance.pdf](http://www.dcy.gov.ie/documents/Publications/Ethics_Guidance.pdf).
- Regarding the collection of personal data of RCSI students, the student signs an agreement from Admissions, which all new students are required to sign. Where students are under 18 their parents/legal guardian will also sign the agreement. This ensures that the students (both over and under the age of 18) have given adequate consent.

### 4) Confidentiality and anonymity:

- Researchers should give consideration when they tell a parent or a child that participation in the research will take place on a confidential basis. The National Guidelines on Child Protection ([http://www.dcy.gov.ie/viewdoc.asp?fn=/documents/Publications/Children\\_First\\_A4.pdf](http://www.dcy.gov.ie/viewdoc.asp?fn=/documents/Publications/Children_First_A4.pdf)) suggest that complete confidentiality should **not** be given, either to parents or to children themselves, since children might disclose, during the course of the research, they are at risk or others might be at risk.
- When preparing consent forms for parents and children it is important that students/researchers:
  - a) Discuss the limits of confidentiality with the supervisor and come to an agreement about appropriate wording for the study information sheet for parents and children. It should be made clear, for example, that if students have concerns the safety of any child is at risk, they will discuss these concerns with the supervisor (see below for guidelines on reporting suspected abuse).
  - b) Ensure a written record is kept of the steps that have been taken to make parents and children aware of the limits of confidentiality. (i.e. if a child is at risk confidentiality is waived)

## **Child Abuse, Neglect and Mandatory reporting**

- The National Guidelines for the Protection and Welfare of Children (2011) <http://www.dcy.gov.ie/documents/Publications/ChildrenFirst.pdf> encourages adults to recognise a shared responsibility for the protection of children. This document provides guidelines on recognising abuse and neglect, and on reporting any concerns that may arise (p.31-33). The Children First Bill, 2014, which puts elements of the "Children First: National Guidance for the Protection and Welfare of Children" (2011) on a statutory footing was published by the Houses of the Oireachtas on 14 April 2014 ([Children First Bill 2014](#)).
- It is considered good practice to explain to children that if they inform the researcher of anything that could make them worry about their safety then they would have to inform somebody about this, but would not do so without informing them first.
- A clinically qualified person (or designated child protection officer should be available for consultation in research involving children) may need to be involved in the project for issues concerning suspected abuse/neglect.
- Research should be conducted in a suitable setting in terms of safety. For example, in schools, it is important to ask for the use of a room that is close to a central office, in which an adult with responsibility for the children can easily see the researcher and the child.
- Researchers should not spend time alone with a child, even if an adult in authority asks them to do so. Neither is it appropriate for researchers to leave the premises with a child in the absence of a carer or legal guardian, (this would not apply to all settings i.e. in a clinical setting where it would be common for a nurse or doctor to be alone with a child).
- A procedure is outlined below for how to deal with any concerns about children's safety or well-being that may arise in the course of research, either through the researchers own observations, or through a disclosure made by the child:
  1. If a researcher becomes concerned about the safety of a child, detailed information should be gathered about the concerns in question and discussed fully with the supervisor, including information about the possible implications for the child and family if concerns are reported to the HSE. There is legal protection for individuals making such reports in good faith.
  2. If it is agreed that child abuse or neglect is suspected or alleged, then the following steps should be taken:
    - a) A report should be made by the supervisor to the HSE by phone or in writing. *Children First* contains a suggested template for a Standard Reporting Form, which can be used by the researcher (or supervisor) to record details of the report. <http://www.dcy.gov.ie/documents/Publications/ChildrenFirst.pdf> (Appendix 3: STANDARD REPORT FORM for reporting child protection and/or welfare concerns to the HSE).
    - b) This should be forwarded to the HSE. In the event of an emergency, or the non-availability of HSE staff, the report should be made to An Garda Siochana.
    - c) The GP should be informed

## **Management and Storage of Data**

- It is important to make clear and documented plans for data collection. Records should be kept of arrangements made with 'gatekeepers' such as parents, teachers and schools.
- The *Data Protection Act (1988 & 2003)* applies to all personal data, whether in electronic or paper form. It gives everyone the right to establish whether personal data are being retained, to have access to any data that relate to them personally, and to have any inaccurate data erased and/or corrected. Data must only be kept for lawful purposes and 'not used or disclosed in any way that is not compatible with those purposes' (Department of Health & Children, 1999, p. 27). The Act applies to both adults and children.
- All data collected should be securely stored and encrypted; all data including audio and video tapes should be coded.
- Identifiable information should not be disclosed without the explicit consent of the participants (except in the case of a concern falling under the scope of the child protection legislation).
- Data should be collected with consent (detailed above) and the researcher should explain who will have access to the data and why.
- Anonymity implies participants would not be identifiable. Confidentiality implies strictly controlled access to data and strict precautions to prevent publication of identifiable information on any participant.
- Data should be retained in line with current RCSI guidelines (i.e. 5-7 years. A new retention policy is to be implemented from July 2015-SJH).
- A document outlining the security controls around the storage, processing and transfer of research data concerning children should be available when requested (IT to provide this policy).
- For policy on access requests please go to: <http://staff.rcsi.ie/wp-content/uploads/20151110-Data-Protection-in-RCSI.pdf>

### **Freedom of Information: Research requests involving children:**

- Requests may be received to release data under the *Freedom of Information Act (2014)*, which gives individuals the right to:
  - Access official records held by public bodies as defined by the Act
  - Have personal information corrected where such information is incomplete, incorrect or misleading.
  - Be given reasons for decisions taken by public bodies that affect them.
  
- Steps that should be taken following an FOI request concerning research with children are:
  - An FOI request received should be referred to the FOI Officer who will ensure that it is handled appropriately in accordance with the guidelines.
  - The relevant ‘Decision Makers’ must decide on the release of information in response to an FOI request.
  - Requests for the release of data about any individual child should be discussed with the supervisor who should be familiar with the circumstances.
  - If there are any concerns that the release of the information would have negative consequences (e.g., where children believed they had given the information in confidence and would not wish it be released, or where the data may be used in ways that place the child at risk in any way), the matter should be brought to the attention of the Decision Maker. The FOI Officer will advise the Decision Maker on how to reply to an FOI request and will inform the Decision Maker of the different provisions, exclusions or restrictions in the Act, which may be employed to withhold information in order to prevent any harm that would be occasioned by release.

### **Good practice / requirements for researchers intending to work with Children include**

#### **1) Child Protection commitments:**

- A risk assessment should be developed before starting the research;
- Garda-vetting and employment checks must be carried out on study personnel; Garda Vetting can take several months to process.
- All researchers must have adequate skills, training and access to relevant expertise in relation to child protection issues;
- A trusted adult or third party must be present throughout the proposed research. This is an explicit and fundamental principle of child protection where an adult is never alone with a child or children, and 2 adults must always be present. Parents should be made aware of this third party involvement prior to the commencement of the research within the information leaflet. (i.e. why they are required, details of who the individual will be and evidence of their confidentiality agreements)
- Protect children, including reporting as per Children First national guidance where appropriate;
- Allow internal investigation into any allegation which occurs (which must not interfere with any statutory inquiry);
- Provide appropriate support for the researcher during the investigation process.
- Legal obligations and policy commitments in relation to children;
- A child-centred, inclusive approach to research.

## **2) Legal requirements and policy commitments:**

- 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.
- 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 legal guardian consent is required for clinical trials involving minors, who are defined in this case as persons under the age of 16 years.
- Research 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).

### **Successful participation of children in research is associated with:**

- Their understanding of the process and making informed decisions to become involved and the ability to do this develops over time.
- Capacity and consent comprising primarily of “box-ticking” does not equal informed consent. Taking time over the discussion around consent versus consent and the different forms of research being conducted involving participants under the age of 18 years, can prevent difficulties at a later stage.
- The opportunity, where feasible, to become actively involved in different stages of the research.

### **Researchers must provide assistance to ensure successful participation. Including:**

- Appropriate methodology; (including the rationale why children, and not over 18s, are required)
- 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 information and research findings to children in appropriate formats;
- Making every effort to ensure that positive change for children is an outcome of the research.

### **Summary:**

- In addition to ethical principles, research with children requires that legal and policy commitments, especially national and international child protection policies and guidelines, are adhered to and that a child-centred, inclusive approach to research is adopted.
- Parental/legal guardian consent is required for a child to participate in research, but good practice also requires the child’s agreement or assent.
- Confidentiality is a key element 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 to parent and child when obtaining consent.

### **Reference material:**

- 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) <http://www.dcy.gov.ie/documents/Publications/ChildrenFirst.pdf>
- “Guidance for developing ethical research projects involving children”: [http://www.dcy.gov.ie/documents/Publications/Ethics\\_Guidance.pdf](http://www.dcy.gov.ie/documents/Publications/Ethics_Guidance.pdf)
- [The National Consent Policy 2014](#)

### Questions from the RCSI REC to the researcher wishing to work with individuals under 18:

- 1) Why is it necessary to do the work with children and not adults (over 18)?
- 2) Please provide evidence that the minimum risks to participants have been established.
- 3) Have the researchers been Garda vetted through the institution in which they wish to conduct their research? (Assuming they are employed by the institution and funding is in place).
- 4) Please provide the REC with a copy of your Garda vetting.
- 5) Have all individuals conducting research with children signed a statutory declaration (**see appendix**) and submitted it to the Head of School for counter-signing? This declaration contains a statement that students and staff have no previous record of offences against children (including barring orders, safety orders, and adult behaviour warnings, are not involved in any court proceedings involving allegations of assault or threatening/abusive conduct and have not been excluded from working with children in the past).
- 6) Do the researchers have the appropriate training to carry out the proposed research with minors (evidence should be provided i.e. evidence of courses taken where this criteria can be met and verified).
- 7) Are the appropriate procedures in place should an adverse event occur?
- 8) Is the appropriate follow up care (where relevant) in place?
- 9) Do the researchers have the relevant documentation for both children and parents/legal guardians such as age appropriate assent, consent and information leaflets?
- 10) Do the benefits for this research clearly outweigh the risks?
- 11) Have both parents and children's perspectives been adequately taken into account?
- 12) Has the lead researcher/PI reviewed the methodology and practices to ensure that any researchers working on the project are subject to review and have assistance available on an ongoing basis to ensure their own health and safety and to ensure child protection and safety at all times?
- 13) Does the methodology provide for review of child protection throughout the course of the research?
- 14) Does the researcher have access to relevant support for themselves throughout the research and at its conclusion? (A person should provide a "debrief" at the end of the study to ensure RCSI, as much as possible, that their involvement in research doesn't give rise to child protection issue elsewhere at a later time).

## APPENDIX I

### Statutory Declaration

The RCSI policy that the REC is implementing is that all members of staff and students who conduct research which involves direct contact with children are required to sign the attached Statutory Declaration Form. The form should be signed in the presence of a Commissioner for Oaths. The Commissioner for Oaths should ask to see identification.

**The form should be submitted to the RCSI REC prior to commencing such research.**

Please be advised that under the Statutory Declarations Act 1938 as amended by the Standards in Public Office Act 2001, any person who makes a Statutory Declaration which to his or her knowledge is false or misleading in any material respect shall be guilty of an offence and shall be liable on summary conviction to a fine not exceeding €2,539.48 or, at the discretion of the Court, to imprisonment for a term not exceeding 6 months or to both such fine and imprisonment.

The signing of a false or misleading Statutory Declaration will be noted on the person's academic record and the College reserves the right to take any action it deems necessary on foot of a false or misleading Declaration being signed.

### Confidential

#### **DECLARATION FROM ALL STAFF AND STUDENTS WORKING WITH CHILDREN AND YOUNG PEOPLE (adopted from Our Duty to Care, Northern Ireland)**

Surname:

Forename:

Date of Birth

Place of Birth

Any other name previously known:

Have you ever been convicted of an criminal offence or been the subject of a Caution or of a Bound Over Order

Yes

No

If yes, please state below the nature and date(s) of the offence(s).

Nature of offence – Date of offence