# Ethics Review Sub-Committee



## **GUIDANCE NOTES FOR INVESTIGATORS**

## **Working with Children and Young People**

It is the responsibility of investigators to ensure that (i) they are aware of any legislation which could affect their research with children and/or young people and (ii) that all of those involved in their research are aware of these guidelines.

These guidelines are intended to apply to any research directly involving participants under the age of 18, whether undertaken independently or in conjunction with a parent, guardian or other responsible adult. Compliance with this guidance should help to:

- · protect the rights of children and young people.
- reassure parents, guardians and other responsible adults that the University encourages staff to
  observe best practice and that research is designed to protect the interests of the children involved.
- protect investigators and enable them to meet their legal and ethical requirements.

## 1. Making Initial Contact

Investigators should not normally contact children or parents directly. Wherever possible, contact should be made via a third party (e.g. head-teacher or sports club).

## 2. Providing Details of the Investigation

- 2.1 Investigators should ensure that both children/young people and their parents/guardians are fully briefed as to what is involved in the research, including details of how and when data collected during the study will be used. Investigators should ensure that all instructions are **clear and easy to understand** and that an opportunity to ask questions is provided.
- 2.2 It is particularly important to ensure that children have fully understood what is expected of them. Investigators should ensure that they use **language appropriate to the age group** of their participants and issue **clear**, **easy-to-understand** instructions. Supporting documents should be presented in an accessible format, see the Nuffield Council on Bioethics report <u>Involving children and young people in health research getting it right</u> (access the Magazine version for examples of formatting).
- 2.3 If **very young children** are participating in a study, investigators should consider whether or not written information is appropriate at all. It may be better to **use pictures** or meet with the children to discuss what is expected of them and demonstrate the techniques to be used.

Please also refer to the sections on Chaperoning and DBS Disclosure below.

## 3. Obtaining Consent and Participants' Right to Withdraw

- 3.1 Consent from a parent, guardian or responsible adult should be obtained for all studies (including observations and demonstrations of procedures and techniques) involving people under the age of 18.
- 3.2 In some **low risk** studies parents can be given the opportunity to **opt-out** their child by completing a form confirming that they do not want their child to participate. If the parent does not opt-out then their agreement is assumed and the child can be asked for their assent. This approach would need to be agreed by the Ethics Review Sub-Committee and will only be approved in exceptional circumstances.



You **cannot** use opt-out consent if you are processing personal data under the legal basis of consent. It can only be used for studies which are carried out under the public task basis or do not involve the collection of any personal data. See **Guidance Note on Compliance with Data Protection Requirements**.

- 3.3 Where research is conducted with the agreement of the school, investigators should also obtain consent from parents, guardians, or other responsible adults.
- 3.4 Children who are **under 16** should be given the opportunity to indicate their **willingness to participate** in a study. It is recommended that researchers ask children/young people to sign an **Assent form** indicating their willingness to participate. This will not be taken as evidence of consent, as legally, this must come from a responsible adult, but is regarded as **good practice** in studies involving children/young people. Children who are 16 or over must be capable of giving consent so they can sign a **Consent Form**, but parental consent is also required for those under 18 years of age.
- 3.5 Parents, guardians and/or other responsible adults should be given sufficient and appropriate written information to allow them to provide informed consent. Precise details of the investigation should be provided wherever possible in a **Parents Information Sheet.** If providing such information could interfere with the validity of the study, advice should be sought from the Ethics Review Sub-Committee.
- 3.6 Consent to observe/record participants should be sought from parents, guardians and/or other responsible adults at the recruitment stage. Further informed consent should be sought for the subsequent release or use of recorded material, including archiving of data if this was not provided in the original statement of consent. Explicit consent for the publication of photographs/videos should be obtained.
- 3.7 Children and their parents, guardians or other responsible adults should be made aware that they are not obliged to take part in, or complete, the study against their will. All parties should understand that they are **free to withdraw** at any point during the study without giving a reason for doing so.

## 4. Chaperoning of Participants

- 4.1 Chaperoning arrangements should seek to ensure that an investigator or other chaperone of the same sex as the participant is always present. Where sensitive issues, such as the physical assessment of maturity will form part of the study, procedures should be explained by an investigator of the same sex as the participant.
- 4.2 Wherever possible, investigators should avoid situations where they will be alone with a child participant. In all cases where investigators will have unsupervised access to children, they must follow the University's Disclosure and Barring Service (DBS) Procedures (see 5. below).

## 5. Disclosure and Barring Service (DBS) Disclosure

- 5.1 The University has produced <u>guidelines</u> to identify situations in which it is necessary to check an individual's criminal record through the DBS procedures. In terms of research involving children/young people, it is likely that the following scenarios will require a DBS disclosure to be undertaken:
  - Investigators with unsupervised access to child participants (i.e. if an investigator is likely to be alone in a room with one or more children/young people).
  - · Taking physical measurements from child participants.
  - Requirement for child participants to remove any clothing.
  - · Recording child participants on video.
  - Testing of new equipment.
  - If requested by the sponsor of the research.



5.2 Investigators who think they may need to follow disclosure procedures should contact Human Resources (for staff) or the Academic Registry (for students) in the first instance. **Investigators are warned that** seeking DBS clearance is a lengthy process which needs to be initiated well in advance of the commencement of a research project.

#### 6. Subject Matter

6.1 When working with children and young people, extreme care should be exercised to ensure that subject matters/procedures which may be upsetting or frightening are avoided wherever possible. Research must not appear to encourage illegal behaviour such as under-age drinking or smoking. If the research involves testing a product/service, special care should be taken to check:

- The product is safe to consume or handle.
- The participant does not suffer from any relevant allergy.
- That ethnicity, religion or culture is not compromised by asking the participant to test the product.
- That the participant is not asked to test a product/service which they are not legally old enough to use.

6.2 When devising questionnaires, care should be taken to ensure that the language used, and the nature of the subject matter, are appropriate for the age of the participants.

#### 7. British Educational Research Association

The British Educational Research Association has adopted a set of <u>ethical guidelines</u> for educational researchers which will be relevant for any investigators conducting research in schools.

#### 8. Further Information

The above is not intended to be an exhaustive list of considerations when planning research involving children or young people. However, it is hoped that these guidelines will encourage researchers to adopt best practice and familiarise themselves with the relevant legislation.

Please refer to the University's Safeguarding Policy.

The following websites may also be of interest:

- Protection of Children Act 1999
- <u>Nuffield Council on Bioethics</u> Report on Involving children and young people in health research getting it right (2015), including a magazine formatted to be accessible.
- The Royal College of Paediatrics and Child Health
- British Psychological Society
- HRA Research Governance Framework
- Disclosure and Barring Service (DBS)
- Market Research Society Code of Conduct
- ICO Guide to the General Data Protection Regulation



#### **Examples of Young Persons Information Sheets**





