Guidance for Research involving Children

Introduction

Ethical research is underpinned by the principles of respect for persons, justice, beneficence and non-maleficence. However, children require additional protections due to their increased vulnerability.

For the purpose of this guidance, children and young adults refers to all persons under the age of 18.

Additional ethical principles that relate to research with children include:

- Children should only be included in research if the knowledge cannot be obtained by research in adults.
- The purpose of the research should be to obtain knowledge relevant to the needs of children.
- A child's refusal to participate, or continue to participate, in research should always be respected. If a child becomes upset by a procedure, this should be accepted as valid refusal.
- Parents/guardians should be involved in the decision to participate wherever possible, and in all cases where the child is not yet competent.
- Any inducement that might result in the child volunteering, or being volunteered by their parents/guardian in the expectation of direct benefit (e.g. financial) should be avoided.
- Researchers should take into account the cumulative consequences (e.g. medical, emotional, social) of the child participating in research to avoid the over-burdening of certain groups.

The following guidelines outline some of the areas researchers may wish to consider when conducting research involving children. These guidelines should be read alongside the Schools standard operating procedures (SOPs).

1. Consent

The information below should be considered in conjunction with standard operating procedure 005 on Informed consent for research, which includes guidance notes for content of a participant information sheet, and template consent and assent forms.

For children and young adults, the consent of the parents and guardians must be obtained in line with local laws, custom and practice.

1.1 Research in the UK and EU Countries

For studies that are **not** classed as clinical trials of medicinal products, common law applies. This means that the age of majority is 18, although between the ages of 16 and 18, they are presumed to be competent to give consent. No Statute governs the rights of those under the age of 16 to give consent for research. However, the Gillick Principles state that 'whether or not a child is capable of giving the necessary consent will depend on the child's maturity and understanding and the nature of the consent required. The child must be capable of making a reasonable assessment of the advantages and disadvantages of the treatment proposed, so the consent, if given, can be properly and fairly described as true consent'. In the absence of case law dealing specifically with research, the Gillick principles might reasonably be applied, although threshold for understanding the complexities of research may vary.

If the study is a clinical trial of an investigational medicinal product being conducted in the UK, under the Clinical Trials regulations[1], the law states that regardless of ethical considerations, the parents or guardians' consent **must** be sought for any child under the age of 16.

1.2 Research in non-EU countries

For research being conducted in non-EU countries, local requirements for consenting child and young adults will depend on national regulations.

1.3 Informed consent – Clinical research

When recruiting a child/young adult under the age of 18 to a clinical study/research project, consent is required from the parent, legal guardian or, if not available, from a legal representative of the participant.

A full explanation of the study must be given to the parent/legal guardian of the child/young adult. That person may then provide consent for the child/young adult to participate.

1.4 Informed consent – Other research

When recruiting a child/young adult to a non-clinical study/research project the researcher may be required to seek consent from other gatekeepers, such as the head-teacher of the school in which the research is to be conducted, in addition to parent/legal guardian's consent.

When recruiting children/young adults from an organisation (such as a school) the researcher's may want to consider whether active or passive parental/guardian consent/assent would be appropriate.

Active consent refers to the use of a consent form, whereby parents/guardians are required to sign and return the form indicating their consent for their child to participate in the study. Passive assent

requires the parents/guardians to respond to the researcher (usually via a slip) to indicate that they do not want their child to take part in the research. The non-response of the parent/guardian is taken as assent for the child to participate[2].

Whichever method is most appropriate will depend on the individual research project. When deciding, researchers should consider the following[3]:

- The age of the participants: If the project involves young children who are unlikely to be able to assent on their own behalf, active consent may be more appropriate.
- The nature of the research: If the research involves sensitive topics, an active approach to consent may be appropriate, whereby the parent/guardian is provided with an information sheet and required to sign a consent form.
- The location of the research: If the project is being conducted in a community setting and consent has already been sought from the gatekeepers, passive assent may be deemed appropriate. If the children will be recruited from home, active consent may be unavoidable.

In some situations it may be appropriate to seek the consent only from the young adult, for example if the young adult has independently accessed the service being researched, or in cases where obtaining consent from the parent/guardian may pose a risk to the young adult. In these cases the researcher will have to justify obtaining consent from the young adult only, and obtain a waiver of parental consent from the ethics committee.

If a young adult aged 16 or over is deemed not to be competent to give consent, researchers must proceed in line with the Mental Capacity Act (England and Wales), or common law (Northern Ireland).

1.5 Assent

Informed Consent by a parent or legal representative should represent the child or young adults presumed will. However, if the child/young adult is deemed competent to understand the research being explained to them, it is best practice to obtain the assent of the child/young adult in addition to the consent of parent/guardian. In such circumstances, a signature should be obtained from the parent/guardian on the consent form and a signature should be obtained from the child/young adult on a separate assent form.

The child/young adult should be given information about the study according to his/her level of understanding (from staff that have experience in dealing with children) and the person seeking assent should respect the child/young adult's wishes.

The Participant Information Sheet should be written in a language that the child/young adult can understand i.e. there should be different versions for different age groups, e.g. under 5's, 6 to 12 years, 13 to 15 years and over 16. There should also be a version produced for the parent/guardian/legal representative.

For children with disabilities specific adaptations may be required. For example, children with visual impairments may need the information to be read out loud, or be provided with information sheets written in braille. Other communication supports could include the use of eye boards, or sign language[4]. Researchers should consider which supports might be needed to support the child during the assent process.

A child/young adults refusal to participate, or continue to participate, in research should be respected.

1.6 Change in participant status

Once a child reaches the age of legal competence parental consent is no longer legally operative, so consent should be obtained from the now adult participant for their continuation in the study.

For long-term studies, consideration should be given to whether assent will need to be renegotiated or confirmed at different stages of the research. For example, children who were too young to assent at the time they were enrolled may reach a stage where they are able to provide assent.

In these cases it is advisable for researchers to consider whether the child's assent should be obtained or confirmed at different stages of the research. For example it could be proposed that assent be confirmed every 2 or 3 years to take into account changes in levels of maturity, or at particular developmental levels. Whichever approach is taken, this should be agreed with the ethics committee in advance.

If the remaining study procedures are limited to the analysis of the data, re-consenting the participant is unlikely to be required. However if the study still involves any activities for which the consent of the parent would have been required, such as study visits, collection of biological samples, or collection of data from medical records, the now adult participant should be re-consented.

If the ethics committee has waived the need for assent, it is still best practice to provide information to the child in a manner that they will understand, and to refresh this information as needed, even if obtaining assent is not required.

In cases where it is expected that children will reach the legal age of competence during the study, plans should be in place for re-obtaining consent from the participant once they reach that age.

For clinical trials in Europe, Article 32 of the clinical trial regulations states that:

"If during a clinical trial the minor reaches the age of legal competence to give informed consent as defined in the law of the Member State concerned, his or her express informed consent shall be obtained before that subject can continue to participate in the clinical trial."

So in these cases if a child participant reaches the age of legal competence their consent must be obtained for their continuation in the trial.

2. Risk and Benefit

The ethical requirements with regard to risks and burdens apply to all research irrespective of the age of the participants. The ethical principles of non-maleficence and beneficence emphasis the important of minimising the risks and maximising the benefits of any research involving human participants.

When planning a research project it is important to consider the types of risk to which participants may be exposed. Types of risk include:

- Physical risk: The risk of harm through bodily contact or administration of any substance, device or other intervention.

- Risk of psychological or emotional harm: The risk of harm due to feeling embarrassed, anxious or upset.
- Social risk: The risk of harm due to loss of privacy, status, or reputation and can include legal, financial, or employment risks[5].

For research involving children there are additional requirements when considering risks and benefits. Studies that may potentially benefit the child taking part could be considered ethical should they offer potential benefits that outweigh the possible risks of the study. However, if there is no likelihood of benefit to the child in question most ethical guidelines, including the Declaration of Helsinki, permit only research entailing "minimal risk and minimal burden" [6].

Healthy child/young adult volunteers can ethically participate in research provided that appropriate consent has been obtained, there is no more than minimal risk and the research is not against the child/young adult's interests.

There are different views on how to assess risk. The Royal College of Paediatrics and Child Health (RCPCH): Ethics Advisory Committee have given the following estimates for what they would consider minimal, low and high risk research procedures[7, 8].

- **Minimal risk**: describes procedures such as questioning, observing and measuring children, provided that procedures are carried out in a sensitive way, respecting the child's autonomy, and that consent has been given. Clinical procedures with minimal risk include obtaining bodily fluids without invasive intervention e.g. taking saliva or urine samples or using blood from a sample that has been taken during treatment. It is expected that research of minimal risk would not result in more than a very slight and temporary negative impact on the health of the child concerned.
- **Low risk**: describes procedures that might cause no more than brief pain or tenderness, small bruises or scars, or very slight, temporary distress e.g. taking a blood sample.
- **High risk**: procedures such as lung or liver biopsy, arterial or lumbar puncture, and cardiac catheterisation are not justified for research purposes alone with children. They should only be carried out when research is combined with diagnosis or treatment intended to benefit the child concerned.

It is important to remember that the above is only an estimate, and depending on the nature of the research, or the child concerned, a procedure that would normally be considered minimal risk could become low, or more than low risk. For example, interviews would normally be considered minimal risk, however if the topic discussed is sensitive there is a risk that the child may become upset or distressed. This could result in the risk of the interview being considered low rather than minimal.

A second example is blood sampling. Blood sampling would normally be considered minimal risk if the blood is taken by a skilled person and the person giving the sample is not blood or needle phobic. However many children are afraid of needles and/or blood and the distress that results from having blood drawn results in more than minimal risk. The Royal College of Paediatrics and Child Health believe it is inappropriate to insist on the taking of blood for non-therapeutic reasons if the child indicates distress either before the start or during the procedure. The child's feelings should not be sacrificed[7].

The assessment of risk should be carried out by all parties involved in the research, including the child/young adult where possible, the parents/guardians, the researchers, the ethics committee, and in the case of clinical research, the clinicians concerned.

When considering the types of risk that participants may be exposed to the researchers should consider the following:

- The vulnerability of the participants
- The sensitivity of the research topic
- The risk/burden the collection of data is likely to put on the participants

When reviewing applications the ethics committee will assess the potential risks, burdens and benefits of the proposed research. Below are some examples of things the committee will consider during their assessment[8]:

Benefits	Risks/Burdens
• **Is the research intended to benefit the child and/or other children?** • **How will the knowledge gained be used?** • **How likely is the research to achieve its aims?**	• **How invasive/intrusive is the research?** • **How severe are the potential harms and how likely are they to occur?** • **Are children being recruited just because they are available?**

3. Minimising Risk

3.1 Clinical trials

In the specific context of clinical trials involving investigational products (e.g. vaccines), there are strict legislative requirements designed to minimise risk and protect participants. In addition to these safety measures there are regulations related to 'Good Clinical Practice' (GCP). GCP is an international ethical and scientific quality standard for designing, conducting, recording, and reporting clinical trials, the principles of which are there to ensure that the rights, safety, and wellbeing of participants is protected.

LSHTM strongly recommends all staff involved in the conduct of clinical research are aware of GCP to ensure they are best prepared to carry out their duties in accordance with Good Clinical Practice Guidelines.

For more information on GCP, including a link to the online training, and to find the Schools SOPs on writing a research protocol to GCP guidelines, please visit the Research Governance and Integrity SharePoint pages.

3.2 Clinical research

In clinical research, there are a number of procedures that can be particularly troubling for children and it is important that steps be taken to reassure the child and that any pain or discomfort be managed[9].

Anxiety about a procedure can result from a lack of information or understanding. The child should be given information about the study according to his/her level of understanding and this should be delivered by staff that have experience dealing with children. It is important that researchers pilot/test the information to be used to ensure that it is appropriate for the target audience. If a

wide range of ages are being included, different versions for different age groups, e.g. under 5's, 6 to 12 years, 13 to 15 years, and over 16 should be provided.

Researchers should consider the sampling techniques they plan to use to ensure that the number of invasive procedures are kept to a minimum. For example, researchers could consider[10, 11]:

- Taking samples for research at the same time as therapeutic samples.
- Making use of left over samples from normal care rather than collect new samples
- Using laboratory techniques that require the smallest volume of the sample as possible.
- Using techniques that require samples that are less invasive to collect e.g. urine.

Any pain or discomfort that the child might experience should be managed appropriately. For blood sampling this may mean the use of an anaesthetic cream.

3.3 Other research

For social research, the main risks to participants are likely to be in the form of emotional or psychological harm. For example, research may reawaken old feelings or memories, may uncover hidden feelings, or may even create additional concerns, such as anxiety about what the participant has shared[12].

Misunderstanding questions or instructions could be a potential cause of anxiety or confusion. It is important that researchers pilot/test the instrument being used to ensure that it will be understood by the target audience. It is recommended that piloting be carried out for not only assent information, but also any debrief information, questionnaires and experimental instructions[3].

Ensuring that the information is understandable to the target audience should also help to limit any false expectations that the children may have with regard to the research. Therapeutic misconception is a term used to describe where participants believe that treatments they are receiving are designed with their therapeutic best interests in mind (that is, they are receiving individual help), rather than in line with a research protocol that benefits the broader good. This should be avoided, for example, by including an explicit statement on the consent/assent form to make clear that there may not be any immediate individual benefit from participation[12].

Researchers should ensure that the data collection tools to be used are appropriate. For interviews and questionnaires, the type, number and order of questions should be carefully considered so that they don't over-burden. For example, interviews should be structured so that the more sensitive material is in the middle so that the child can move back to 'normal' conversation before the interview ends[12, 14]. Children should always be informed that they do not have to answer any questions that they do not want to.

Data collection should be designed to prevent over-burdening. For example, researchers may consider scheduling rest breaks during interviews, or leaving gaps between data collection when multiple interviews or questionnaires are required.

If the subject of the research is sensitive, researchers should provide information about support services that can be accessed by the child/young adult if needed. Researchers should also consider not scheduling interviews for Friday afternoon if the support services available will be closed over the weekend[12].

Depending on nature of research, researchers should consider debriefing the child at the end so that any additional needs can be identified. For interviews, researchers should consider a scripted

interview finish that differs depending on what the child has disclosed and explain to the child what will happen as a result (e.g., whether social services will be contacted)[13].

Researchers involved in both clinical and social research should take into account the cumulative consequences (e.g. medical, emotional, social) of the child participating in research to avoid the over-burdening of certain groups.

4. Safeguarding

Related to the issue of risk are the issues of child protection and how to safeguard children during research. For the purpose of this guidance the definition from Working Together to Safeguard Children, 2015, will be used, and defines safeguarding as[15]:

- Protecting children from maltreatment.
- Preventing impairment of children's health or development.
- Ensuring that children grow up in circumstances consistent with the provision of safe and effective care.
- Taking action to enable all children to have the best outcomes.

Issues relating to the safety and wellbeing of children may be observed, or disclosed to a researcher during the research process, therefore it is important that researchers have a procedure in place for the safeguarding of children before the research commences.

An important aspect of safeguarding children is the ability to identify issues defined as child protection issues and to respond to those issues appropriately. Therefore, in order to fulfil their responsibilities to children researchers need to be aware of the types of abuse and the possible indicators of abuse. Abuse can be physical, emotional or sexual and includes neglect which is the persistent failure to meet a child's basic physical and/psychological needs. Below is a table of possible indicators of abuse, adapted from 'Safeguarding Children in Research Contexts' by Sheffield Hallam University[16].

Physical indicators	Behavioural indicators
• Injuries which are unexplained or where the explanation is not consistent with the injury. • Multiple/excess bruising • Frequent minor/significant bruises or injuries • Wariness of adults • Inappropriate/dirty/unkempt/unchanged clothing • Poor hygiene • May be late/absent/frequently not picked up on time. • Tired/lethargic • Poor/limited language development	• May have difficulty forming friendships • Inappropriate or emotional responses • Clingy to teachers/or conversely unwilling to engage • High criticism offered about the child from an adult directly to the child or to others • Absence of affection between the child and their carer • Parent/carer is under the influence of drugs/alcohol

It is important to remember that these are only possible indicators of abuse and that there may be other explanations for many of these that researchers may not be aware of. Researchers should use their judgement and any relevant policies/procedures when deciding whether to refer a child.

4.1 Responding to suspicions of abuse

In the UK, it is a legal requirement for all organisations regarding children and young people to have a safeguarding policy. When working with such organisations it is strongly recommended that researchers familiarise themselves with this policy and the process for reporting child protection issues[3].

If children will be recruited outside of a child/youth based organisation, for example from home, then it is recommended that the researcher liaise with the local authority and familiarise themselves with the local safeguarding policies and procedures.

When conducting research overseas there may be cultural and legal differences in the way safeguarding is handled. There may be no effective child protection systems in place and the authorities may have different views on child protection. For example, in a country where the physical punishment of children is not prohibited by law, researchers may have few avenues to report abuse if they come across it. Researchers will need to think of how best to handle this scenario before the research commences. It is recommended that researchers seek the advice of local organisations as well as international agencies such as UNICEF or Save the Children before data collection begins[17].

It is important to note that the researcher's role is not to investigate or to determine if abuse has taken place. These tasks should be undertaken by child protection professionals. The researcher's responsibility is to report any suspicions of abuse as soon as possible through the appropriate channels.

Researchers should ensure they are familiar with the LSHTM Safeguarding and Security Screening Policy. This policy includes information on dealing with reported suspicions or allegations.

4.2 Other points to consider

- Background checks should be carried out when recruiting individuals who will have access to children (such as Data and Barring Service checks in the UK) or, where this is not possible, alternative measures should be put in place to screen out individuals who may be seeking a research position to increase their contact with children for malicious reasons. This could include securing and following up written references[14].
- If the research involves spending one to one time with children, researchers may want consider organising this so that the researcher and child can still be seen but not heard by another appropriate adult.
- Researchers may want to consider the gender of the researcher in relation to the child, particularly if the research topic is sensitive. For example, having male interviewers interview male children, and female interviewers interview male (if they are comfortable) and female children[13].

5. Confidentiality

It is the School's view that unless stated otherwise in the terms of an informed consent form, all Personal Data, i.e. identifiable, should be kept confidential, and should not be shared, unless with the express permission of the participant, or in a fully anonymised fashion and/or with the approval of the School's Ethics Committee. However whilst maintaining confidentiality is a priority, some of the key issues for research involving children and young adult are around safeguarding and child protection.

Because of these issues, it is recommended that researchers do not guarantee anonymity and confidentiality when conducting research with children and young adults. It is vital that this is communicated to the child/young adult during the informed consent process and that the limits to confidentiality are explained in a way that will allow the child/young adult to make an informed decision about the information they choose to share. In situations where confidentiality may need to be breached, this should be discussed, wherever possible, with the child/young adult before disclosure.

For more information on confidentiality and anonymisation of research data please see LSHTM SOP-036 on Confidentiality and Anonymisation of Research Data

6. Additional points to consider when conducting research involving children

- Participants should not be offered inducements, financial or otherwise, that would encourage them to take greater risks than they would otherwise consider acceptable. This is based on both the ethical principle of respect for persons, which states that informed consent should be free from coercion, and justice, which states that risks should not be unequally born by the disadvantaged. Therefore, any inducement that might result in the child volunteering, or being volunteered by their parents/guardian in the expectation of direct benefit should be avoided.
- Research that is poorly designed is unethical. Participants should not be expected to volunteer for studies that are unlikely to generate new and useful knowledge. In addition, children and young adults should not be asked to volunteer for studies where the knowledge could reasonably be obtained using adults and/or where the knowledge is not relevant to their needs. For a study to be ethical it must be scientifically sound, there should be a defined research aim and research question, the aim should be relevant and unknown, and the methodology should be likely to achieve the aim by answering the question [18]. The purpose of the research should be to obtain knowledge relevant to the needs of children. The LSHTM Ethics Committee usually require some evidence of scientific review and researchers are asked to provide details of this when completing the ethics application form.

7. Useful documents

The LSHTM Safeguarding and Security Screening Policy can be found on the Safeguarding webpage here: https://www.lshtm.ac.uk/aboutus/organisation/governance/safeguarding

All SOPs can be found on the Research Governance and Integrity Intranet pages here: https://lshtm.sharepoint.com/Research/Research-Governance/Pages/standard-operating-procedures-(sops).aspx

The Standard operating procedures that may be particularly helpful when planning research with children include:

- SOP-003 Ethics approval
- SOP-004 Writing a research protocol to GCP guidelines
- SOP-005 Informed consent for research
- SOP-036 Confidentiality and anonymisation of research data
- SOP-042 Recruitment of healthy volunteers

8. Useful links/helplines

Disclosure and Barring Service (DBS). For information on applying for a DBS check. https://www.gov.uk/government/organisations/disclosure-and-barring-service

NSPCC - 24 hour Helpline: 0808 800 5000 (advice for adults concerned about a child's welfare) Website: http://www.nspcc.org.uk/

Childline - 24 hour Helpline: 0800 1111 (advice for children) Website: http://www.childline.org.uk/Pages/Home.aspx

CEOP – Online reporting if you suspect a child or young adult is at risk from online sexual abuse and exploitation in the UK. Website: https://ceop.police.uk

Save the Children – International agency concerned with child welfare. Website: http://www.savethechildren.org.uk

UNICEF - International agency concerned with child welfare. Website: https://www.unicef.org.uk/

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