Introduction

Ethical principles aim to ensure that all aspects and stages of research conducted by and on behalf of Edge Hill University (whether by staff, students or associates), either with children and young people directly or through impact upon their lives, should ensure respect and fairness and protect vulnerable participants from potential harm. It is understood that research is undertaken to promote the general good. Research with children and young people makes an important contribution to the general good as it recognizes that children and young people are citizens with agency. Children and young people are experts in their own lives. Research with children and young people enables them to contribute to research agendas about issues that affect them.

It is increasingly recognised that the quality of research (research focus, design, management and dissemination) can be improved through meaningful consultation with representatives from the population under investigation. This consultation (within health called Patient and Public Involvement) is not governed by research ethics approval but any work with children and young people should adhere to the core ethical principles outlined below and requires a full research risk assessment. Similarly, the United Nations Children’s Fund (UNICEF) and the Information Commissioners Office (ICO) states that it is good practice to invite the views of children to help researchers identify risks, design safeguards and develop their understanding to inform future research.

*Ethical research and the best interests of the child or young person*

Article 3 of the United Nations Convention on the Rights of the Child states that “in actions concerning children, whether undertaken by public or private social welfare institutions…the best interests of the child shall be a primary consideration”. New data protection regulations introduced under the GDPR (2018) offer another layer of specific protection for children “as they may be less aware of the risks, consequences and safeguards concerned and their rights in relation to the processing of personal data”
GDPR, Recital 38, 2018). Researchers must demonstrate compliance with these regulations by ensuring the best interests of children and young people are served by:

- Demonstrating privacy by design and default.
- Following the principle of data minimisation by only collecting data if it is necessary.
- Following the principle of storage limitation by not retaining data any longer than is necessary.

**Definitions of children and young people**

The Information Commissioner’s Office (ICO) defines anyone under the age of 18 as a child. This definition is in accordance with the UN Convention on the Rights of the Child which defines a child as everyone under the age of 18, unless, “under the law applicable to the child, majority is attained earlier” (Office for the High Commissioner for Human Rights, 1989). The UK government has ratified this convention. The General Medical Council uses the term ‘young people’ to refer to older children, generally over the age of 16, who can make important decisions for themselves.

This document should be read in conjunction with the Edge Hill University Code of Practice for the Conduct of Research (RO-GOV-01), Edge Hill University Framework for Research Ethics (RO-GOV-03), Edge Hill University Health, Safety and Environmental Policy [https://www.edgehill.ac.uk/documents/files/health-safety-amp-environmental-policy.pdf](https://www.edgehill.ac.uk/documents/files/health-safety-amp-environmental-policy.pdf) and the Edge Hill University Data Management Policy (RO-GOV-04).

**Overview**

This guidance document applies to all aspects and stages of research projects undertaken by those working on behalf of Edge Hill University that involve or impact upon the lives of children and young people.

It covers the following areas:

1. Choice
2. Consent and Assent
3. Risk, Harm and Distress
4. Benefit
5. Privacy and Confidentiality
6. Dignity
Choice

- Children and young people have the right to be informed, to express a view and to influence decisions.
- Information about research should be provided in a language style and format that is accessible to the specific group of children or young people from whom assent, or consent is sought.
- It should be clear that if a child or young person declines participation at any stage, then their relationship with those around them will not be affected.
- Children or young people should be provided with time to question about how participation in the research will affect them or their parent / guardian.
- Including minority groups in research is important and research should be sensitive to an individual's culture or learning needs. Cultural sensitivity within the research process will attend to the need for interpreters, the language used and a consideration of a range of issues, for example, religious fasts, that may affect the conduct of the research.

Consent and Assent

- Research with children and young people should be carried out with appropriate assent and consent.
- Assent, in most cases, acts as a supplement to the requirement of consent from a parent or guardian.
- Informed assent should involve a clear agreement to participate, rather than the absence of any objection.
- As with informed consent, informed assent should be an on-going process where the decision to participate should be checked throughout the research process.
- For research with children or young people, written assent or consent, as appropriate, should be obtained, but if the participant cannot sign, a mark on the document is acceptable.
- Despite the absence of a law outlining the process for obtaining consent, the ‘competence principle’ demands that it must be established that an individual is competent to consent to research. This means that the researcher must ensure that the opportunity is given by which it can be established whether or not the individual has ‘sufficient understanding and intelligence’ to know what the research involves.
- Young people are normally presumed to be competent to give consent to participate in research on attaining the age of 16. Exceptionally a child may be deemed Gillick1 competent in which case "Parental right yields to the child’s right to make his own decisions when he reaches a sufficient understanding and intelligence to be capable of making up his own mind on the matter requiring decision."2

- If there is concern about whether the child is competent to consent for the research project the voluntary consent of an adult parent / guardian should be sought before the child or young person becomes involved in research.

- Children and young people are often invited to participate in research as members of cohorts, particularly in educational research. In such cases, persons in authority in schools, colleges and educational, sporting, youth work or other community settings may act as gatekeepers. The researcher must gain the informed consent of the gatekeeper prior to seeking the informed consent of the child and their legal parent/guardian.

- When permission for research is through a gatekeeper, the interests of the gatekeeper should also be taken into consideration.

- The consent process should include a clear discussion about GDPR and the use of any personal data in line with Edge Hill University’s privacy policy https://www.edgehill.ac.uk/about/legal/privacy/

- Consent for cohort research is sometimes assumed in the event of legal carers raising no objections within a reasonable time scale. This should only be the case where the research is non-intrusive and of low risk level. Ethics committees should not approve such a process if they have doubts about the potential welfare of any participant for whom consent is assumed through non-objection.

- It is important to note that there are additional strict guidelines regarding consent and assent for children and young people who participate in clinical trials or studies involving Human Tissue that must be adhered to.

- Ethics committees have a duty to satisfy themselves that those involved in obtaining consent and assent are competent to do so.

Risk, Harm and Distress

- Historically children and young people have been excluded from research that may have benefited them or other children because of a desire to protect them from harm and risk. There is a balance, however, to be struck between the risk of harm and the potential benefits to children and young people through participation in research

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1 See Gillick v West Norfolk & Wisbech Area Health Authority [1985] UKHL 7 (17 October 1985) from the British and Irish Legal Information Institute (BAILII) website

2 http://www.nspcc.org.uk/inform/research/questions/gillick_wda61289.html#Further_reading
• The response to risk of a child or a young person may be unpredictable and a procedure or research process that, 'bothers one child may not bother another'. All concerned in the process of the research need to identify what they understand as 'risks' that are involved for the child or young person because of their participation in the research project. Risk assessments should clearly identify potential risks to participants and researcher and include an action plan detailing what steps will be taken to mitigate risks.

• Children and young people who are involved in illegal activities (for example, under age sex) will need special precautions to safeguard their participation in research. Those who are key workers for the child or young person may need to be consulted in anticipation of ethical dilemmas.

• Expectations must be carefully managed during the research process. The limitations of the research should be explained at the outset so that children or young people do not have their hopes raised that issues or problems discussed in an interview will be resolved. The limitations of the researcher role must be clearly explained.

• Details of support services should be known to the researcher and available and accessible for the participant. Support during the research from a parent, carer or friend may assist the child or young person if sensitive issues are raised. The facility to debrief after participation should be made available where necessary.

• Research with children and young people may also pose a risk of harm or distress to the researcher, or other workers with access to the data. This is a risk in qualitative research where data may have an emotional content through the disclosure of distressing aspects of children's lives. Such risk should be anticipated and structures to support those affected by such processes as the coding of interviews should be available.

• Researchers who work directly with children or young people must undergo security screening, for example, through enhanced Disclosure and Barring Service (DBS) clearance. In the case of foreign nationals undertaking research, the equivalent clearance must be obtained from the relevant government or agency, and the additional time in obtaining such clearance needs to be taken account of in planning the research.

• As a potentially vulnerable and relatively powerless group in society children and young people are often not in a position to challenge potential misrepresentations of themselves in research. This should be taken into consideration when developing mechanisms for the involvement of children and young people in research, particularly in terms of a dissemination strategy.

• The following are some questions that may help guide the researcher in the assessment of harm and distress:
  o How severe may the harms associated with the research process and procedures be?
  o How likely are the harms to occur?
  o How invasive or intrusive is the research? (Note that these concepts would be applied just as much to the possibility of social/psychological invasion and intrusion as physical)
  o Might adverse effects be brief or long-lasting, immediate or not evident until years later?
  o Are a few children drawn into many research studies because they are available?
  o Might an effect not regarded as adverse at the time of the research become so in the future when the child is older?
Benefit

- The research may not benefit the participant directly but have a recognised benefit for other children and young people in the future.
- The following are some questions that may help guide the researcher in ascertaining the benefit of the research to children and young people:
  - How is the knowledge gained likely to be used?
  - Will the research benefit the child or young person participating in the research study or only other children and young people?
  - Are the benefits immediate, brief, long lasting or not evident until years later?
  - Should a wider range of children be offered the potential benefit of participating in the research?

Privacy and Confidentiality

- A consideration of a child’s or young person’s best interests may mean that the researcher encourages the inclusion of their parent or guardian in the collection of data. However, if a child or young person does not want to involve their parent / guardian this should be respected.
- Researchers are responsible for familiarising themselves with the safeguarding policies and procedures that are operating within the research site.
- Researchers have responsibilities within the context of safeguarding children if they have reasonable cause for concern that a child or young person is suffering harm. In this case, the researcher has a responsibility to liaise urgently with the designated safe guarding lead in school settings, social services or the clinical carers of the child or young person. Relaying sensitive information should be discussed with the child by the researcher prior to disclosure.
- Any decision to disclose confidential information to a third party must be explained to the child before disclosure.
- Research data given in confidence may be liable to a court subpoena and research participants should be informed of this fact in relevant circumstances.
- In the case of interventional health care research (e.g. clinical trial of medicinal product), general practitioners or clinicians for the child’s care may need to be informed if the research is related to the child’s or young person’s health care. The consent form should request permission to inform and update the child’s GP and clinical team of their involvement in the research. If the child or young person resists relevant health information being provided to their clinical care team when deemed necessary, the researcher must refer to the ethics committee that assessed the protocol for research.
• When personal records are explored retrospectively (for example in public health research) data protection issues need to be adhered to. Research data should be stored securely and adhere to the Data Protection Act (2018) and the requirements of the General Data Protection Regulation (2018 which states children and young people ‘merit specific protection’ as they may be ‘less aware of the risks, consequences and safeguards concerned and their rights in relation to the processing of data’ (GDPR, 2018, Section 38).

Dignity

• Dignity should be preserved for all involved in research. Therefore, the researcher needs to minimize any inconvenience, intrusion, embarrassment, coercion or distress within the design of the protocol.

• Researchers should be sensitive to cultural issues, concerns and values that the child or young person may hold. For example, the acknowledgement of religious fasts should be taken into consideration.

• Where the child or young person displays special needs, information should be provided in an appropriate format and the skills of a specialist colleague may be required as a facilitator or as an advocate.

• Disparity between the power and status of the researcher and the participant child(ren) or young person(s) should be addressed within the research design.

• Researchers should acknowledge the participants and dignify their involvement by having a clear plan in place for how findings will be shared with children and young people who have taken part in the research study.

References and Further Reading

Child-Centred Research Ethical Codes

Ethical Research Involving Children (2018) Ethical Guidance, available at:
https://childethics.com/ethical-guidance/


Relevant Professional Organisations Ethical Codes


Books and Journal Articles


Reports and other Publications


Gillick v West Norfolk and Wisbech Area Health Authority (1985); available at: http://www.swarb.co.uk/c/hl/1985gillick.shtml


Date of issue by the University Research Ethics Sub-Committee (URESC) November 2012

Last reviewed in 2018/19 and approved by URESC April 2019

Date of next review September 2022