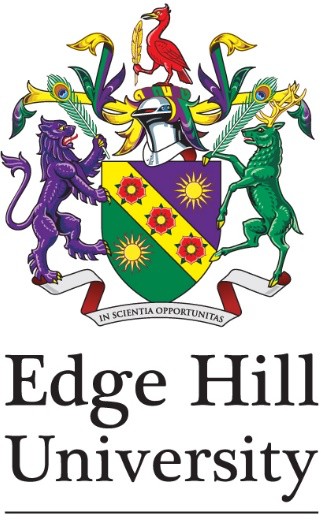
**September 2023 – 2026**

Ethical Guidance for Undertaking Research with Babies, Children, and Young People



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# Summary

In this document ‘babies, children and young people’ refers to any person under the age of 18 years old.

The term ‘baby’ includes neonates (up to 28 days), newborns (0-2 months), infants (2-12 months) and toddlers (1-3 years).

*The term ‘children’ or ‘child’ will be used throughout and should be applied as appropriate to the population of a study.*

# Purpose

* 1. 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 babies, children, and young people directly or through impact upon their lives, should ensure respect and fairness and protect participants from potential harm. It is understood that research is undertaken to promote the general good. Research with babies, children and young people makes an important contribution to the general good as it recognises that they 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.
  2. It is increasingly recognised that the quality of research (research focus, design, management and dissemination) can be improved through meaningful consultation, involvement, and co-production with representatives from the population under investigation. This approach (called Patient and Public Involvement and Engagement within health) is not usually governed by research ethics approval but any work with children and young people should adhere to the core ethical principles outlined below and requires an appropriate research risk assessment led by the Principal Investigator or a designated senior member of the research team. Similarly, the United Nations Children’s Fund (UNICEF) and the Information Commissioner’s Office (ICO) states that it is good practice to invite the views of children and young people to help researchers identify risks, design safeguards and develop their understanding to inform future research.

# Ethical research and the best interests of the baby, child, or young person

* 1. Article 3 of the United Nations Convention on the Rights of the Child (UN, 1989) 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).1 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;
    - Robust processes to ensure consent, safety and anonymity for participants where data will be shared or made available to other researchers via repositories such as Open Science Framework (OSF), Figshare and Zendo.

# Definitions of babies, children, and young people

* 1. 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 (UN, 1989) 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 ratified this convention in 1991. The term ‘baby’ includes neonates (up to 28 days), newborns (0- 2 months), infants (2-12 months) and toddlers (1-3 years).The General Medical Council uses the term ‘young people’ to refer to older children, generally aged 16 and over, who can make important decisions for themselves. Under Article 8 of the UK GDPR, children aged 13 years and over can lawfully provide their own consent for processing of their personal data. However, children’s ability to make decisions about participating in research will be influenced by more than their chronological age, so a child’s cognitive level, situation, and preferences need to be considered in all research interactions.
  2. 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), the Edge Hill University Data Management Policy (RO-GOV-O4) which can be found on the research governance pages https://[www.edgehill.ac.uk/collection/research-governance/](http://www.edgehill.ac.uk/collection/research-governance/) and the Edge Hill University Health, Safety and Environmental Policy https://[www.edgehill.ac.uk/documents/health-safety-and-environmental-policy/.](http://www.edgehill.ac.uk/documents/health-safety-and-environmental-policy/)

1 https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection- regulation-gdpr/children-and-the-uk-gdpr/

# Overview

* 1. This guidance document applies to all aspects and stages of research and evaluation projects undertaken by those working on behalf of Edge Hill University that involve or impact upon the lives of children.
  2. It covers the following areas:
     + Choice
     + Consent and Assent
     + Risk, Harm and Distress
     + Benefit
     + Privacy and Confidentiality
     + Dignity

# Choice

* 1. Children have the right to be informed, to express a view and to influence decisions. A child who can form their own views has ‘the right to express those views freely in all matters affecting the child, the views of the child being given due weight in accordance with the age and maturity of the child” (Article 12, UN, 1989).
  2. Information about research should be provided in a language, style, and format that is accessible to the specific group of children from whom assent or consent is sought. This may include written or printed materials, spoken words, different art forms such as drawings and objects or through any other media of the child’s choice (Article 13, UN, 1989).
  3. It should be clear that if child declines participation at any stage that their relationship with those around them will not be affected.
  4. Children should be provided with appropriate time to ask questions about the research and their involvement, including how participation in the research will affect them or their parent/guardian, friends, or peers.
  5. Including ethnic minority groups and others who may experience social marginalisation in research is important and research should be sensitive to an individual’s culture, preferences 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

* 1. Research with children should be carried out with appropriate assent or consent for the age and abilities of the child, along with any other requirements necessary for the research to proceed ethically and in an age and developmentally appropriate manner (https://childethics.com/charter/).
  2. For babies and young children, or where there is concern about whether a young person under the age of 16 years is competent to consent for the research project, the voluntary consent of an adult parent/guardian should be sought and acquired, along with the child assent where possible before the child or young person becomes involved in research.
  3. Assent is the agreement given by a child who may not be legally empowered to give consent but can be involved in the decision-making process by receiving personalised information which matches their capacity. Assent, in most cases, acts as a supplement to the requirement of consent from a parent or guardian.
  4. Informed assent (verbal and non-verbal) should involve a clear agreement to participate, rather than the absence of any objection.
  5. As with informed consent, informed assent should be an on-going process where the decision to participate should be checked throughout the research process.
  6. For research with children, assent or consent, as appropriate, should be obtained in the most appropriate way for the individual. This may be in writing or recorded verbally. However, where this is not possible due to physical and/or communication challenges a parent/guardian can confirm that the child is expressing consent in a way that suits their ability and comprehension (Article 13, UN, 1989).
  7. 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/assent to involvement in research. Competence is task and context dependent and key factors can include the child’s age and intelligence. However, it should be presumed that a child has the capacity form his or her own views rather than begin with the need to prove their capacity (UN, 2009, para 20). Where there is any doubt, the researcher must ensure that the opportunity is given to establish whether or not the child has sufficient understanding to know what the research involves so they can give informed consent/assent. ‘*It is not necessary that the child have comprehensive knowledge on all aspects of the matter affecting her or him, but… has sufficient understanding to be capable of appropriately forming her or his own views on the matter’* (UN, 2009, para 21).
  8. Young people are normally presumed to be competent to give consent to participate in research on attaining the age of 16. However, children’s ability to give consent is influenced by more than age and younger children can give consent where appropriate. For example, a child may be deemed Gillick2 competent in which case "*Parental right yields to the child’s right to make his own decisions when he*

2 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

*reaches a sufficient understanding and intelligence to be capable of making up his own mind on the matter requiring decision*."3

* 1. Children are often invited to participate in research as members of cohorts, such as school classes or groups like the Brownies. 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 passive consent or consent from their legal parent / guardian and the informed consent/assent of the child.
  2. Consent for cohort research is sometimes assumed in the event of legal carers raising no objections within a reasonable time scale (passive consent). This should only be the case where the research is non-intrusive and 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.
  3. When permission for research is through a gatekeeper, the interests of the gatekeeper should also be taken into consideration, and it should be ensured these interests do not override the interest of the child or young person.
  4. The consent and assent 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/departments/support/ig/](http://www.edgehill.ac.uk/departments/support/ig/)
  5. It is important to note that there are additional strict guidelines regarding consent and assent for children who participate in clinical trials or studies involving Human Tissue that must be adhered to. See the Edge Hill University’s [Human Tissue policy](https://www.edgehill.ac.uk/document/human-tissue-quality-manual/)
  6. 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

* 1. Historically children 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 through participation in research and the related advancement in understanding about a matter.
  2. Expectations must be carefully managed during the research process. The limitations of the research should be explained at the outset so that children do not

3 <http://www.nspcc.org.uk/inform/research/questions/gillick_wda61289.html#Further_reading>

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.

* 1. The response to risk of a child 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 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 and a safeguarding protocol which refers to the Edge Hill Safeguarding policy.
  2. A child may become upset or distressed during the research process so researchers should be prepared for this and take appropriate actions such as offering opportunities for breaks, skipping a question, re-arranging the data collection for another day, or stopping and supporting the participant to withdraw from the study. Seeking support from an appropriate adult such as a parent, guardian, or teacher may also be helpful.
  3. Where appropriate to the study, details of available support services which would be accessible to participants should be known to the researcher and information provided to participants. Support during the research may include that from an appropriate adult including parent, guardian, family member or teacher if sensitive issues are raised. Depending on the nature of the study, a debrief after participation should be made available where necessary.
  4. Children who are identified as being involved in illegal activities (for example, under age sex) will need special precautions to safeguard their wellbeing during participation in the research. Those who are responsible for the child’s wellbeing and safety, e.g. parents or key workers, may need to be consulted in anticipation of ethical dilemmas.
  5. Research with children may also pose a risk of harm or distress to the researcher, or other workers with access to the data, including transcribers. This is a particular 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, people informed about the nature of the research, and structures to support those affected by such processes as the coding of interviews should be available.
  6. Researchers who work directly with children must undergo security screening, for example, through enhanced Disclosure and Barring Service (DBS) clearance. The DBS certificate for any staff who will have contact with children should be submitted as part of the ethical review of the study by the appropriate REC.

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. Where the type and level of screening available in other countries is not clear, the researcher should seek advice from the safeguarding team. The researcher should also check on any requirements for the country, or countries, where the research will take place to ensure all checks or permits requirements are fulfilled.

* 1. As a potentially vulnerable and relatively powerless group in society children are often not able to challenge potential misrepresentations of themselves in research. This should be taken into consideration when developing mechanisms for the involvement of children in research, particularly during the analysis and write up stage of the study and planning the dissemination strategy.

7.9 The following are some questions that may help guide the researcher in the assessment of harm and distress:

* How severe may the harms associated with the research process and procedures be?
* How likely are the harms to occur?
* 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)
* Might adverse effects be brief or long-lasting, immediate, or not evident until years later?
* Are only a few children drawn into many research studies because they are available?
* Are some populations not being given the opportunity to be involved due to marginalisation or challenges in recruiting and engaging with them?

# Benefit

* 1. The research may not benefit the participant directly but have a recognised benefit for other babies, children, and young people in the future.
  2. The following are some questions that may help guide the researcher in ascertaining the benefit of the research to children:
* How is the knowledge gained likely to be used?
* Will the research benefit the child participating in the research study or only other babies, children, and young people once the study has finished?
* Will participation enable the child to share their story or views?
* 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, Confidentiality, and Safeguarding

* 1. A consideration of a child’s best interests may mean that the research is designed to allow their parent or guardian to be present or actively engaged when the researcher is collecting data. However, if a child does not want to involve their parent / guardian this should be respected.
  2. Researchers are responsible for ensuring that an appropriate safeguarding protocol is in place and that participants are aware via the information sheet and consent form (or other appropriate methods) that the researcher will need to abide by this in the event of risk or harm being disclosed or identified during the research. Any protocol developed for a study should align with the safeguarding policies and procedures that are operating within the research site, context, and Edge Hill University. **All researchers working directly with children are required to complete the Edge Hill University safeguarding training.**
  3. Researchers have responsibilities within the context of safeguarding children if they have reasonable cause for concern that a child is suffering harm or is likely to suffer harm. In this case, the researcher has a responsibility to liaise urgently with the designated safeguarding lead in settings, social services or the clinical carers of the child. Relaying sensitive information should be discussed with the child by the researcher prior to disclosure.
  4. Any decision to disclose confidential information to a third party must be explained to the child before disclosure.
  5. Research data given in confidence may be liable to a court subpoena and research participants should be informed of this fact.
  6. 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 heath 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 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.
  7. When personal records are explored retrospectively (for example in public health research) data protection issues need to be adhered to. Research data should be anonymised and stored securely adhering to the Data Protection Act (2018) and the requirements of the General Data Protection Regulation (2018) which states babies, 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

* 1. Dignity should be preserved for all involved in research. Therefore, the researcher needs to minimise any inconvenience, intrusion, embarrassment, coercion, harm, or distress within the design of the protocol.
  2. Researchers should be sensitive to cultural issues, concerns, and values that the child may hold. For example, the acknowledgement of religious fasts should be taken into consideration.
  3. Where the child displays additional or special education needs, including communication needs, learning needs or disabilities, 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.
  4. Disparity between the power and status of the researcher and the participant child(ren) should be addressed within the research design.
  5. Researchers should acknowledge the participants and dignify their involvement by having a clear plan in place for how findings will be shared with children who have taken part in the research study.

# References and Further Reading

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# End matter

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