



Medical
Research
Council



Economic
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Research Council

MRC/ESRC Joint Guidance on Involving Children in Research



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Background

It is important to give children the opportunity to take part in research that may improve understanding of their lives or increase knowledge about childhood conditions. Research with children is essential to ensure they can benefit from new interventions designed for their needs.

Researchers who are working with children will need to consider additional ethics issues arising from working with this group, as well as general ethics guidance on human participant research. Children and young people must be understood within the context of their stage of growth and development and it is often not scientific or ethical to apply findings from research with adults to children, for example adult drug formulations are often inappropriate for children. Children also require special protection because they are less likely than adults to be able to express their needs or defend their interests; and may not have the capacity to give consent.

Key challenges to undertaking research with children include their potential vulnerability, issues of capacity, legal protections, and the need to adapt study designs and outcome measures for this age-group. Above all, research with children involves a partnership with both the child and their family.

Principles

Research with children, as with all research involving human participants, must ensure that there is an acceptable balance of risk and benefit, approval is obtained from an independent research ethics committee, and that informed consent is taken from participants.

Specific ethics principles apply to research with children:

- research should only include children where the relevant knowledge cannot be obtained by research in adults
- research aims must be relevant to child health and/or wellbeing
- assent from children is needed
- researchers should involve parents/guardians in the decision to participate wherever possible, and always if the child is not yet competent
- a child's refusal to participate or continue should always be respected
- the child and/or family should be kept informed and have the opportunity to consent to separate stages of the project.

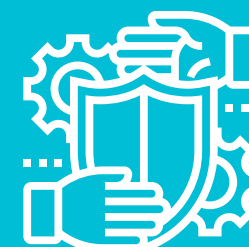


Principles

Expectations

UKRI expects researchers who are undertaking specific research projects that involve working with children to:

- **Seek research ethics approval** from an institutional Research Ethics Committee or NHS Research Ethics Committee.
- **Include children in decisions to participate and obtain their assent:** consent should also be taken from parents/legal carers where children are under 16 years; consent should be freely given based on information about the research and with the opportunity for children and their carers to ask questions.
- **Provide adequate age-appropriate information about the research to children to elicit informed decisions about participation:** this should include information regarding images, recording, sample and data storage and re-use where relevant.
- **Inform children and families about the balance of benefits and risk:** research participants should be informed about the potential negative consequences or lack of personal benefits from their involvement in research where relevant.
- **Ensure that appropriate Child Protection or Safeguarding measures are in place at study outset:** researchers working with children in health and social care settings should have appropriate training in child protection and understand when and how to raise a concern; researchers should ensure they have procedures in place to manage any safeguarding concerns that may arise and that information for participants explains that disclosure of confidential information may be necessary in relation to safeguarding concerns.
- **Observe relevant legal requirements for working with children:** this may vary according to the UK country in which the research is undertaken and whether the study is a Clinical Trial of an Investigational Medicinal Product (CTIMP) or not; Disclosure and Barring Service clearance will often be required.
- **Ensure that any incentives and compensation for participation are age appropriate and not coercive.**
- **Involve children in co-production, public and participant involvement or engagement (PPIE) opportunities to support and inform the research project:** these should be appropriate to the project; they may involve seeking advice from established young people's advisory groups, working with relevant support groups or involving individual children, or schools and families, as co-researchers.



Integrity

Guidance

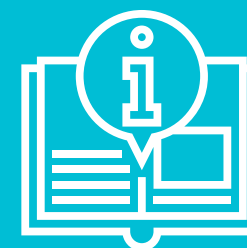
Assessing risk and benefit

- A primary consideration for research involving children should be whether the research is needed and whether children need to be involved in it. Children should be given the opportunity to take part in research that may improve their lives, or increase understanding about childhood diseases and the development of new treatments to help them.
- The potential risks and benefits for young participants should be considered. Most research guidelines allow children to be exposed to risks for the benefit of others, provided the risks are not too great and the information to be gained is important enough to justify the risks.
- It is best practice to carry out a risk assessment before starting the research and to consider specifically the risks of harm to children and young people and how these will be mitigated, monitored and managed.
- Harm can occur in biomedical, health and social science research. Examples include the risk of clinical treatment or procedures, and the risk of harm from interviews that may uncover suppressed feelings or memories, concerns about sharing, or trauma and distress related to current or past experiences.
- A particular concern in research involving children is safeguarding (or child protection). There are clear procedures for managing safeguarding concerns in health, care and education settings within the UK and researchers should be aware of these and ensure that they understand how to access these for advice and support or to raise a safeguarding concern. Researchers working with children should have sufficient training in child protection so that they are able to recognise potential safeguarding issues and understand their own role in protecting children. Information for participants must explain that disclosure of confidential information may be necessary in relation to safeguarding concerns.

- It should be clear from the outset of the study who a child or family will be referred to for further support if, for example, taking part in the research causes distress or raises a safeguarding concern; a procedure for managing this should be developed before the study starts.

Safeguarding

- Safeguarding includes 'child protection' and prevention of harm to children. The government laid out the roles and responsibilities of different agencies to safeguard children in *Working Together to Safeguard Children 2018*.
- Although this is not governed by a legal duty, researchers have a responsibility to protect children from harm during the conduct of research.
- In practice, researchers should
 - (a) be trained to recognise indicators of physical, emotional, sexual abuse and neglect
 - (b) understand when and how to access child safeguarding/child protection services to raise concerns and/or seek advice about potential or actual abuse
 - (c) ensure that, before starting a new study involving children or young people, they clarify the process to access advice from, or make a referral to, child safeguarding services
 - (d) advise children and families about the limits of confidentiality relating to any disclosure that raises concerns about abuse or safeguarding issues.



Disclosure and Barring Service (DBS)

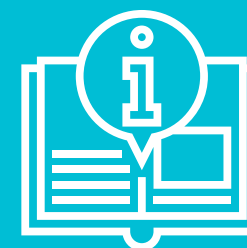
- The responsibility for ensuring that researchers are suitable to work with children and young people rests with individual employers.
- In most cases, researchers working with children and young people will need to secure Disclosure and Barring Service (DBS) clearance. The DBS offers organisations a means to check the criminal record of researchers to ensure that they do not have a history that would make them unsuitable for work with young people.
- Sometimes other individuals, such as a head teacher or social services manager, may be better placed to provide information on relevant disclosures (see the Safeguarding Vulnerable Groups Act 2006; Rehabilitation of Offenders Act 1974 and the Rehabilitation of Offenders Act 1974 (Exceptions) Order 1975).

Confidentiality

- Researchers should discuss confidentiality with children and their carers at the start of the research. This includes explaining that anything discussed in research sessions will not be shared with anyone else outside of the research team in a way that will identify the child or family. However, researchers must also make clear that confidentiality will be broken when necessary, for instance if a child is at risk of harm and action needs to be taken to protect them (i.e. in relation to safeguarding).

Involving children in research/co-production with children and young people

- Wherever possible, children and/or families should be actively involved in the co-production of research. The level of involvement and stage of the research at which children are involved will vary depending on the specific research project and the age of the children.
- Involving children, and their families, in developing and designing research ensures that it is relevant to them and that the risk to young people is minimised.
- Young Persons' Advisory Groups (YPAGs) have 10-15 members aged 8-18 years who provide advice on research involving children and young people. Researchers in health disciplines can take their research proposals to a YPAG for scrutiny and advice. In particular, they can provide advice on information leaflets for young people. YPAGs often consider the wider impacts of the research topic and study design on participants, such as school attendance, friendships and social activities.



Consent

■ Best practice

(a) Children and their parents (or those with parental responsibility) should be involved in the decision-making process around consent to take part in research, regardless of whether the child or young person is legally competent to give consent. This includes involving children or young people who are not considered competent to give consent.

(b) Assent should be sought from a child who is not considered competent as long as this is practicable and the child is not too young.

(c) In some situations, a young person who is competent may object to the involvement of their parents and their confidentiality should be respected.

(d) Before giving consent, children and young people should be provided with age-appropriate information that enables them to understand participation in research. Information may be provided using a layered, or staged, approach so that it is more easily understood.

(e) Children and young people should be given the opportunity to ask questions and to get support in their decision-making, such as talking to a trusted adult.

(f) Good records should be kept of any discussions about consent and of the final decision.

(g) Inducements and coercion must be avoided.

(h) Seeking consent is a process and it is good practice to engage regularly with the child and family over the course of research to confirm they are willing to continue. In studies in which children who are not competent will become competent during the study period, then consent from young people should be sought as soon as possible after competency is reached. A decision about how this will be managed should be made at the start of the study and included in the protocol.

■ Consent for health and biomedical research

The Health Research Authority provides clear and regularly updated guidance on the right of children and young people to give consent for clinical treatment and for health or medical research: <https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/research-involving-children/> The laws relevant to a child's ability to consent to take part in research differ between the devolved countries of the UK.

■ Consent to clinical trials of investigational medicinal products (CTIMPs)

The **Medicines for Human Use (Clinical Trials) Regulations** applies to England, Wales, Scotland and Northern Ireland. The regulations allow children aged 16 years and over to give consent to take part in a Clinical Trial of an Investigational Medicinal Product (CTIMP). Under these same regulations, children aged under 16 years are prohibited from giving consent to take part in a CTIMP and consent is required instead from a parent or someone with parental responsibility (agreement of only one parent is required). If someone with parental responsibility cannot be contacted before inclusion of the child in the trial, then a personal or professional legal representative may consent on the child's behalf. Further details on who might act as a legal representative and their role can be found on the website of the Health Research Authority. Although children aged under 16 years cannot give consent, they should be involved in the decision-making process whenever possible.



■ Consent to medical treatment and research

In England, Wales and Northern Ireland, for situations not covered by the Clinical Trials Regulations, children are considered to reach the age of majority at 18 years.

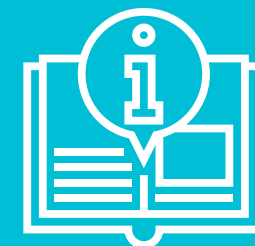
- (a) Under common law, young people aged between 16 and 18 years are presumed to be competent to give consent to medical treatment;
- (b) There is no specific provision in law for research that is not a CTIMP and does not fall under the Clinical Trials Regulations, however the principle of Gillick competence is usually considered to apply.
- (c) Case law suggests that children under the age of 16 years may give consent to medical treatment if they are considered to be 'Gillick competent'. Gillick competent means that a young person can understand what is proposed, weight up the risks and benefits, and make a decision about consent using this information. If a child is Gillick competent, then consent from an individual with parental responsibility is not legally required, however it is best practice to involve them whenever possible in the decision. If a young person does not wish to involve parents, then this should be respected.
- (d) If a child is not competent then decisions about consent for treatment should be taken by parents or those with parental responsibility.

In Scotland, for situations not covered by the Clinical Trials Regulations, children are considered to reach the age of majority at 16 years.

- (a) Under Scottish statute young people aged 16 years and over have legal capacity to consent to medical procedures and treatment.
- (b) Young people under 16 years can also give legally binding consent if they are considered competent to do so by a medical practitioner. This is interpreted as being able to consent and refuse treatment.
- (c) It is not clear whether Scottish statute covers research as well as treatment, however it is generally considered to apply.

■ Children who are not competent

- (a) Legally, consent is only required from one parent or person with parental responsibility. However it is good practice to involve both parents and, if there is disagreement, then it is advisable to exclude the child from the research (unless it provides access to treatment that is otherwise unavailable).
- (b) Parents can consent if research procedures offer potential benefit to the child. If there is no potential benefit, then parents should consider whether the risk from the research is sufficiently low and whether research is against the child's best interests or not.
- (c) If a child or young person who is not competent objects to taking part in research or wishes to withdraw from a research project, then their wishes should be respected.
- (d) If the parents are under 16 years, then they can only give consent if they are considered competent.
- (e) If a young person aged 16 or over is not considered competent then the Mental Capacity Act (England and Wales) or common law (Northern Ireland) will apply.



Resources

Relevant UKRI guidance

UKRI Good Research Resource Hub – sets out principles for Human Research Participants and Co-production in research

UKRI guidance for researchers and teachers doing research in schools <https://www.ukri.org/files/legacy/scisoc/schoolspolicy-pdf/>

ESRC guidance on Research with children and young people

MRC guidance documents include:

Human tissue and biological samples for use in research

Good Research Practice

Using information about people in health research

Ethics of involving children in research

Ethical Research Involving Children (ERIC) <http://childethics.com/>

Risk, harm and benefits – a report with examples

<https://childethics.com/wp-content/uploads/2013/10/ERIC-compendium-Ethical-Guidance-Harm-and-benefits-section-only.pdf>

Working paper by Virginia Morrow focusing on social research with children – The Ethics of Social Research with Children and Families in Young Lives

Nuffield Council on Bioethics working party report – Children and clinical research: ethical issues

Training course (with certificate) exploring the issues raised in the Nuffield Council's report: <https://globalhealthtrainingcentre.tghn.org/children-clinical-research/>

Report on a study exploring children's views on taking part in surveys by NatGen – Children's perspectives in participating in survey research

NIHR report on paying children for taking part in research <https://www.nihr.ac.uk/documents/children-payment-for-participation-report/12085>

Royal College of Paediatrics and Child Health (RCPCH) Charter on involving young people in research <http://www.rcpch.ac.uk/cyp-research-charter> and resource list <https://www.rcpch.ac.uk/resources/research-charter-resources>

Co-production and PPIE

Tips for involving children in research from INVOLVE <http://www.invo.org.uk/wp-content/uploads/2016/01/involvingcyp-tips-keyissues-January2016.pdf>

Website of GenerationR, an alliance of Young People's Advisory Groups (YPAGs) who provide advice to researchers <https://generationr.org.uk/>

Save the Children's web resources on doing research with children <https://resourcecentre.savethechildren.net/library/so-you-want-involve-children-research-toolkit-supporting-childrens-meaningful-and-ethical>



Online resources

Safeguarding

Link to the Disclosure and Barring Service for England and Wales:
<https://www.gov.uk/dbs-check-applicant-criminal-record>

Link to the Disclosure and Barring Service for Scotland: <https://www.mygov.scot/disclosure-types/?via=https://www.disclosurescotland.co.uk/index.htm>

Link to the AccessNI criminal record checking service:
<https://www.nidirect.gov.uk/campaigns/accessni-criminal-record-checks>

Various resources on child safeguarding from the Association of Directors of Children's Services: <https://adcs.org.uk/safeguarding/subject-results/safeguarding>

Consent

The Health Research Authority (HRA) provides details of the legal frameworks relevant to research with children: <https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/research-involving-children/>

HRA toolkit for undertaking health and biomedical research with children in England, Wales, Scotland and Northern Ireland: <http://www.hra-decisiontools.org.uk/consent/principles-children.html>

Information about the specific requirements when undertaking paediatric clinical trials of investigational medical products (CTIMPs): https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/ethical_considerations_en.pdf

Information from the UK Data Service about seeking consent for data sharing from children (see Special considerations): <https://ukdataservice.ac.uk/learning-hub/research-data-management/ethical-issues/consent-for-data-sharing/documenting-consent/>

Case studies

Learning outcomes and teacher effectiveness for children facing multiple disadvantages

Professor Pauline Rose's project aimed to identify strategies to improve children's learning outcomes, regardless of their background, and support children who face multiple disadvantages. Ethical approval was first sought from the UK university ethics committee, and then each developing country partner applied for local in-country ethical approval.

All participants – adults and children – were given structured and age appropriate information about the research. This was available in accessible format (eg braille) and if needed, explained through a translator or sign language specialist. Agreement to take part was sought from children, as well as consent from parents/carers. Household members in poor communities, who might have little schooling, could express consent by giving their signature, thumb print or verbal (audio-recorded) approval.

As children with disabilities were central to the study, the survey instruments and qualitative research tools were suitably adapted for full participation of all children.

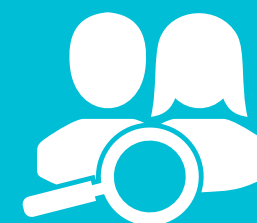
<https://www.ukri.org/councils/esrc/guidance-for-applicants/research-ethics-guidance/ethics-statement-examples/learning-outcomes-and-teacher-effectiveness-for-children-facing-multiple-disadvantages/#contents-list>

Involving young people brings benefits to research studies

Encouraging public and patient engagement and active involvement in research studies can have great benefits, especially in challenging areas. The Adolescents and Adults Living with Perinatal HIV (AALPHI) study evaluates the impact on young people of living with perinatal HIV. Young people were enabled to become advocates for the study. They were asked to develop the AALPHI research findings into a format that was easily accessible and used language that was understandable to young people. A filmmaker and graphic designer worked with them to develop a film and a leaflet about the study.

The project demonstrated that if you involve young people in research that is about them, it helps ensure results are communicated in a way that young people understand and, in this case, successfully increases their knowledge about HIV.

<http://www.chipscohort.ac.uk/related-trials/aalphi/>



Child research

