Research involving young people aged 3 to 16 years as participants

Introduction

While it is good practice to recruit research participants from non-vulnerable groups, it is sometimes necessary to include vulnerable participants in order to address the aims of the research and/or to give voice to their experiences and perspectives. All research participants must be treated with dignity and respect, but particular care needs to be taken when participants are vulnerable. Participants younger than 16 years of age are generally considered to be vulnerable because of their age.

In light of the more complex ethical issues, the default classification for research involving vulnerable participants is **high-risk** (definitions of risk levels and associated review process are detailed in our FAQs). The purpose of Approved Procedure 25 is to establish whether suitable measures are in place to enable the research involving young people as participants to be reviewed as a **medium-risk** ethics application. Research involving participants under the age of 16 cannot be classified as **low-risk**.

Note that the online ethics application system will automatically assign any project involving vulnerable participants as high risk, and applicants cannot change the risk level themselves. The Secretariat of your ethics committee will review your application against AP25 and reassign risk where suitable mitigation is detailed.

The focus of this Approved Procedure is for research that is conducted within the UK[1]. Much of this Procedure can also apply to research that is conducted in other countries, though researchers will also need to address any local differences. For example, most countries set the age of majority at 16 or 18, but some jurisdictions have a higher age and others, lower. Researchers wishing to recruit participants based outside the UK should also follow the guidance within CUREC's Best Practice Guidance 16 (Social science research conducted outside the UK).

Scope

What is meant by young people?

- Minimum age: **3 years**. If younger than 3, a high-risk application is needed, unless a separate Approved Procedure can be applied.
- Maximum age: **16 years**, unless there are reasons to adopt an older maximum age, such as
    - local laws (for international research);

[1] Legal/education systems differ across England, Wales and Scotland. The researcher should check local requirements when conducting research outside of England

- the research topic;
- Where 16 and 17 year olds are being recruited alongside younger classmates for the same research study;
- the research methods, or
- other characteristics of the pool of potential participants which might make them more vulnerable.

For research involving 16 and 17 year olds, researchers should refer to the CUREC Best Practice Guidance for research involving competent youths (BPG04).

Permitted Research Activity

Circumstances when this Approved Procedure may apply to research involving young people are listed in column two of the following table. The procedure can not be cited and review by committee is necessary where your research involves *anything* listed column 3.

	Medium-risk **(allowed under this procedure)**	**High-risk** **(not allowed under this procedure)**
Participants	Aged 3-16 years Not considered vulnerable in the context of the research, other than because of their age. Atypically developing children are recruited as part of a larger cohort (i.e. not recruited specifically because of their atypical development).	Babies and toddlers under 3 years of age, unless a separate Approved Procedure can be applied. Participants are vulnerable in the context of the research for a reason other than their age, e.g. the circumstances through which they are recruited (such as from detention centres, prisons or refugee camps), or specifically targeting atypical development or neurodivergence. Research sets out specifically to recruit a cohort of atypically developing children, (e.g. a study in which autistic spectrum or Down's Syndrome defines the group targeted for recruitment).
Advertising and Recruitment[2]	Research advertised via posters or newsletters. Participants or their parents/ guardians contact the researcher if they are interested in taking part. Online recruitment through advertising the study on social media sites such as Facebook pages or groups or via X, targeted specifically at parents/guardians. Parents/ guardians	Contacting potential participants directly, eg through emails to specific individuals or direct messages on social media. Online recruitment targeted specifically at young people. Parent/ guardian not informed/aware of their child taking part in the research.

[2] Refer to Information Compliance's Data Protection by Design framework.

	Medium-risk (allowed under this procedure)	High-risk (not allowed under this procedure)
	contact the researcher if they are interested in their child taking part. For online research, the researcher must have appropriate measures in place to ensure informed consent from the parent/ guardian is obtained (see examples in Appendix). This aspect will be considered on a case-by-case basis by the ethics committee as the risks will differ according to study.	Parent/ guardian consent not sought.
Access to young people	Through schools (with permission of headteacher Via residential and/ or non-residential institutional settings, (such as day centres or places of worship), provided the approach to potential child participants is always through parents or legal guardians Via another organisation, provided that the approach to potential child participants is always through parents or legal guardians Via online advertising targeted specifically at their parents/guardians	
Gatekeeper access conditions	Potential participants are identified by the organisation through a process that is in line with their policies. *Note that, as the organisation will be processing data on behalf of the University of Oxford, a data sharing agreement will be needed.*	
Research setting	Research takes place in the organisation through which young people are recruited, or at the University. Research is conducted in a public place, provided a teacher, parent or guardian is present. In-person in a private setting (e.g. the participant's home), with the parent/ guardian present.	The research takes place in-person in a private setting (e.g. the participant's home), without the presence of the parent/ guardian. Online research where it is not possible to obtain informed consent from the parents/ guardians.

	Medium-risk (allowed under this procedure)	High-risk (not allowed under this procedure)
	Interviews conducted online with parent/ guardian present.	
Research Topics	No sensitive topics	Sensitive topics, including emotionally or politically sensitive topics (e.g. potentially abusive or conflicted situations, domestic violence, parental separation or divorce, body image, asylum seekers) or issues that children may not previously have considered significant (e.g. asking them about their parent's or classmate's skin colour)
General requirements for activities	Age-appropriate and similar to everyday activities the participants undertake. No risk of harm to the participants, or to the researchers. Incidental findings (findings that fall outside of the scope of the research questions) unlikely. Potential participants are not at a disadvantage if they decide not to take part, e.g. if participation involves extra teaching that might benefit participants, pupils can still opt to have the extra teaching without their data being used for the research.	Prolonged involvement in the research. Disruption to usual activities, either inside or outside the classroom. Activities that are markedly different from the participants' usual activities. Research may present risks or harm to participants (e.g. MRI, brain stimulation[3]/therapy). Invasive procedures (e.g., involves skin prick tests or blood samples). Incidental findings possible. Non-participation may result in young people being at a disadvantage.
Activities permitted with Parental/ guardian agreement (via opt-in or opt-out process) and participant's assent.	Questionnaires on non-sensitive topics. Observation at the organisation through which the participants were recruited, with permission, without identifying individual young people. In-person observation of a specific task during usual session time. In-person focus group or interviews, with participants in Year 12 or above, conducted at the school/organisation	All other types of in-person observation. Inclusion of sensitive topics

[3] Including, but not limited to, Deep Brain Stimulation, Vagus Nerve Stimulation, Electroconvulsive Therapy, transcranial magnetic stimulation, transcranial direct current stimulation, transcranial alternating current stimulation, magnetic seizure therapy, and cranial electrostimulation.

	Medium-risk (allowed under this procedure)	High-risk (not allowed under this procedure)
Justification for the approach must be given.	through which the participant was recruited. *When organisations are communicating with parents/ guardians on behalf of researchers and collecting opt-in or opt-out consent forms, a data sharing agreement needs to be in place.*	
Activities permitted with Parental/ guardian consent (opt-in) and participant's assent.	1:1 interviews/sessions, if conducted at the school/organisation through which the participant was recruited or at the University. Must be conducted in sight of another adult (e.g. in a corridor (with door open) or open room adjacent to classroom or offices). 1:1 interviews/sessions in a private setting, e.g. the participant's home, with the parent/ guardian present. 1:1 interviews/sessions conducted online with parent present. In-person focus groups, conducted at the school/organisation through which the participant was recruited. Online observation of a specific task (e.g., verbal/ paper and pencil tasks, measurement of motor behaviour).	1:1 interviews/sessions in a school/organisation or the University where a suitable place in sight of another adult cannot be identified. 1:1 interviews/sessions conducted online without parent present. In-person 1:1 interview in a private setting without the parent/ guardian present. In-person 1:1 interview in a public place. Inclusion of sensitive topics.
Research Data	If personal data is collected, this is pseudonymised at the earliest opportunity. Personal data is not shared outside the research team. No collection of special category data Personal data is destroyed at the end of the research project, unless opt-in consent from the parent/ guardian is in place for the data's retention and use. Use of existing data (e.g. exam results), with permission from the data owner	Identifiable research data is shared with third parties. Collection of special category data. Retention, transfer or sharing of personal data without consent from the parent/ guardian.

	Medium-risk (allowed under this procedure)	High-risk (not allowed under this procedure)
	and without identifying individuals in the research outputs.	
Audio recording	The recording must be necessary for the research activity (guidance). Audio recording of the participants, with opt-in informed consent from the parent/ guardian. Not shared outside the research team. The recording is deleted once transcribed.	Recording of individual participants to be shared outside the research team. Recording needs to be retained (with justification) beyond the end of the research.
Video recording	The recording must be necessary for the research activity (guidance). Justification of the need for the recording is provided. Video recording of the participants, with opt-in informed consent from the parent/ guardian. Not shared outside the research team. The recording is deleted once transcribed.	Recording of individual participants to be shared outside the research team. Recording needs to be retained (with justification) beyond the end of the research.
Photography	Photography of participants' work, eg drawings or answers to tasks, without identifying the individual participants.	Individual participants are identifiable from photographs.
Reimbursement	Travel costs Certificate or sticker for the young person Money or voucher for the organisation, eg to buy books. Money or voucher provided to the parent.	Refreshments other than water Money or voucher provided to the young person
Safeguarding concerns	Safeguarding concerns unlikely. Researchers follow the guidance set out in the University's Safeguarding Code of Practice, especially guidance for activities involving adults at risk or children. Researchers complete the online training course An introduction to Safeguarding provided by the Oxford Safeguarding Children Partnership, as well as undertaking risk assessments of the proposed research. Any risk assessment should also include details	Potential for safeguarding concerns. NB: in some circumstances researchers may have a statutory duty to disclose confidential information to relevant authorities. Researchers are in a situation that could leave them exposed to accusations of abuse.

	Medium-risk (allowed under this procedure)	High-risk (not allowed under this procedure)
	of how research participants can report concerns about any member of the University with whom they will be interacting. Researchers must take responsibility for complying with safeguarding regulations and research practices that relate to the setting(s) (country, institution) of their research.	
Researchers	All have received training and checks needed to work with children, e.g., • Research ethics and integrity • Information Security • Applicable research methods • How to engage children • Safeguarding training • DBS checks Researchers with little or no experience must be supervised by an academic with relevant research experience.	
Existing relationship/ position of responsibility/ position of authority, e.g., teachers, colleagues, relatives	Clear boundaries between the researcher's role as researcher and their involvement with the participants/ group/ organisation in another capacity. Participants must be able to distinguish between the activities that are part of the research and other activities. It must be easy for participants or their parents/ guardians to decline or to withdraw from the research. Participant-facing materials make it clear that participants have a real choice about taking part. *NB: If personal data owned by the other organisation is used for the research project a data sharing agreement will be required.*	

	Medium-risk (allowed under this procedure)	High-risk (not allowed under this procedure)
Research outputs	Summary of research findings shared with the organisation through which they were recruited and/ or the parents/ guardians, without identifying individual participants. Individual participants are not identifiable from the research outputs.	Individual research participants are identifiable from the summary. Individual research participants are identifiable from the research outputs.

Recruiting participants

Methods for recruitment/ sampling will depend on the study. For example, researchers recruiting children through schools or other responsible institutions will have to (i) gain permission of the institution (in the case of a school, usually through the head teacher), for the research; and (ii) gain permission from parents or legal guardians for their children to take part. For recruitment of children outside an institutional setting, the approach to potential child participants must always be through parents or legal guardians. Arrangements for receiving and verifying parental/ guardian consent must be outlined in the ethics application. In the case of research conducted online, a message from the parent/ guardian should be required separate from any message received from the participating child. In all types of setting, it is expected also to seek assent from the children themselves.

In most cases a participant or their parent/ guardian is provided with the information they need to make an informed decision and then they decide whether they would like to 'opt-in' to take part in the research. There is evidence to suggest that 'opt-in' recruitment samples are less representative than samples recruited by 'opt-out' methods, which could introduce sample bias, an incomplete picture and/ or misleading findings. 'Opt-out' sampling may therefore be justified in some research. 'Opt-out' recruitment would involve giving potential participants or their parent/ guardian the option to withdraw, i.e. 'opt-out' of the research project or a particular task before they are enrolled. If they do not actively withdraw, by completion of an 'opt-out' form, then they will be included in the research.

'Opt-in' recruitment and consent

'Opt-in' recruitment - where children/ families invited to take part are not defined as participants unless the parent/ guardian actively agrees to the child's participation – is permissible with no extra conditions. In all cases, criteria for inclusion would be specified.

'Opt-in' recruitment is always required where personal data of children under the age of 13 will be obtained and processed in the course of the research.

'Opt-out' recruitment

‘Opt-out’ recruitment means that participants may be included unless they, or their parents/guardians, actively say ‘no’. However, the fact that people may find it difficult to say ‘no’, and that opting-out usually involves taking some action (e.g. returning a signed form), makes ‘opt-out’ potentially coercive and undermines the principle that consent to participate in research should be freely given. ‘Opt-in’ recruitment is preferable, unless you have good reasons to justify ‘opt-out’.

‘Opt-out’ recruitment is not acceptable where personal data of children under 13 years of age will be obtained and processed in the course of the research. For children aged 13 and over, personal data can be obtained, processed and stored in a study through an ‘opt-out’ process from the parent/guardian, provided that specific assent is given by the young person (i.e. they are opting-in).

In justification, please consider how important it is that the sample is representative of the population being studied (i.e. could opt-in sampling skew the data significantly), and whether response rate matters for the research being conducted.

It is important to distinguish between using ‘opt-out’ in relation to the *initial approach* to potential participants, and using ‘opt-out’ in *consent* itself. ‘Opt-out’ recruitment is generally acceptable if there is a gatekeeper (such as a parent/ carer) being asked to ‘opt-out’ to an *initial approach*, but the child is still being asked to *actively assent* to taking part in the research.

Research using an ‘opt out’ recruitment method is only permissible under this Approved Procedure under the following conditions:

Condition 1: the giving of information and facilitation of ‘opt-out’:

- Children/ families should be invited to take part in the research using standard information-giving documents (at minimum a participant information sheet, together with other documents as appropriate), and an ‘opt-out’ form.
- The ‘opt-out’ form should allow and facilitate the ability of parents/ guardians to object to their child’s inclusion in the research within a reasonable timeframe (to be justified by the researcher when they apply for ethical review).
- If no opt-out form, or other way of objection or active refusal, is received by the researchers within the given timeframe, the child is automatically included in the research, subject to their agreement to take part.
- Researchers must be careful to check which children have been opted out at every session conducted, even if a repeat visit

Condition 2: the nature of the research topic (NB this is an exception to the general scope of this Approved Procedure described in Section 1 above):

The research should only examine issues that could be reasonably predicted not to be contentious to parents/ guardians (an example of a contentious issue may be interviewing children about sexual behaviour or identity, or about self-image). If the research proposes to cover contentious or sensitive issues and proposes to use an ‘opt-out’ approach to recruitment and consent, this Approved Procedure cannot be cited.

If your research fails either condition above but it is proposed that the research uses an ‘opt-out’ recruitment method, you will need to provide a detailed explanation as to why this approach is justified, and the study will be considered high risk.

Considerations where opt-out recruitment is proposed in school settings

University of Oxford ethics committees have received parent/ guardian complaints where children were included in research because an 'opt-out' form was not returned to the school, likely due to information about the research never reaching the parent/ guardian. Thus, when an opt-out approach to recruitment is desired, the following should be considered by researchers and the schools they work with to ensure information reaches a student's home:

- Physical letters should have names of students written on them to clearly indicate those who have received their letter. If records show that a letter has not been sent, these students must not be included in the research.
- Targeted email from the school to parents of the involved classes to inform them about the research, including parent information sheet and opt-out form as attachments.
- Targeted text from the school to parents of involved classes to inform them of upcoming research (drawing their attention to typed letter in schoolbags and/ or email as appropriate).
- Possible follow-up text to remind parents of deadline for opt-out return.
- Information included in school newsletter.

Data management and protection

"Where an organisation shares its data with researchers, those researchers have a responsibility to account for how, and with what consent, these data were gathered; they must also consider the authorship of the data and who owns them and, consequently, whether it is necessary to approach the relevant individuals for consent concerning their use. Researchers should keep up to date with changes in data use regulations and advice, which are often specific to particular jurisdictions." (BERA guidelines).

"Researchers who are researching their own practice should also consider how to address any issues arising as a result of collecting data for different purposes – for example, using data collected for evaluation purposes for research purposes, or vice versa." (BERA guidelines).

Researchers should limit the personal data collected to only that which is essential for the conduct of the research, e.g. do not obtain date of birth if age will suffice. Particular care should be taken to ensure confidentiality of video/ audio recordings, where it is not possible to anonymise materials. These will be labelled with code numbers and date only, and kept securely, typically in an encrypted form. Researchers using video/ audio recordings should follow IDREC's guidelines on procedures for storing such data.

Where possible, opt-out forms should be returned directly to the school and the school should then provide the researchers with a list of students that may be included in the research, or present those students to the researcher. Where researchers receive opt-out forms directly, these should be taken to the school when the researchers visit, and then be left at the school. It is then up to the school to determine when they will delete opt-out forms.

If researchers do intend to divulge results to anyone outside the research team, this must be made clear at the outset in the information sheet. For instance, the information sheet should say, "Your child's results on the reading test would be made available to his/ her teacher".

There is no time limit on retention of anonymised data. Identifiable data should be retained only as long as strictly necessary and participants should be informed in advance of these retention periods.

Associated templates that should be used and adapted for the research

Please download from the Approved Procedure web page

- AP25_Information Sheet 6-10 years
- AP25_Information Sheet 11-15 years
- AP25_Information Sheet_Parent
- AP25_Consent_Form_Parent
- AP25_Assent_Form_under_16s
- AP25_Opt-out_form

Further resources

Ethical Research Involving Children

The British Educational Research Association (BERA) guidelines Ethical Guidelines for Educational Research

The British Psychological Society Code of Ethics and Conduct

UKRI guidance

Royal College of Paediatrics and Child Health resources

CUREC's BPG 04 Competent Youths

Data protection by design

CHANGE HISTORY

Version No.	Significant Changes	Previous Version No.
2.0	Incorporates reference to the University Safeguarding Code of Practice and related requirements. Retitled 'Approved Procedure' (previously 'Protocol'). Approved by CUREC, 19 November 2015	N/A
3.0	Widened remit to include children and/ or teachers in section 1.3, and to include photography, video recording and audio recording of and/ or by the participants with specific consent from parents	2.0

Version No.	Significant Changes	Previous Version No.
4.0	Added further information about the use of 'opt-out' recruitment methods. General re-write to clarify some sections. Addition of reference to information sheet and assent form templates for children. Update of section 3 to comply with upcoming new data protection regulations.	3.0
5.0	Addition of considerations where opt-out recruitment is proposed in school settings. Added information as to how competent youths may be recruited.	4.0
5.1	Addition of a statement that researchers must be careful to check which children have been opted out at every session conducted, even if a repeat visit	5.0
5.2	Clarification that 'opt-out' recruitment is not 'consent' Text changes in section 3.3 to match Approved Procedure 15 Section 7 updated to include information about DBS clearance	5.1
5.3	Updated to improve accessibility	5.2
6.0	Section 1 (scope) re-written to clarify what is/is not allowed under this procedure. Removed information about Competent Youths – instead directing readers to BPG04 Section 3 (recruitment) updated for clarity. Administrative updates.	5.3
6.1	Added reference to Worktribe Ethics online application system	6.0

Version No.	Significant Changes	Previous Version No.
7.0	Complete re-write to make easier to follow, including a table of permitted activities under this procedure Include online recruitment of participants, provided parent/guardian is aware of the research and informed consent from the parent/guardian is obtained Include online activities, provided parent/guardian consent is obtained Include option to conduct 1:1 interviews within an organisation, provided this is in sight of at least one additional adult Add a list of possible approaches to ensure informed consent is obtained from the parent/ guardian for research conducted entirely online Change title from 'Non-invasive research involving participants aged 3 to 16 years, recruited via an organisation' to 'Research involving young people aged 3 to 16 years as research participants' to reflect above changes	6.1

Appendix

Possible approaches to ensure informed consent is obtained from the parent/ guardian for research conducted entirely online

Note that the process of seeking consent must be considered alongside the risk of the research to the young people. The below is not an exhaustive list, and other examples may be appropriate, depending on the research.

- Arrange a Teams meeting with the parent and adolescent to explain the study and seek both parental consent and adolescent assent before granting access to the study tasks. This would be the ideal 'gold standard', but is unlikely to be practical for large studies, or to gain a representative sample of the adolescent population.
- Advertise on 'adult' oriented sites (e.g. Facebook and X) for parents of adolescents to follow a link to study information, then refer the study on to their children. This could include sending the parent a link to the study tasks after they have consented (so no link to the actual research activity is included in adverts).
- Ask the adolescent to talk with their parents and then provide a parental email address if the parent agrees to this. Researchers would email information about the research to parents and ask them to complete the online consent form (or opt-out where they do not wish for their child to take part) – which could then be followed by adolescent assent and study completion.
- Initial parental opt-out – this will need a convincing opportunity for all parents to hear about, understand and have sufficient time and means to opt out. This process is unlikely to work for recruitment outside of an organisation.
- Trust adolescent to talk with their parents and ask the parent to provide online consent before the adolescent assents and proceeds to study tasks.
- For participants who do not 'speak' with their parents, one would have to make a case as suggested by Hunter & Pierscionek that: "Gillick competency might be legitimately applied: (1) when the research is likely to generate significant **advantages for the participants** while exposing them to relatively minor risks, and (2) when it is likely to **generate great societal benefit**, pose minimal risks for the participants **and yet raise parental objection**." In both cases, to ensure that autonomy is genuinely respected and to protect against personal interest, Gillick competency should be assessed by an individual who has no interest or involvement in the research.