

## **NON-INVASIVE METHODS WITH CHILDREN AS PARTICIPANTS IN INSTITUTIONAL AND NON-INSTITUTIONAL SETTINGS**

### **1. SCOPE**

Several research groups in the University carry out studies of, and with, children or young people, i.e. less than eighteen years old. Participants between 16 and 18 years old may be classed as ‘competent youths’, and some types of research, involving such participants in some locations, can be approved without citing an Approved Procedure. For further information, please refer to our website [FAQs](#) and [Best Practice Guidance](#) on involving competent youths. See also section 3.4 on the recruitment of competent youths below.

Because children are “people whose ability to give free and informed consent is in question”, research projects involving them generally cannot be approved purely on the basis of CUREC 1 / 1A checklist completion. This Approved Procedure details specific information that will be acceptable to the IDREC for research falling into this category, and where parental consent is explicitly obtained, i.e. where parents have "opted-in" to the research.

This Approved Procedure is intended to cover research recruiting children / young people as participants (with a lower acceptable recruitment age limit of 3 years of age), generally within an institutional setting, though please see section 1.2 for other permissible settings. It is also permissible to study atypically developing children as participants under this Approved Procedure (e.g. those with learning disabilities) when they appear in a sample arising from unselective recruitment in a school or elsewhere. This includes the case, for example, where children with a specific learning difficulty are identified in the research and treated as a distinct subgroup in the analysis.

This Approved Procedure does **not** apply to research that:

- sets out specifically to recruit a cohort of atypically developing children, for example a study in which autistic spectrum or Down’s Syndrome defines the group targeted for recruitment;
- includes babies and toddlers under 3 years of age;
- is conducted in private homes;
- is conducted in places that would raise more complex ethical issues, such as detention centres, prisons or refugee camps
- includes cognitive brain training

For such research, please apply using a CUREC 2 application form.

The applicable scope of this Approved Procedure is further dependent on the level of research risk, research setting, and types of research methods involved.

#### **1.1 Level of Research Risk**

The level of permissible research risk in order to apply this Approved Procedure is based on a risk analysis of a given research project at three levels:

1. Does the research cover a “risky topic” – a field of research that may be ethically, emotionally or politically sensitive (e.g. HIV/Aids, domestic violence, contact with children after separation or divorce, asylum seekers, and in general the raising of issues children may not previously have considered significant e.g. asking them about their parent’s or classmate’s skin colour)? In analysing this level of risk, it need not be assumed that risky topics carry risk in themselves, provided that proper safeguards are put in place (see sections below);
2. Might the research bring risks or harm to participants? (e.g. young children who are in potentially abusive or conflicted situations);
3. Might the research bring risks to researchers?

This Approved Procedure covers situations that are assessed as carrying no significant risk (level 1). If the project classes as level 2 or 3 above, this Approved Procedure does not apply and approval should be sought using a full CUREC 2 application.

## 1.2 Research Setting

This Approved Procedure applies to research:

- where participants are accessed through schools and the research is conducted either anywhere on school premises or elsewhere. Researchers should also check Approved Procedure 15 as this may be more appropriate for some research in schools.
- in responsible residential and non-residential institutional settings (except private homes and higher-risk settings), provided the approach to potential child participants is always through parents or legal guardians.

If the research setting is likely to define the child participant as ‘vulnerable’ please contact the relevant IDREC Secretariat (via the [SSH IDREC’s email](#) or the [MS IDREC’s email](#)) or to determine whether a full CUREC 2 application is needed.

## 1.3 Research Methods

The following methods are permissible under this Approved Procedure, with children and/or teachers:

- Unstructured interview
- Structured interview
- Questionnaire
- Participant performs verbal/paper and pencil/computer based task
- Measurement/recording of motor behaviour
- Observation of participant
- Focus groups

The following methods are permissible after having gained specific consent from the parents/guardians **and assent** from the participants (see section 5):

- Audio recording of or by participant
- Making still images of or by participant
- Video recording of or by participant
- Collection and storage of personal data

## 2. TRAINING OF RESEARCH STAFF

All researchers working with children must be trained:

- to use appropriate research methods
- how to engage children
- to recognise and deal with ethical issues
- to recognise and deal with situations where abuse and/ or serious risk is identified (this is unlikely in the situations covered by this Approved Procedure)

Researchers using published standardised psychological tests need to be aware that many such instruments are restricted, with the recommendation that they should only be used by a person with a formal qualification that includes training in psychological assessment. In practice, most publishers recognise that there are occasions when undergraduates need to use standardised tests for a student project. In such cases, CUREC recommends following the British Psychological Society (BPS) [Code of Human Research Ethics](#), i.e. a qualified user should ensure that the test is being applied and interpreted appropriately, and is responsible for training the student in principles of assessment such as eliciting optimum performance, following standard administration procedures, probing responses, and maintaining test security.

In other cases, no specific training beyond those listed above is usually required for this kind of study, but it is crucial that senior researchers ensure that those working under their supervision are able to establish and maintain a good rapport with children, and that they have appropriate safeguarding clearance.

Researchers need to be sensitive to Child Protection issues, and avoid working in situations that could leave them exposed to accusations of abuse. They must follow the guidance set out in the University's '[Safeguarding Code of Practice](#)', especially '[guidance for activities involving adults at risk or children](#)'. Researchers must complete the online training course '[An introduction to Safeguarding](#)' provided by the Oxford Safeguarding Children Board, as well as undertaking risk assessments of the proposed research. Any risk assessment should also include details of how research participants can report concerns about any member of the University with whom they will be interacting.

Researchers should also take responsibility for complying with safeguarding regulations and research practices that relate to the setting(s) (country, institution) of their research. As well as such compliance, researchers should consult guidance from the relevant professional associations. For example, for research settings in the UK, it is likely that researchers will require Disclosure and Barring Service (DBS) clearance - detailed guidance on obtaining safeguarding clearance can be found on the DBS website. Note that there are different levels of DBS check – the level you require will depend on the frequency and type of activity carried out.

## 3. METHODS FOR 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 study; 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 project application. In the case of a study recruiting participants through the internet, 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 recommended also to seek assent from the children themselves.

### 3.1 '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](#) will be obtained and processed in the course of the study. Note, however, that 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. Please see section 3.4 for details on the consent process in cases where the category of 'competent youths' can be applied.

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.

### 3.2 '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 study. 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. Please see section 3.4 for details on the consent process in cases where the category of 'competent youths' can be applied.

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 study.

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 1.1, part 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 should complete a CUREC 2 full application with a detailed explanation as to why this approach is justified.

### **3.3 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 study 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 indicate clearly which students have been given a 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

Please refer to the **Opt-out Form template associated with this Approved Procedure, and adapt this for the research as appropriate.**

### **3.4 Recruitment of Competent Youths**

Where it has been determined that participants between 16 and 18 years old can be classed as 'competent youths' ([see the best practice guidance BPG 04](#)) for the purposes of the research project, and the level of research risk remains at 1 (see section 1.1 above), then additional parental/guardian consent is not required. The youths should consent for themselves by signing a consent form similar to that aimed at adults. However, the parent/guardian still needs to be made aware of the research project via a brief information sheet. Please refer to the templates section of the [Informed Consent page on the CUREC website](#).

## **4. INFORMATION PROVIDED TO PARTICIPANTS**

The specific details provided will vary depending on the study, but should always be on University headed paper, showing the departmental name and address. It is usual to have separate information sheets for parents/guardians and simpler versions for the children.

The Information Sheet should be written in simple but non-patronising language. Most word-processing packages provide readability statistics for a document, and one should aim for a 12-year-old (Year 7) reading level for adults. Any information for children and young people should be worded and illustrated very clearly and simply.

Please refer to the [Information Sheet templates](#) associated with this Approved Procedure, which should be adapted for the research.

Please also see CUREC's [guidance on the informed consent process](#).

## 5. CONSENT OF PARTICIPANTS

If parents (or those in loco parentis) agree for their child to take part, or a competent youth is able to consent for themselves, they sign a consent form, and this can be returned to the school or institution.

The researcher will also explain in simple language to the child what is involved in the study, and make it clear that participation is voluntary – appropriate forms of assent are always desirable. In practice, for most types of study, it is not possible to obtain meaningful data from an uncooperative child, and it is practical, as well as ethical, to discontinue testing in such a situation. As noted in the BPS guidelines (see below): "when testing children, avoidance of the testing situation may be taken as evidence of failure to consent to the procedure".

### 5.1 Consent for audio, photographic or video data

In the case where audio or video recordings (including still images) are to be made, the consent form will contain an additional statement for the parent to sign to give explicit consent for this procedure e.g. "I agree that my child can be photographed/videoed". The information sheet will give a guarantee from the researchers that recordings will not be made available to those outside the research team without their written consent. If images or recordings may be used in a publication or scientific presentation then specific consent for this should be sought in the consent form e.g. "I understand that any photographs/videos may be used in conference presentations/on a project website/in peer-reviewed journal publications".

Please refer to the [Consent / Assent form templates](#) associated with this Approved Procedure, and adapt this for the research as appropriate.

Please also see CUREC's [guidance on the informed consent process](#).

## 6. FINANCIAL AND OTHER REWARDS TO PARTICIPANTS

For research in institutions, researchers may give participating children a sticker or certificate. It is not appropriate to offer participating children any rewards of monetary value, as this can create division in the classroom. It is not acceptable to offer food/sweets to children, as this not only creates division, but can also meet with disapproval from parents at best, or risk medical problems from food allergies at worst. To motivate parents to reply, it is acceptable to offer a reward to the school. For instance, the school may be given a voucher for books.

In the case where parents agree to bring their child to the University (or any other location away from the school/institution where they were recruited) to take part in a study, parents may be offered vouchers as a 'thank you' to the family. Travelling and other out-of-pocket expenses may also be reimbursed to parents.

## **7. POTENTIAL RISKS TO PARTICIPANTS/RESEARCHERS/OTHERS AND WHAT WILL BE DONE TO MINIMISE**

As outlined in section 1, the scope of this Approved Procedure is confined to research which carries minimal risk to participating children or to the researchers.

Researchers should take advice from the Department and host schools about [DBS clearance](#). Researchers must be sensitive to child protection issues and not work in situations that could leave them open to accusations of abuse. Researchers must be aware of, and conform to, the requirements of the General Data Protection Regulation (GDPR); the Children and Young Persons Act (2008); and the BERA Ethical Guidelines for Educational Research (2018).

## **8. MONITORING AND REPORTING OF ADVERSE OR UNFORESEEN EVENTS**

If a child should become unwell or distressed in the course of the study, the session will be terminated, and the event reported to the child's teacher or other responsible adult.

## **9. COMMUNICATION OF RESULTS**

As a general rule, it is recommended that results from individual children should not be fed back to schools or parents, and this should be stated in the information sheet. However, wherever possible, researchers should provide feedback about the results from the study as a whole.

There may be situations when researchers decide to deviate from this procedure. For instance, in a survey of children's reading, head teachers may find it valuable to have results of the reading test for participating children, and would regard it as unhelpful if researchers withheld such information. Researchers should take into account the following factors when deciding whether to communicate results:

- Role of researchers in relation to service providers - researchers need to be careful not to cut across service providers, such as educational psychologists or speech-language therapists, who have a professional role in assessing children. In such a case, the researcher should discuss with the head teacher how best to liaise with other professionals.
- Nature of the information provided - if test results are divulged, the results must be accompanied by a full explanation of what the results do and do not mean. If a standardized test has been used, it is recommended that results be presented as percentiles, which can be understood more readily than standard scores or 'age equivalent' scores. In other cases, raw scores (e.g. the number of letters which the child recognises) may be reported. However, for many non-standardised experimental measures, individual results are difficult to interpret, and the researcher should consider carefully whether there is any point in divulging them. The researcher should be aware that laypersons may be inclined to over-interpret test results and regard them as more stable and precise than they actually are.

## **10. RESPONSIBILITY OF RESEARCHER / CONFIDENTIALITY**

Researchers should be very cautious about offering advice to a child's parent or teacher on the basis of research findings, particularly when the researcher is not qualified to offer assistance. On the other hand, the researcher must take responsibility for the care of their participants, and should not withhold information that could have serious implications for the child. The question that the researcher needs to consider is whether drawing attention to a potential problem could lead the child to gain access to services that might be of help. Simply telling parents or teachers about a problem that cannot be remedied will only cause needless alarm and anxiety.

For instance, if a researcher suspects the child may have a treatable medical condition that has not been diagnosed, such as a hearing loss or visual impairment, then advice should be sought from a senior researcher. In such a case, it is likely that a decision would be made to inform the parents, and recommend that the child has a fuller assessment.

Where typically-developing children are studied using standardized tests of attainment or ability, it sometimes happens that a child obtains an unusually poor score. In general, this would not be divulged to teachers or parents, because a single low test score is not sufficient grounds for action in a case where no prior concern has been raised about the child's progress. Revealing results in such a case may cause needless anxiety. If the pattern of results is so unusual that the researcher is seriously concerned about the child, this would be discussed with a senior researcher, who will establish whether parents or teachers have any concerns about the child, and whether the child is likely to have a condition that might benefit from intervention.

## 11. DATA PROTECTION

Each child should be given a code number, and this, rather than the name, be used to label all data from the study, including any paperwork (drawings etc.) the child has created. If it is necessary to retain any personal information (e.g. contact details in the case that participants may be re-tested) the key linking codes to personal details should be kept in a locked filing cabinet or, as a minimum, a password-protected data file. Researchers should limit the personal data collected for the study to only that which is essential for the conduct of the study, 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 study, 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 how long they will retain opt-out forms for.

The basic rule is that if you 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 completely anonymised data. If non-anonymised data is to be retained, the consent form should seek consent for this retention.

## 12. FURTHER INFORMATION

[Guidance from the British Educational Research Association.](#)

Other appropriate professional codes may apply.

For more information see CUREC's [guidance from professional associations web page.](#)

## 13. 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



Version No.	Significant Changes	Previous Version No.
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
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