NON-INVASIVE RESEARCH INVOLVING PARTICIPANTS AGED 3 TO 16 YEARS, RECRUITED VIA AN ORGANISATION

1. SCOPE

Where research involves participants who may be more vulnerable due to their youth, close scrutiny of the research and its ethical issues is advised as a safeguard. For most research involving participants under the age of 18 years, a CUREC 2 form must be submitted and reviewed by the relevant CUREC subcommittee. However, if the research is conducted in accordance with the criteria set out in this Approved Procedure, a CUREC 1 (MS IDREC), 1A (SSH IDREC) or minimal risk application (OxTREC) form can be completed.

Note that, for recruitment of 16 and 17 year olds, researchers should refer to the CUREC Best Practice Guidance for research involving competent youths (BPG04). Where 16 and 17 year olds cannot be considered to be competent youths, or are being recruited alongside younger classmates for the same research study, this Approved Procedure can be applied provided below criteria are met.

This Approved Procedure may be applied to minimal risk research[1] involving child participants aged 3 to 16 years under the following conditions:

- where participants are accessed through schools, and the research is conducted on school premises, at the University, or online; and/or
- where participants are accessed 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; and/or
- where participants are accessed via another organisation, provided that the approach to potential child participants is always through parents or legal guardians; and/or
- involving atypically developing children, as long as they are not recruited specifically because of their atypical development.

Where research meets the above criteria, applications for ethics review may be submitted using a CUREC 1 (to MS IDREC) or CUREC 1A (to SSH IDREC or DRECs) form, provided no other Approved Procedures apply.

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-person in private homes;
- involves participants who are vulnerable for any reason other than their age, e.g. due to the circumstances through which they are recruited - such as from detention centres, prisons or refugee camps;

[1] That which would usually be applied for via the CUREC 1, CUREC 1A or OxTREC minimal risk process with no Approved procedures cited.

- includes ethically, 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);
- may present risks or harm to participants (e.g. MRI, brain stimulation[2]/therapy);
- is invasive (e.g., involves skin prick tests or blood samples)
- requires ethics review by a committee external to the University (e.g., NHS ethics review).

For such research, ethics applications must be made using a CUREC 2 application form or the form relevant for another reviewing body.

If the research setting is likely to define the child participant as 'vulnerable' for reasons other than their age please contact the relevant CUREC subcommittee for guidance as to whether this procedure may be applied.

The focus of this Approved Procedure is for research that is conducted within the UK. Much of this Procedure will 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 18, but some jurisdictions have a higher age and others lower. Researchers wishing to recruit participants based outside the UK should follow the guidance within CUREC's Best Practice Guidance 16 (Social science research conducted outside the UK).

1.1 Research Methods

The following methods are permissible under this Approved Procedure:

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

The following methods are permissible after having gained informed consent from the parents/ guardians:

- 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

It is the responsibility of the Principal Investigator to ensure that all researchers working with children are trained:

- in Research Ethics and Integrity – this needs to be evidenced on the CUREC application

[2] 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.

- in Information Security and Data Privacy – this needs to be evidenced on the CUREC application
- in Safeguarding children
- to use appropriate research methods
- in 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 (unlikely in the situations permissible under 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 their research. 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 in the bullet points above is usually required for this kind of research, 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 obtained from the University's HR Support web pages. 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 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.

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 of children under the age of 13 will be obtained and processed in the course of the 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 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 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 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

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

4. INFORMATION PROVIDED TO PARTICIPANTS

The information provided should be appropriate to the specific research and presented in an accessible way. If there is not enough information, potential participants might not be able to make an informed decision. On the other hand, if the information sheet is too long or unclear (e.g. through using overly-technical language) they might not read it properly or it could deter them from taking part. It is usually necessary to have separate information sheets for parents/ guardians and simpler versions for the children.

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, and tailored to their age. It may be helpful to have different versions for different age groups.

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, 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 research, and make it clear that participation is voluntary. Appropriate forms of assent are always desirable. In practice, for most types of research, 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

Consider whether there is a need to record participants. For research, the University generally relies on 'task in the public interest' as its lawful basis for processing personal data. To rely on this lawful basis, the recording must be necessary for an active research activity and there must be ethical approval in place to conduct that activity. If you only need to audio record interaction with participants, then you may not also collect video, as this would be unnecessary collection of personal data. The device used for recording should be encrypted and password-protected (if possible) and automatic back-up to the cloud turned off.
In the case where audio or video recordings (including still images) need 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 also be sought on the consent form.

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. COMPENSATION

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 research, 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. Refer also to the guidance within BPG 05 Payments and incentives in research.

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 UK General Data Protection Regulation (UK 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 research, the session will be terminated, and the event reported to the child's teacher or other responsible adult.

9. COMMUNICATION OF RESULTS

Generally, 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 standardised 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 might 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 based on 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 have a fuller assessment.

Where typically developing children are studied using standardised 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 MANAGEMENT AND PROTECTION

Each child should be given a code number, and this, rather than the name, be used to label all data from the research, 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. Ideally, this list should be held by the school/ institution and not shared with researchers.
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 completely anonymised data. Any identifiable data should be retained only as long as strictly necessary and participants should be informed in advance of these retention periods.

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
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
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