STUDIES USING NON-INVASIVE METHODS WITH CHILDREN

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 youth’, and some types of research in some locations can be approved straightforwardly, without an approved procedure (see ‘competent youth’ FAQ and Best Practice Guide on the CUREC website at http://www.admin.ox.ac.uk/curec/).

Because children are “people whose ability to give free and informed consent is in question”, research projects in this category generally cannot be approved purely on the basis of checklist completion. This approved procedure has been devised with the aim of specifying a set of procedures that will be acceptable to 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 and young people more generally 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.

However the 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. (For such research, please apply using a CUREC 2 full application.) Babies and toddlers of 2 years or under are also not covered by this approved procedure.

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 on school premises or elsewhere, though researchers should also be aware that Approved Procedure 15 also covers some research in schools. The present Approved Procedure also applies to research in other responsible institutions including (but not limited to) non-NHS care facilities, youth groups, orphanages and places of worship. This procedure may apply to non-institutional settings, provided the approach to potential child participants is always through parents or legal guardians. However, it does not apply to research conducted in private homes.

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

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 standardized tests for a student project. In such cases, IDREC recommendations following the BPS ethical guidelines i.e. a qualified user should ensure that the test is being used and interpreted appropriately, and is responsible for training the user in principles of assessment such as establishing and maintaining rapport, 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 obtain 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’, including completing 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 which 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, detailed guidance on obtaining safeguarding clearance can be found on the Disclosure and Barring Service (DBS) website.

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-out’ research

Research using an ‘opt out’ recruitment method is only permissible under this approved procedure under certain conditions. These are laid out below.

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.

Condition 2: the nature of the research topic (NB this is an exception to the general scope of this approved procedure described in Section 2 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 sex). If the research proposes to cover contentious or sensitive issues using an opt-out recruitment method, this approved procedure would not apply.

If your research fails either condition above but it is necessary that the research uses an “opt out” recruitment method, you should complete a CUREC 2 full application, or consider whether the research falls under Approved procedure 15. Otherwise, please consider using an opt-in research recruitment method.

3.2 ‘Opt-in’ research

‘Opt-in’ research - 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.

4. INFORMATION PROVIDED TO PARTICIPANTS

The specific details provided to parents will vary depending on the study, but will always include:

- the name of the study
- the name(s) and status(es) (e.g. doctoral student) of the researchers carrying out the study and how to contact them
- a brief rationale of the study, including its purpose and value
- why potential participants are being invited to take part in the research
- an explanation of what the child would do, including estimated duration of the test session and when it would take place (e.g. during lesson or break time at school). NB in all studies, consideration should be given to the appropriate length of time a child may be involved in the activity.
- that potential participants can ask questions about the study before they decide whether to participate
- that potential participants can choose whether they participate and, if they agree, they may withdraw from the study without penalty at any time by advising the researchers of this decision
- information about any additional personal information that would be obtained
Central University Research Ethics Committee (CUREC)

Approved Procedure_IDREC_25_Version 3.0

Title: Studies using Non-invasive Methods with Children

- information about who would have access to the data, how it will be stored and what will happen to the data at the end of the study
- statement that the data would be anonymised
- what benefits (direct or indirect) may accrue to the participants in the study
- what risks are involved in the study
- that the project has received ethics clearance through the University of Oxford’s ethical approval process for research involving human participants.
- where applicable, a note to explain that the research will be written up as a student’s thesis and how the personal data included in that thesis will be published and stored
- the procedure for raising a concern or making a complaint

The Information Sheet is 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 sheets for children and young people should be worded, and illustrated very clearly and simply.

Please refer to the Information Sheet associated with this Approved Procedure.

Guidance on the informed consent process can be found at:
http://www.admin.ox.ac.uk/curec/resources/informed-consent/

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 (see example attached). 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 and 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.

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

Note that explicit consent must be obtained both for obtaining this type of data e.g. “I agree that my child can be photographed/videoed” and for using this type of data for research purposes 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 Form associated with this Approved Procedure.
Guidance on the informed consent process can be found at: http://www.admin.ox.ac.uk/curec/resources/informed-consent/

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 sweets to children, as this not only creates division, but also can 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, and this may be in proportion to the number of participating children. 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 2, the scope of this approved procedure is confined to research which carries minimal risk to participating children or to the researchers.

8. MONITORING AND REPORTING OF ADVERSE OR UNFORSEEN EVENTS

If a child should become unwell or distressed during a test session, 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 unstandardized 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. DUTY OF CARE ISSUES / 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 does have a duty of care, 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 ISSUES

Each child is given a code number, and this, rather than the name, is 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. Particular care should be taken to ensure confidentiality of video 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 recordings should follow IDREC’s guidelines on procedures for storing such data.

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".
12. FURTHER INFORMATION

Guidance from the British Educational Research Association can be obtained from:
https://www.bera.ac.uk/researchers-resources/publications/ethical-guidelines-for-educational-research-2011.

Other appropriate professional codes may apply.
For more information see CUREC’s guidance from professional associations web page at
http://www.admin.ox.ac.uk/curec/resources/associations-guidance/.

13. CHANGE HISTORY

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.0</td>
<td>Incorporates reference to the University Safeguarding Code of Practice and related requirements. Retitled ‘Approved Procedure’ (previously ‘Protocol’). Approved by CUREC, 19 November 2015</td>
<td>N/A</td>
</tr>
<tr>
<td>2.0</td>
<td>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</td>
<td>1.0</td>
</tr>
</tbody>
</table>