Note: This Approved Procedure is intended to be used in association with CUREC_AP_IDREC_25 "Non-invasive methods with children as participants in institutional and non-institutional settings"

STUDIES USING PSYCHOPHYSIOLOGICAL METHODS WITH CHILDREN

1. SCOPE

An existing Approved Procedure (Approved_Procedure_25) covers most procedures used in research with typically developing school children, but explicitly excludes psychophysiological recordings. This Approved Procedure is intended to extend the existing Approved Procedure 25 to cover additional points that need to be taken into consideration when making such recordings.

Note that this Approved Procedure requires that researchers seek explicit 'opt-in' consent from parents of participating children. If 'opt-out' consent is to be used, then this Approved Procedure is not appropriate, and, for those departments not using the Worktribe Ethics application system, researchers should complete a CUREC 2 application.

The types of physiological recordings that are covered by this Approved Procedure are those specified by the term "invasive procedures (Class B)" in the CUREC glossary, and include recording of electroencephalogram (EEG), magnetoencephalography (MEG), eye movement recording by electrooculogram (EOG), electromyogram (EMG), recording of heart rate or galvanic skin response (GSR), and eye blink conditioning.

The main way in which this research differs from that covered by Approved_Procedure_25 is that children will be involved in procedures very different from their usual daily experience, and which involve apparatus that potentially could cause anxiety or mild discomfort. Special measures therefore need to be taken to ensure the child is genuinely willing to take part and is not intimidated by the research context. In addition, specific training of researchers in use of apparatus and hygiene considerations will apply.

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

Training in application of physiological equipment and setting up the recording should be given by a researcher with appropriate experience in the particular technique being used, and no inexperienced person should be left in sole charge of a physiological study. Where air cylinders are involved, researchers should have attended a gas cylinder safety course.

It is crucial that senior researchers ensure that those working under their supervision are able to obtain a good rapport with children; as noted below, the context of a physiological recording can be intimidating for a child, and it is vital that children feel comfortable with the adult(s) working with them. 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. Whilst it is not necessary for two researchers to always be present, a lone researcher must conduct in-person research within sight of another adult.

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, it is likely that researchers will require Disclosure and Barring Service (DBS) clearance - detailed guidance on obtaining safeguarding clearance can be found on the Disclosure and Barring Service (DBS) website.

Before beginning research, new researchers will:

- Read and agree to the relevant sections of the following professional guidelines:
  - CUREC Best Practice Guidance 09 'Management and Protection of Data Collected for Research Purposes'
  - DOH 'Seeking Consent: Working with children' (2001), Department of Health
  - RCP 'Guidelines for the ethical conduct of medical research involving children', (2000) Compiled by the Royal College of Paediatrics, Child Health: Ethics Advisory Committee and Prof. Sir David Hull, *Arch. Dis. Child*, 82, 177-182.
- Undergo a British Disclosure and Barring Service (DBS) background check, or other checks that may be required by law in future

While DBS approval is pending, new researchers may 'shadow' experienced researchers, but **will not** a) seek consent for children's participation from parents, b) be alone in a room with a child, c) gain access to identifiable data. During this period, new researchers will be able to familiarise themselves with the procedures of the research group, according to current documentation, including the details of this Approved Procedure. Once ethical approval and DBS clearance have been obtained, and the PI is satisfied that the new researcher is adequately trained, the new researcher may conduct research independently and have full access to identifiable data concerning participants.

3. METHODS FOR RECRUITING PARTICIPANTS

Methods for recruitment/sampling will depend on the research. 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 a study recruiting participants through the internet, an email from the parent/guardian should be required indicating interest in their child participating,

separate from any message received from the potential child participant. In all types of setting, it is required, where possible (depending on age), also to seek assent from the children themselves.

Depending on the protocol for the particular research, it may be most appropriate for the study to take place at schools, in a mobile testing facility, or at the researcher's Department.

Note that if research is to be carried out at health or higher education institutions other than the University of Oxford (e.g., NHS premises), it is likely that ethical approval will be needed from the bodies which cover those sites as well as from CUREC, and in such cases, this Approved Procedure **is not sufficient** to cover the research.

3.1 'Opt-in' recruitment

'Opt-in' research - where children/ families invited to take part are not defined as participants unless the parent/guardian, and the child themselves, actively agree to the child's participation – is the only permissible means of recruitment covered by this Approved Procedure. In all cases criteria for inclusion would be specified.

4. INFORMATION PROVIDED TO PARTICIPANTS

It is usual to have separate information sheets for parents/guardians and simpler versions for the children. The information provided should be appropriate to your 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. 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.

Researchers should be aware that the unfamiliarity of physiological recordings may in itself cause anxiety, especially if the child is reminded of a medical setting. The information sheet should, if possible, contain a picture demonstrating what will be involved in the physiological recording, as well as the usual verbal description. Researchers may also consider making a short video recording or simple picture-based story-book showing what is involved; this could be distributed to potential participants or made available on a website to help both parents and children decide whether to take part.

Where relevant, it is recommended that the word 'sensors' be used rather than 'electrodes' when describing a procedure.

The information sheet should make it clear that the procedure is for research and is not designed to identify health problems, and that the researcher has no training in identifying health-related problems from the recordings. A section such as the following may be included in the information sheet: "In the unlikely event of the researchers noting an irregularity in the recording they would discuss this with a clinical specialist and inform you if it was felt necessary for you to discuss further with your GP." (The precise wording might need modifying depending on the specific procedure).

Please refer to the **Information Sheet templates** **associated with Approved Procedure 25, which should be adapted for the research.**

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".

As well as formal consent from a parent, it is important to have assent from the child. This can be facilitated by making available in advance the kind of visually-based information as described in section 4. Particular care should be taken to explain to the child what is involved before attaching any recording device. For young children it can be helpful to demonstrate the procedure first using a large teddy bear or similar toy. Before commencing, researchers must have a clear indication from children that they are willing to take part, as well as parental consent. It is important to be aware that children may find procedures aversive that adults find innocuous, and if this is the case, the research should be halted. In addition, researchers should be aware that a child may feel trapped once connected to recording equipment, and it is important to explain that it is possible to pause or halt the procedure if they wish. Where appropriate, the researcher should demonstrate that recording devices can readily be detached. For instance, the researcher may say “And if you need to go to the toilet, just let me know, and we can take this off like this”. For MEG studies, researchers should follow the procedures developed for the study of children at the MEG centre, which involves the option of using a session with a mock scanner to desensitise the child, as well as scheduled breaks during the MEG session.

Please also see CUREC’s guidance on the informed consent process.

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 study website/in peer-reviewed journal publications”. It must be clear how the recording will be securely stored, and how long for.

Please also see CUREC’s current 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 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.

Further guidance is available within CUREC's Best Practice Guidance 05 on Payments and incentives in research.

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

All the procedures covered by this Approved Procedure have been used safely for many years, including with children, and the equipment comes from certified medical suppliers. We are aware of no cases of adverse events associated with these procedures.

Nevertheless, although the equipment itself is safe, a physiological laboratory can contain hazards, and researchers should be alert to potential dangers from trailing wires, uncovered sockets, or heavy air cylinders. These will be covered by relevant Health and Safety procedures, and researchers must familiarise themselves with these and be vigilant in monitoring them.

In addition, where sounds or other stimuli are presented in the course of a study, it is important to ensure that the level is controlled. The researcher should always test the sound level before any auditory test to ensure that there is no risk of damaging the hearing of the participant; where air puffs are presented as stimuli, the level should be regulated so it cannot go above 7 psi.
During the session, the researcher should monitor the child carefully, and if they show signs of distress or discomfort, they should be asked if they want to stop. Researchers should be sensitive to the fact that children may be intimidated by the situation and reluctant to say spontaneously they want to stop.

In the case of EEG and similar studies, a further consideration for researchers is hygiene: the electrodes, caps and instruments used to apply gel must be cleaned/disinfected after each use; if necessary, participants may wash their hair to remove gel at the end of the session, and freshly laundered towels should be provided. Anti-allergenic gel and cleaning solutions should be used.
In the case of EEG studies, brain potentials vary widely from individual to individual. Researchers should undertake not to make any judgemental comments on the type of brain potentials seen in individual participants, to avoid causing unnecessary anxiety. e.g. the researcher should not make a comment, even in jest, such as "we can't find any brain responses".

Risks to researchers: Again, the main way to avoid risk is to adhere to a regime of hygiene. Hands are washed after any contact with the skin of a participant.

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 becomes unwell or distressed during a test session, the session will be terminated, and the event reported to the child's teacher, parent or other responsible adult.

All adverse events will be recorded and discussed with the study's principal investigator.

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.

It is unlikely that results from experimental physiological recordings will be meaningful to people other than the researchers. It should be made clear at the outset to parents that the procedure does not have diagnostic significance.

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 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 MANAGEMENT AND PROTECTION

The research must be conducted in accordance with the Research Data Policy researchdata.ox.ac.uk/university-oxford-data-management-policy; CUREC's Best Practice Guidance 09 on Data collection, protection and management; and Research Data Oxford's guidance on data backup, storage and security.

Each child should be 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 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.

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 anonymised data. If non-anonymised data is to be retained, the consent form should seek consent for this retention.

Where data has been anonymised (all identifying information removed, including any linkage document), there is no limit as to how long this may be retained by the researchers. However, the period of retention should be stated on participant information.

Sharing of Data

Research teams will be encouraged to make their data available for reuse and validation. In all cases, the data will be shared as openly as possible and as closed as necessary in order to protect the privacy of participants. Online repositories will be assessed by research teams for their appropriateness with regard to:

- the required treatment and de-identification of unique brain and biometric data in line with UK GDPR;
- control of how the data are accessed and re-used, including terms to protect the ongoing privacy of participants;
- required attribution of the data to the originating research team, the University and funding bodies;
- management of data withdrawal requests made by participants.

12. FURTHER INFORMATION

Guidance from the British Educational Research Association.
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
2.1	Updated hyperlinks for new CUREC website	2.0
2.2	Removed reference to sections of the old CUREC 1 checklist	2.1
2.3	Updated to improve accessibility	2.2
3.0	Quinquennial review Administrative revisions to bring statements in line with AP25 Removal of reference to a template Information sheet for this procedure (there never was one)	2.3
3.1	Administrative changes, including revision of section 4 to reflect other Approved Procedures	3.0
3.2	Updated to include reference to Worktribe Ethics	3.1