



Central University Research Ethics Committee (CUREC)

Approved Procedure: IDREC_18_Version 2.0

Title: Studies using Psychophysiological Methods with Adults

STUDIES USING PSYCHOPHYSIOLOGICAL METHODS WITH ADULTS

1. SCOPE

An existing approved procedure **IDREC_16** covers the use of psychophysiological recordings used in research with typically developing school children. This approved procedure is intended to extend the existing approved procedure to such recordings in adults.

This approved procedure is intended to cover research where all the boxes in Section D of the IDREC checklist are in unshaded boxes except:

- Question 10 (Does the research involve any *invasive procedure (Class B)?), where the shaded box is ticked because physiological recordings (see below) are used.

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), Near Infrared Spectroscopy (NIRS), recording of heart rate or galvanic skin response (GSR), and eye blink conditioning.

2. TRAINING OF RESEARCH STAFF

Training in application of physiological equipment and setting up the recording must 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.

Before beginning research, new researchers will:

- Read and agree to the relevant sections of the following professional guidelines:
CUREC Best Practice Guidance 02 ‘Storage of data collected for research purposes’
- Become signatories of the CUREC 1 Checklist

While CUREC 1 signatory approval is pending, new researchers may ‘shadow’ experienced CUREC 1 researchers, but **will not** a) seek consent for the participant, b) 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 has been obtained, the new researcher may conduct research independently and have full access to identifiable data concerning participants.

3. METHODS FOR RECRUITING PARTICIPANTS

For general procedures, see CUREC Approved Procedure IDREC_3.

Participants for psychophysiological studies are typically recruited via posters around the University. It is acceptable to mention that there will be compensation in recruitment advertisements for this kind of study, provided the amount is not stated, where competent adults volunteer themselves to take part. There is no significant risk to the participant other than boredom.



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Depending on the approved procedure for the particular research project, it may be most appropriate for the study to take place 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.

4. INFORMATION PROVIDED TO PARTICIPANTS

Researchers should be aware that the unfamiliarity of physiological recordings may in itself cause anxiety. 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 showing what is involved; this could be distributed to potential participants or made available on a website to help the participant 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 must 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).

The Information Sheet must 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.

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

5. CONSENT OF PARTICIPANTS

All participants sign a consent form which will always be on University headed paper.

Participants will sign, print and date their names and the researchers who secure the consent will also sign, print and date their names.

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/>



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6. FINANCIAL AND OTHER REWARDS TO PARTICIPANTS

Participants are typically rewarded with payments or vouchers for music or books to compensate them for the time spent in the study.

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 must be regulated so it cannot go above 7 psi.

During the session, the researcher should monitor the participant carefully, and if they show signs of distress or discomfort, they should be asked if they want to stop the experiment.

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 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.

8. MONITORING AND REPORTING OF ADVERSE OR UNFORSEEN EVENTS

If a participant should become unwell during the test session, the session will be terminated. Such a case will be reported in the Departmental Safety Book and discussed with the study’s principal investigator. The appropriate CUREC Sub-Committee Secretariat will also be informed.

9. COMMUNICATION OF RESULTS

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 participants that the procedure does not have diagnostic significance.



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10. DUTY OF CARE ISSUES / CONFIDENTIALITY

None.

11. DATA PROTECTION ISSUES

Each participant is given a code number, and this, rather than the name, is used to label all data from the study, including computerised EEG files and any paper records. 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 will be kept in a locked filing cabinet.

12. FURTHER INFORMATION

None.

13. CHANGE HISTORY

Version No.	Significant Changes	Previous Version No.
1.0	Retitled 'Approved Procedure' (previously 'Protocol'). Approved by CUREC, 19 November 2015	N/A
2.0	Quinquennial review and update	1.0