

**Note: This Approved Procedure can be combined with Approved Procedure CUREC\_AP\_IDREC\_03 “Studies Involving Electrophysiological Recordings from the Scalp in Adult Volunteers” and/or Approved Procedure CUREC\_AP\_IDREC\_08 “Studies Involving Magnetoencephalographic (MEG) Recordings from Adult Volunteers” and/or Approved Procedure CUREC\_AP\_IDREC\_20 “Studies Involving the Non-invasive Measurement of Blood Pressure in the Arm”**

## **STUDIES USING PSYCHOPHYSIOLOGICAL METHODS WITH ADULTS**

### **1. SCOPE**

This Approved Procedure is intended to cover the use of specific psychophysiological recording methods in adult healthy volunteers.

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

- eye movement recording by electrooculogram (EOG)
- electromyogram (EMG)
- Near Infrared Spectroscopy (NIRS)
- recording of heart rate by electrocardiogram (ECG)
- skin conductance response (SCR) / galvanic skin response (GSR) – for details see Appendix A
- eye blink conditioning
- functional transcranial Doppler ultrasonography (fTCD) – for details see Appendix B
- high-resolution retinal imaging with the adaptive optics scanning laser ophthalmoscope (AOSLO) – for details see Appendix C

Note that recordings of electroencephalogram (EEG) and magnetoencephalography (MEG) are covered by separate Approved Procedures (see IDREC\_03 for EEG and IDREC\_08 for MEG). If the procedures listed above are to be combined with either EEG or MEG, requirements specified in this Approved Procedure (IDREC\_18) and in the Approved Procedures for EEG or MEG have to be met.

**This procedure may be combined with Approved Procedure 03 to conduct recording of electroencephalogram (EEG), or with Approved Procedure 08 for magnetoencephalography (MEG).**

### **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.

Where lasers or other powerful light sources are present in the laboratory, researchers must have attended a laser safety course.

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'
- Receive satisfactory ethical and methodological training from the Principal Investigator or designee, such that the Principal Investigator is satisfied that they may conduct research independently

While training is ongoing, new researchers may 'shadow' experienced 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 satisfactory training has been signed off, the new researcher may conduct research independently and have full access to identifiable data concerning participants.

### 3. METHODS FOR RECRUITING PARTICIPANTS

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, and there is no significant risk to the participant other than boredom.

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.

For studies involving electrodermal responses (skin conductance response (SCR) / galvanic skin response (GSR)) or functional Transcranial Doppler Ultrasonography (fTCD), please use the appropriate template information sheet associated with this Approved Procedure.

For all other studies, please see our [template information sheet](#) (under the heading 'templates').

## **5. CONSENT OF PARTICIPANTS**

All participants sign a consent form which will always be on University headed paper. Consent will be obtained for each study by a researcher trained in taking informed consent.

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**.

Please also see our [guidance on the informed consent](#).

## **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, with the exception of the AOSLO, have been used safely for many years. The AOSLO is a newer technology, but has been used widely in vision research labs, including with patients with eye-disease. We are not aware of any 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, heavy air cylinders, dim lighting or lasers. 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; where light is used to image the eye the level of light at the eyepiece must be checked with a power meter before a participant looks into the instrument.

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 procedure. It is usually possible to pause the procedure if a participant needs to take a break or visit the bathroom, or if a fire alarm goes off.

If the procedure requires skin contact, a further consideration for researchers is hygiene: electrodes, headsets and instruments used to apply gel must be cleaned/disinfected after each use; if necessary,

participants may wash off gel at the end of the session, and freshly laundered towels should be provided. Anti-allergenic gel and cleaning solutions should be used. Where dental impressions are used for head-stabilisation during retinal imaging, each participant will receive a fresh piece of impression compound on a support structure, prepared by the researcher. The participant will hold the support structure and bite into the soft compound to make their own impressions. At the end of the session, the dental impressions will be destroyed and the support structure cleaned/disinfected.

Physiological responses vary from individual to individual. Researchers undertake not to make any judgemental comments on the type of responses seen in individual participants, to avoid causing unnecessary anxiety. e.g. the researcher should not make a comment such as “you’ve only got very small responses”.

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

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

## 10. 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 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.

## 11. 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
2.1	Removed reference to associated information sheet and consent form	2.0
3.0	Removed EEG and MEG, referring instead to the specific procedures for these recordings, and stating that this procedure may be combined with either the Approved Procedure for EEG or that for MEG. Updated section on training of research staff.	2.1

Version No.	Significant Changes	Previous Version No.
3.1	Updated hyperlinks for new CUREC website	3.0
3.2	Text to indicate procedure may be combined with AP20	3.1
4.0	Incorporated Approved Procedure 10 (Functional Transcranial Doppler Ultrasonography to Measure Cerebral Lateralisation in Adult Volunteers) Incorporated Approved Procedure 14 (Recording of Electrodermal Responses (Skin Conductance) from the Hand) Added high-resolution retinal imaging with the AOSLO	3.2
4.1	Updated to improve accessibility	4.0

## APPENDIX A - RECORDING OF ELECTRODERMAL RESPONSES (SKIN CONDUCTANCE) FROM THE HAND

The Skin Conductance Recording (SCR) provides a measure of changes in the electrical conductance or resistance of the skin that originate primarily from movement of sweat within the eccrine sweat ducts. SCR fluctuates spontaneously and also in response to the presentation of stimuli which are novel, unexpected or significant, or by the omission of an expected response. A basic distinction can be made between tonic and phasic SCR. Phasic SCR refers to changes in SCR (increases or decreases in resistance/conductance) that are superimposed on a background – tonic – level of activity. SCR can be quantified in a number of ways. Sometimes researchers will be interested in spontaneous fluctuations in SCR (non-specific skin conductance responses – NS-SCR) whilst at other times they will be interested in changes in skin conductance in response to the presentation of particular stimuli or the participant's conduct of particular activities (event-related SCR – ER-SCR).

A number of measurements of SCR can be derived. These include *frequency* over a particular recording period, *amplitude* (the mean amplitude averaged across trials where an ER-SCR is observed) and *magnitude* (the mean maximum amplitude averaged across all trials). These measures are derived through off-line analysis of data collected during experimental sessions. Usually a latency window of 1-4 seconds post-stimulus presentation is employed in order to identify skin conductance responses that are likely to originate from the stimulus presentation. On some occasions a longer post-stimulus window may be utilised, depending on the nature of the stimulus.

In experimental paradigms, the SCR is usually recorded whilst people view stimuli, perform cognitive tasks or sit at rest. Recording of the SCR is achieved by measurement of current flow between two electrodes placed on the skin of the fingers or palm (see below for precise locations). A constant voltage is maintained between the two electrodes such that current flow reflects the reciprocal of skin resistance.

Electrode placement and preparation should typically take no more than 5 minutes. The participant is asked to wash their hands with a non-abrasive soap prior to electrode placement. Depending on the set-up employed, two electrodes will then be attached to either the volar surfaces of the medial phalanges, the volar surfaces of the distal phalanges or thenar and hypothenar eminences of the palms. Electrodes are usually attached to the non-dominant hand since this is less likely to be affected by cuts or callouses and since this leaves the dominant hand free to make responses (e.g. button presses). Silver-silver chloride cup electrodes are typically used. In order to establish electrical contact between the skin surface and the electrodes, a unibase electrolyte paste is inserted into the cup electrodes, which can be attached to the skin surface either using double-sided adhesive collars, or in some custom made systems via specially designed Velcro pouches.

Usually after the electrodes have been applied the participant will be asked to sit at rest for a few minutes to stabilise SCR activity before beginning cognitive tasks.

## **APPENDIX B – FUNCTIONAL TRANSCRANIAL DOPPLER ULTRASONOGRAPHY**

Functional transcranial Doppler ultrasonography (fTCD) is a non-invasive method of measuring cerebral blood flow that has been used in research contexts to assess cerebral lateralisation since the early 1990s.

Cerebral blood flow velocities in the supplying arteries increase with neural activation in the corresponding brain region. Blood flow velocities in the middle cerebral arteries can be measured by transcranial Doppler ultrasonography using the Doppler Effect. An ultrasound signal directed at a blood vessel is reflected and back-scattered from moving objects (e.g. blood cells) with a positive or negative frequency shift. The faster the blood cells are moving, the higher the Doppler shift.

Doppler probes are mounted on the left and right sides of the head, just in front of the ears, with an angle of approximately 90 degrees to the direction of blood flow. A small amount of conductive gel is applied between the probes and the skin. The probes emit ultrasound with a given wavelength, which is reflected back with a shortened wavelength (Doppler shift). From the degree of shift one can compute blood flow velocity. The angle of the probe is adjusted to get the best signal. Because the insonation angle is not precisely known, measures of absolute blood flow are not very reliable. However, relative changes in flow in the two sides can be more reliably measured, and have been shown to provide a good index of cerebral lateralisation for speech, with excellent agreement with more invasive procedures (e.g., the Wada test, where a barbiturate is injected into the bloodstream to temporarily 'shut down' one cerebral hemisphere).

## **APPENDIX C - HIGH-RESOLUTION RETINAL IMAGING WITH THE ADAPTIVE OPTICS SCANNING LASER OPHTHALMOSCOPE**

Whilst low-resolution images of the human retina (the light sensitive tissue at the back of the eye) can be obtained routinely in optometry and ophthalmology clinics, the image quality is limited by the relatively poor optics of the eye, so that small features such as individual photoreceptors – rod and cone cells – are not resolved. Adaptive Optics (AO) imaging systems measure optical distortions and compensate for them. Thus, AO retinal imaging systems (such as the adaptive optics scanning laser ophthalmoscope, AOSLO) allow visualisation of individual cells (< 4 µm) in the living human eye, and are revolutionising our understanding of functional vision, both in health and in disease. Additionally, the scanning nature of the AOSLO allows for highly accurate eye-tracking, beyond that capable of research-grade eye-trackers that are based on reflection from the front surface of the eye.

Researchers will typically use a dental impression to help stabilise head position, made from a resin-based compound often used by dentists. Impressions will be made for each participant and will be destroyed on the participant's last imaging session. Minimising head motion is particularly important when a video-based eye-tracker is to be used simultaneously with the AOSLO and for some specific psychophysical experiments. In other cases, if a good level of stability can be maintained with a chin rest, a dental impression may not be required.

Before collecting retinal images, the power at the eye-piece must be checked with a power-meter. In current operation of the AOSLO (Jan 2019), this level is expected to be below 140 µW, which is well below (<20%) of the maximum permissible exposure (MPE). Only after the power level at the eye has been confirmed, will the participant be invited to look into the system.

During imaging, a tiny spot of light will be scanned over a small patch of the participant's retina (a patch with angular extent of about 1.0° by 1.6°, corresponding to approx. 300 µm by 480 µm on the retinal surface).

Safety calculations of light exposure are performed for worst-case scenarios. The Maximum Permissible Exposure (MPE) from the viewing position based on two hours continuous viewing (and incorporating the field sizes and wavelengths to be used) has been calculated, and the maximum corneal exposure is <20% MPE. In practice, the corneal exposure is kept to the minimum required to obtain good images, which is typically <12.5% MPE, and viewing will not be continuous as imaging will take place in short bursts of a few minutes with breaks in between.

As at January 2019, the AOSLO is not used for research with children.