Note: This Approved Procedure can be combined with one of:
CUREC_AP_IDREC_08 "Magnetoencephalographic (MEG) Recordings from Adult Participants";
CUREC_AP_IDREC_17 "Non-invasive Magnetic Resonance Imaging (MRI) Investigations in Research Participants"
CUREC_AP_IDREC_18 "Studies using Psychophysiological Methods with Adults".

ELECTROPHYSIOLOGICAL RECORDINGS FROM THE SCALP IN ADULT PARTICIPANTS

1. SCOPE

Several research groups across the Medical Sciences Division do research involving measurements of electrical activity from the brain, known as electroencephalography (EEG). This Approved Procedure is intended to cover the use of EEG in adult participants, not recruited because of any clinical condition.

EEG provides a readout of the electrical activity of the brain while people perform cognitive tasks by measuring voltage changes directly from sensors (electrodes) that are attached to the scalp, and is particularly well-suited for studying the time-course of mental events. By averaging together EEG activity that follows a specific type of event, it is possible to extract brain activity that is specific to the processing of that event type. The averaging procedure eliminates random electrical noise in the environment and from ongoing mental activity that is unrelated to the event of interest; and reinforces the consistent brain activity associated with the analysis of the event. Several types of averaged waveform can be computed, and all offer many advantages to the investigation of cognitive functions. They provide a direct measure of brain activity in real-time without requiring overt behavioural responses. The ability to measure information processing in the brain without requiring responses is of great value in the study of several cognitive functions, such as perception, attention and language processing.

Sensor placement and preparation typically requires about half an hour. The procedure involves placing a snug fitting cap made of an elasticated cloth material on the participant's head. This cap contains electrodes made up of a conductive metal (tin or silver/silver chloride), which establishes electrical contact between the scalp and the electrodes by means of an electrolyte gel that contains conductive salts. In order to achieve a low-impedance connection, it is often necessary to prepare the area of the scalp under the sensor by cleaning it with rubbing alcohol and rubbing an abrasive substance using a cotton swab. The procedure should never cause pain or harm to the participant - any discomfort should be reported immediately by the participant, who is encouraged to do so.

2. TRAINING OF RESEARCH STAFF

Training in application of sensors and setting up the recording should be given by an experienced researcher, and no inexperienced person should be left in sole charge of an EEG study.

Researchers who wish to test outside working hours should refer to their own departmental Standard Operating Procedure (SOP) for lone working.

3. METHODS FOR RECRUITING PARTICIPANTS

Potential participants will be identified by one of the methods outlined on the CUREC application. When a potential participant registers interest, further information (prepared using the associated template information sheet) will be sent, together with details as to how to confirm they would like to take part. It is acceptable to mention rewards in recruitment advertisements for this kind of research, where competent adults volunteer themselves to take part, and there is no significant risk to the participant other than boredom.

4. INFORMATION PROVIDED TO PARTICIPANTS

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.

Please refer to, and use, the template **Information Sheet associated with this Approved Procedure.**

5. CONSENT OF PARTICIPANTS

Written consent will be obtained from all participants using the **Consent Form associated with this Approved Procedure.**

Written consent will be obtained from all participants on the day of the first session, following a suitable (at least 24 hour) period during which they will have had an opportunity to read the Information Sheet and discuss their participation with others and with the researchers. An experienced researcher will answer all and any questions before consent is obtained. Consent will be taken by a member of the research team who has appropriate training, as confirmed by the Principal Investigator. Participants will be reminded that they are able to change their mind and withdraw from the study at any point without penalty. Vulnerable populations or participants who are unable to provide informed consent in English are not covered by this Approved Procedure.

Copies of the signed consent forms will be provided to the participants along with the information sheet. The originals, along with the TMS safety questionnaires administered before every session, will be kept in the files of the researchers.

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

6. COMPENSATION

Compensation (either financial or in kind) may be offered to participants for their time and travel expenses. Some studies (for example, those investigating reward processing) may offer a performance-related reward. Individual proposals will detail the value (if any) of compensation to be offered. Compensation is limited to the time and inconvenience incurred as well as reasonable travel expenses and will in no circumstances consist of course credits for student participants.

Consideration should be given to how and when participants are told about any recompense. Participant information sheets and recruitment materials should state that recompense will be made so that potential participants are not discouraged from participating by the associated costs. If reimbursement values are included, advertisements must not emphasise the value of the payment

(for example, through the use of formatting). 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

7.1 Risks to participants

EEG recording has been used safely for many years, and we are aware of no cases of adverse events. EEG equipment comes from certified suppliers, who are obliged by law to adhere to published guidelines on electrical and mechanical safety (IEC-601).
During the session, participants are asked to indicate if they feel any discomfort, in which case the procedure is stopped. It is possible to pause the procedure if a participant needs to take a break or visit the bathroom, or if a fire alarm goes off.
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 such as "you've only got very small brain responses".
One consideration for researchers is hygiene: the sensors, caps and instruments used to apply gel are soaked in a disinfectant solution after each use. In the majority of cases, participants wash their hair to remove gel at the end of the session, and freshly laundered towels are provided in each case.

7.2 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 scalp of a participant.

7.3 Infection Control

8. INFECTION CONTROL MEASURES ARE IN PLACE AT WIN AND THE DEGREE OF THESE MEASURES MAY VARY DEPENDING ON THE LEVEL OF RISK PRESENTED AT THE TIME. INDIVIDUAL RESEARCHERS SHOULD COMPLETE A RISK ASSESSMENT FOR THEIR PROJECT IF THERE ARE PARTICULAR CONCERNS WITH THEIR RESEARCH POPULATION AND/OR RESEARCH TEAM REGARDING RISK OF INFECTION.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 would be reported in the Departmental Safety Book.

9. DATA MANAGEMENT AND PROTECTION

The research must be conducted in accordance with the University's Policy on the Management of Data Supporting Research Outputs; CUREC's Best Practice Guidance 09 on Data collection, protection and management; and Research Data Oxford's guidance on data backup, storage and security.

Participants' informed consent must be obtained for participation in the study, which includes the collection, storage and retention of all data related to the study. Directly identifiable personal information held by the research team (such as contact details, consent forms and screening forms, which include name or other identifiers) must be held securely - either in paper format in lockable filing cabinets with access only by the University researchers, or in a password-protected database,

on an encrypted machine or on a protected server. These should be servers provided by the University where the risks and access have been professionally managed. Other servers will require security assessment by University Information Security. Other research data (e.g., EEG files, behavioural reaction time files, questionnaires) must be labelled with a code number rather than a name or initials, and accessed via a password- and firewall-protected server.

The keys linking personal details to the codes used to label other research data may be kept in paper format in lockable filing cabinets with access only by the researchers, or in a password protected spreadsheet on University approved servers. The keys should be kept separately from other study data. Such keys should be destroyed as soon as no longer needed, as should other personal data (with due regard to University and other guidelines on data retention, e.g. of consent forms).

Contact details may be retained after the end of the research where the participant agrees to be contacted for future studies. These should be held separately from the study data, and a copy of the consent form retained as evidence of agreement to be contacted. For participants who do not wish to be contacted in the future, contact details will be destroyed as soon as possible after completion of their research participation. Personal and research data may be viewed by regulatory bodies and designated individuals within the University of Oxford for the purposes of monitoring and auditing the research with the written consent of the participant.

Anonymised data may be shared with other research institutions, including researchers outside of the UK and the EU, for use in other and future research studies. For detail on anonymisation, please refer to the Information Commissioner's Office (ICO) Code of Practice –'Anonymisation: managing data protection risk', especially Appendix 2 and Annex 1.

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.

10. CHANGE HISTORY

Version No.	Significant Changes	Previous Version No.
3.0	Retitled 'Approved Procedure' (previously 'Protocol'). Approved by CUREC, 19 November 2015	N/A

Version No.	Significant Changes	Previous Version No.
4.0	Section 1 updated by members of Experimental Psychology to reflect current practice	3.0
4.1	Updated hyperlinks for new CUREC website	4.0
4.2	Added a statement to say this procedure can be combined with AP17 (MRI)	4.1
4.3	Removed reference to sections of the old CUREC 1 checklist	4.2
5.0	Revision of section 1 to reflect current practice. Addition of a statement about lone working to section 2.	4.3
5.1	Administrative revisions.21	5.0
5.2	Complete update of data management section - text approved by CUREC Nov 2021	5.1
5.3	Addition of section 7.3 about infection control. This is to replace an additional supplementary document that had been in place during the COVID-19 pandemic	5.2