STUDIES INVOLVING ELECTROPHYSIOLOGICAL RECORDINGS FROM THE SCALP IN ADULT VOLUNTEERS

1. SCOPE

Several research groups across the Medical Sciences Division do research involving measurements of electrical activity from the brain. This is known as electroencephalography (EEG).

This approved procedure is intended to be used for cases where:

- all responses in section D of the CUREC 1 form are in unshaded boxes, except for question D12
- where the participants are adult volunteers, 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 elastics cloth material on the subject’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 or by scratching the surface of the scalp with a blunt wooden stick. The procedure does not ordinarily cause pain or harm to the participant, though some participants do report a little discomfort or itching when the signal quality is being checked at the beginning of the recording. However, this is brief, typically lasting less than 30 seconds, and only occurs once during the testing session.
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.

3. **METHODS FOR RECRUITING PARTICIPANTS**
   
   Participants for EEG studies are typically recruited via posters around the University (see example attached). It is acceptable to mention rewards in recruitment advertisements for this kind of study, 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 specific details provided will vary depending on the study, but should always be on University Headed paper, showing the Departmental name and address.

   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. Information sheets must be submitted with the CUREC 1 form for specific projects.

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

5. **CONSENT OF PARTICIPANTS**

   - Written informed consent must be obtained from all participants using the Consent Form associated with this approved procedure. 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.

   Guidance on the informed consent process can be found at: http://researchsupport.admin.ox.ac.uk/governance/ethics/resources/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

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.

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 would be reported in the Departmental Safety Book.

9. 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.

10. CHANGE HISTORY

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<td>3.0</td>
<td>Retitled ‘Approved Procedure’ (previously ‘Protocol’). Approved by CUREC, 19 November 2015</td>
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<tr>
<td>4.0</td>
<td>Section 1 updated by members of Experimental Psychology to reflect current practice</td>
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<tr>
<td>4.1</td>
<td>Updated hyperlinks for new CUREC website</td>
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Central University Research Ethics Committee (CUREC)

Approved Procedure: IDREC_03_Version 4.2

**Title:** Studies Involving Electrophysiological Recordings from the Scalp in Adult Volunteers

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<td>4.2</td>
<td>Added a statement to say this procedure can be combined with AP17 (MRI)</td>
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