# PROCEDURAL PROTOCOL APPLICATION:

**STUDIES INVOLVING NON-EVASIVE ELECTROPHYSIOLOGICAL RECORDINGS FROM THE SCALP IN ADULT VOLUNTEERS**

1. **SCOPE: Please outline the methodology for which procedural protocol approval is sought:** Researchers within the psychology division of the University of Stirling have been conducting studies employing electroencephalography (EEG) recordings for many years. This approved protocol procedure is intended to be used for all cases of EEG recordings from the scalp (by qualified researchers) using healthy adult volunteers, and not for clinical populations or purposes.

EEG measures the electrical voltage signals of brain activity directly from electrodes that are positioned on the scalp, and is particularly well-suited for studying the time-course of cognitive events. The electrodes are small circular metal (Ag/AgCl) discs, embedded within an elasticated cap. By averaging together segments of EEG time-locked to a specific type of event, it is possible to extract measures of neural activity related to the processing of that event type, including the time course and frequency of brain oscillations. This averaging procedure reduces random electrical noise in the environment that is unrelated to the event of interest. The resulting averaged waveform is known as an ‘Event-Related Potential’ (ERP). ERPs afford many advantages to the investigation of cognitive functions and their neural bases. 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 is of great value in the study of several cognitive functions, such as perception, attention, memory, and language processing.

Electrode placement and preparation typically requires fifteen minutes to about half an hour. The procedure involves the placement of a fitted electrode cap made of an elasticated cloth to the participant’s head. Conductive gel containing salts are then placed under each electrode using a syringe with a blunt ended gel delivery device in order to form a connection with the scalp. To further ensure a stable connection, it is also necessary to use a blunt wooden stick. The stick is used to move hair out of the way and push the gel onto the scalp, removing dead skin cells in the process. The skin is not broken at all during this procedure. Prior to partaking in any activity in the lab, participants are verbally briefed about the procedure, shown all the materials, and asked whether they are phobic of needles (any participants phobic of needles are not tested even though needles are not used). The procedure does not ordinarily cause pain or harm to the participant.

## TRAINING OF RESEARCH STAFF:

Training in application of electrodes and setting up the recording should be given by an experienced lab technician or researcher. Under no circumstances will an inexperienced researcher be left in sole charge of an EEG study. (SOPs attached).

## METHODS FOR RECRUITING PARTICIPANTS:

Participants for ERP studies are typically recruited via posters placed around the University campus, Stirling portal adverts. Participant are generally paid her hour at a level agreed with the ethics committee. Research participation tokens for student’s course credits may be awarded where the ethics committee has approved this practice in relation to course accreditation by the British Psychological Society It is acceptable to mention compensation for the participant time in advertisements for EEG studies, where people volunteer themselves to take part, and there is no significant risk to the participant.

## INFORMATION PROVIDED TO PARTICIPANTS:

The specific details provided to participants will vary depending on the study, but will always be given using our information sheet template (see attached), and will always include:

* the name of the study;
* the most recent date and the version number of the information leaflet that has been approved by the Ethics Committee in the header/footer;
* the name(s) and status(es) (e.g. doctoral student) of the researchers carrying out the study and how to contact them;
* a brief rationale of the study, including its purpose and value;
* why potential participants are being invited to take part in the research (e.g. because they are residents of a particular place, users of a particular facility, speakers of a particular language);
* an explanation of what the potential participant would do, including estimated duration of the test session and where it would take place;
* that potential participants can ask questions about the study before they decide whether to participate;
* that potential participants can choose whether they participate and, if they agree, they may withdraw from the study without penalty at any time by advising the researchers of this decision (if the potential participants are students there should be particular reassurance that there is no academic penalty for non- participation or withdrawal, i.e., withholding course credit);
* information about any additional personal information that would be obtained;
* information about who would have access to the data, how it will be stored and what will happen to the data at the end of the study;
* statement that the data would be anonymised;
* what benefits (direct or indirect) may accrue to the participants in the study;
* what risks are involved in the study;
* that the project has received ethics clearance through the University of Stirling’s ethical approval process for research involving human participants;
* where applicable, a note to explain that the research will be written up as a student’s thesis and how the personal data included in that thesis will be published and stored;
* the procedure for raising a concern or making a complaint;

The information leaflet should be written in simple language that is understandable by a 12 year old. Word processing packages are available to assist with ensuring a suitable reading age.

## CONSENT OF PARTICIPANTS

All participants will always sign a consent form which will be given using our consent form template (see attached), and will always include:

* the name of the study;
* the most recent date and the version number of the information leaflet that has been approved by the Ethics Committee in the header/footer;
* the name and status (e.g. doctoral student) of the researcher collecting the information and how to contact him/her;
* declarations that the participant:
	+ has read the participant information sheet with the version number and date that was approved by the Ethics Committee;
	+ has had the opportunity to ask questions about the study and has received satisfactory answers to questions, and any additional details requested;
	+ understands that s/he may withdraw from the study without penalty at any time by advising the researchers of this decision;
	+ understands that this project has been reviewed by and received ethics clearance through the University of Stirling’s Research Ethics Committee;
	+ understands who will have access to personal data provided, how the data will be stored, and what will happen to the data at the end of the project;
	+ understands how to raise a concern and make a complaint;
	+ agrees to participate in this study.

Participants will initial boxes, print and sign their name with the date, and the researchers who secure the consent will also print and sign their name with the date.

## FINANCIAL AND OTHER REWARDS TO PARTICIPANTS

Participants may be compensated for their time with either course credit (via psychweb) or money at a University of Stirling approved rate.

### POTENTIAL RISKS TO PARTICIPANTS/RESEARCHERS/OTHERS: Identify and outline steps taken to minimise risks

* 1. **Risks to participants**

EEG recording has been used safely for many years, and we are aware of no cases of adverse effects of participation. EEG equipment comes from certified suppliers of medical equipment, who are obliged by law to adhere to published guidelines on electrical and mechanical safety (IEC-60601). During the session, participants are asked to indicate if they feel any significant 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 are strictly advised 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 electrodes, caps, and instruments used to apply gel are soaked in an alcohol solution after each use. The instruments and consumables used to apply the gel which are in contact with the scalp are discarded after use. The syringes which have not been in contact with the participant are rinsed clean. Participants are provided with hair washing facilities to remove gel at the end of the session, and freshly laundered towels are provided in each case.

### Risks to researchers

Again, the main way to avoid risk is to adhere to a regime of hygiene. Hands are washed before and after any contact with a participant.

## 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 division’s Safety Book. First aid help is available through the division’s designated health and safety officers.

## DISCLAIMER

The following information shall be included in the Participant Information Sheet:

Please note that researchers at Stirling are not trained to detect abnormal brain activity. EEG research scans at the University of Stirling are not appropriate or used to diagnose medical conditions affecting the brain, or for detecting structural abnormalities.

## 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:**

|  |  |  |
| --- | --- | --- |
| VersionNo. | Significant Changes | Previous Version No. |
| 1 | N/A | N/A |
| Date of Review |  | e.g., 28/02/17 |  |
| Date for Next Review |  | e.g., 28/02/21 |  |

# EEG Researcher Training Checklist

**EEG Researcher Training Checklist:** This form should be used for all researchers/students undergoing EEG training in the PIL lab, and should be completed by a qualified researcher. When completed, please print and send to the lab manager, Catriona Bruce, for our records.

**Name of researcher/student:**

**Number of training sessions completed:**

**Name of supervising trainer: Date:**

The named researcher/student above has completed sufficient training in these given criteria below (check boxes), and is therefore qualified to conduct EEG studies at the PIL lab.

### Participant Welfare:

* Information sheets; Consent forms; Debriefing
* Hair-washing
* Participant comfort throughout testing

### Cap Placement:

* Measuring head; placement of mastoid, VEOG, and HEOG electrodes; alignment

### Preparing Electrodes:

* Scalp preparation
* Impedance checking
* Bad/broken channels

### Handling systems:

* Amplifiers
* System display
* Neuroscan & eprime
* EEGO sports system (if applicable)
* Data storage, back-up, and archiving

### Laboratory Hygiene:

* Cap washing procedures & sterilisation
* Storage of equipment
* Notification of faulty equipment
* Consumables (includes all stock such as towels, shampoo, sticks, gel, etc.)
* Cleaning lab workbenches & computer desks

**Any additional comments:**

# COLLECTING ERP DATA

This is a list of equipment required:

* Electrode cap
* Electrode collars
* Syringe
* Blunt Applicator
* Sticks
* Gel
* NuPrep Skin Preparation
* Alcohol
* Gauze swab
* Towel

#### *Before the Participant Arrives*

* Make sure the electrode gel is easily accessible by making sure there is plenty of gel in the bottle and that it has been allowed to stand in order to get all the gel to the bottom for ease of dispensing. The gel should be returned to the fridge when not in use.
* Fill the syringe with electrode gel by removing the plunger, squeeze in some gel until about three quarters full. Replace the plunger and depress it gently to expel any air bubbles and until the gel comes through the applicator. The aim is to have no air bubbles in the syringe. Once filled, leave the cap on the applicator until ready to use.
* Layout 6 electrode collars to be attached to the ‘drop-down’ electrodes, the wooden stick, alcohol swab, NuPrep

and gauze swab for applying the NuPrep.

* Switch on both computers and logon to the local account. (user account “pilusers”, password “erpers”) On the experiment presentation PC, load the EPrime programme and open the experiment to be run. On the second data acquisition PC, open ‘Scan 4.3’ and select ‘Aquire’ in readiness to record data. Check that the appropriate setup file for your study is loaded. (default is aegis.ast but individual researchers may use their own)

#### *Participant Arrives*

* Remember to hang the ‘EXPERIMENT IN PROGRESS’ sign on the main lab door so that there are no disturbances. The Participants may feel uncomfortable with the cap on their head when people are walking in and out of the room. In addition, the noise of the door opening and closing may produce unwanted noise on the EEG recordings when the experiment is in progress.
* Try and make the participant as comfortable as possible on arrival.
* Give the Participant the opportunity for a comfort break.
* Give them the lab information sheet and answer any questions they may have before getting them to read and sign a consent form. This should be filed along with all other information on the experiment in a dedicated file.
* Sit the participant down in front of the mirror in the capping area of the lab.
* Measure the circumference of the participant’s head just above the eyes and the ears and select the appropriate cap. (Small: 53cm – 56cm. Medium: 56cm – 59cm). The cap should be tight enough so that the electrodes are flush against the head otherwise it will be difficult to ensure a good connection between the electrode and the scalp. If the correct sized cap is used the cap will not be uncomfortably tight for the subject.

#### *Skin Preparation*

* Use the skin prepping gel – NuPrep to scrub the areas where electrodes will be positioned directly onto the surface of the skin: the mastoids (bone behind the ears), the forehead, the left cheek directly below the eye, and the temples. Apply the gel to the gauze swab and firmly wipe these areas.
* Clean these areas with an alcohol pad to take away any gel residue and dry if necessary to ensure that the electrode collars can be securely attached.

#### *Electrode Cap Placement*

* Chat to the participant and explain every step as you are doing it to keep them fully informed and comfortable with the procedure.

### In particular, warn them about the blunt applicator before producing it.

#### *Mastoid Electrodes*

* Apply the mastoid electrodes first; they need to be detached from the cap in order to do this. They should be positioned on the most prominent part of the mastoid bone behind each ear. Place the electrode collars on the skin and position the mastoid electrodes (M1 and M2) **firmly** on top ensuring that the holes on the collars and the holes in the electrodes align. Fill the electrodes with conductive gel by inserting the blunt applicator into the electrode hole until it touches the skin, gently depress the syringe plunger while pulling it out slowly to leave a small blob of gel in the sub electrode area. Use the wooden stick in a twisting motion, **lightly** abrade the area and push the gel down against the skin.

## CARE MUST ALWAYS BE TAKEN WHEN ABRADING THE SKIN AND FEEDBACK SHOULD ALWAYS BE SOUGHT FROM THE PARTICIAPNT.

#### *Cap Placement*

* Put the cap on the subject’s head by placing the FPZ electrode in the middle of the forehead (you can ask the participant to hold it in place) and then enclose the head from front to back. Rest the electrode leads on their shoulder so that their weight is not pulling on the cap.
* Ensure correct positioning of the cap. Measure from the nasion (area in between the eyebrows) to the inion (bottom of the occipital bone). Half the measurement to determine the exact position of the central electrode (CZ) and adjust the cap position until CZ is correctly sited.
* Next adjust the cap so that the midline electrodes (characterised by ‘z’ in their labels) are in a straight line from the front to the back of the head. It is helpful to use the mirror to do this. Once in position, apply the chin strap to ensure a secure but comfortable fit. Re-attach the mastoid electrodes.
* Attach the vertical (VEOG) electrodes, placing one just above the left eyebrow central to the eye (VEOU) and the other (VEOL) on the cheekbone in a line directly below the upper one. Then attach the horizontal (HEOL) to the outer edge of the left eye and the HEOR to the equivalent position on the right.
* Do a final check that the cap is still correctly positioned by re-checking the CZ electrode is central on the vertex, the midline is still straight and the Participant is comfortable with the cap and electrode positioning. **N.B. It is essential that all the electrodes are in the correct position with regard to the skull otherwise the EEG will be confounded.**
* Insert gel into all of the cap electrodes using the same technique as for the mastoid electrodes. Be systematic so that no electrodes are missed. Take care not to use too much gel you can always add more. This is important as gel can spread under the electrodes causing a bridge between them. This means that two single electrodes will effectively be combined into one larger one, which will confound the EEG.

###  Take great care injecting gel into the eye electrodes. Ask the Participant to close their eyes and always protect the area by holding the electrode between two fingers to help shield the eye before introducing the syringe.

#### *Impedances*

* Take the Participant through to the experiment room and connect the cable to the headbox securely. Make sure they are comfortable and positioned in such a way that they will not have to move to participate in the experiment.
* ‘Aquire’ should already be open on the data acquisition PC so click the impedences (Z) icon. A new screen opens showing a series of coloured boxes (usually bright pink to begin with); each box represents the impedence of an electrode and the layout of the boxes reflects the positon of the electrode on the cap. There is an impedence scale on the right hand side that shows a range of colours from bright pink that represents 50kΩs to black representing 2kΩs.
* Starting with the **reference** electrode, use the wooden stick to move the hair, push the gel down onto the scalp and lightly abrade the area under the electrode. The electrode boxes should flash and may change colour. Do the same to the **ground** electrode and this should result in the layout of electrodes whose boxes are an assortment of colours that indicate a level on the impedance scale (the boxes representing the mastoid electrode may have turned black due to having been prepped earlier.) **PLEASE NOTE: IF THE CZ ELECTRODE AND/OR CPZ ELECTRODE APPEAR BLACK AT THIS STAGE THEN THE REFERENCE ELECTRODE HAS BEEN BRIDGED AND DATA SHOULD NOT BE RECORDED AS THE EEG DATA WILL BE CONFOUNDED)**
* Move onto the eye electrodes and then work through all of the electrodes using the wooden stick until all boxes have turned to dark blue. **Keep asking the subject if they are okay and to tell you if they feel any discomfort.**

#### *Troubleshooting*

* More gel can be added if required to improve the scalp/electrode connection.
* Boxes that do not change colour at all are indicative of a broken electrode. In this situation, data recording can usually continue as the affected channel can be reconstituted during data processing. Make a note of which electrode is affected so that this can be done and also alert the technician so that a repair can be made.
* If two or more electrodes flash simultaneously then this indicates they have been bridged by gel. Again, data recording can usually continue but affected electrodes should be noted as this may impact on the data analysis.
* An electrode that appears black one minute but then is bright pink the next may just need a bit more gel but could also indicate a broken electrode that requires repair.