Note: This Approved Procedure can be combined with Approved Procedure CUREC_AP_IDREC_18 "Studies using Psychophysiological Methods with Adults".

MAGNETOENCEPHALOGRAPHIC (MEG) RECORDINGS FROM ADULT PARTICIPANTS

1. SCOPE

This approved procedure concerns the recording of magnetic signals from outside the head using a magnetoencephalography (MEG) brain scanner. The purpose of MEG experiments is to non-invasively explore the time courses and/or locations of human brain activity. Many MEG experiments use visual or auditory stimuli to investigate perceptual or cognitive processes; this approved procedure is for studies that do NOT use stimuli that will be emotionally upsetting, painful or harmful. This approved procedure is intended for cases where the participants are adult volunteers, not recruited through the NHS or because of any clinical condition.

MEG studies will frequently require participants to undergo structural and/or functional magnetic resonance imaging (MRI) scanning in order to locate the brain structures that are the sources of recorded MEG signals. MRI scanning will take place in a separate visit, of maximum two hours duration, to the Wellcome Centre for Integrative Neuroimaging (WIN – formerly FMRIB), the Oxford Centre for Clinical Magnetic Resonance Research (OCMR) or the Oxford Centre for Human Brain Activity (OHBA) scanner, and will comply with the Approved Procedure described in CUREC_AP_IDREC_17. MRI and MEG are complementary, but different, brain scanning techniques; consequently, functional MRI scanning will aim to answer the same experimental questions as with MEG by using similar stimuli and tasks optimised for MRI. Similarly to the MEG data, the MRI data will not contain identifying information, but will be automatically assigned a code that links the data with the participant's identity in a secure database that can only be accessed by a limited number of key personnel. Within a study, both the MEG and MRI data will be labelled with the participant's ID code for that study, and in this way the data can be linked for analysis. Sometimes researchers want to use structural MRI data from previous studies at WIN, OCMR or OHBA; to enable this all sites have a standard operating procedure, which will be followed by researchers and requires informed consent from the participant.

MEG recording may also be combined with simultaneous electroencephalography (EEG) recording (see below); and/or with electromyogram (EMG); and/or with eye-movement recordings using an eye-tracker. Eye tracking is a safe and non-invasive technique, which utilizes infrared light and a standard digital camera to record instantaneous gaze directions.

MEG scanners allow researchers to view brain activity whilst a particular task is performed, showing both where and when different parts of the brain are active. The scanner measures the tiny magnetic fields generated by the electrical currents related to brain activity. MEG scanners allow the participant to either sit upright, or lie supine, with her/his head inside a helmet-shaped measurement device, which contains a sensor array.

The MEG scanner is housed in a magnetically shielded room as otherwise the magnetic fields in the environment would obscure the tiny magnetic fields produced by brain activity. MEG measurements

can be affected by metal in the shielded room and so participants will be asked to remove metallic objects that they are carrying or wearing, for example, jewellery, body piercings, removable dental braces and clothing with metal parts. Participants who wear glasses will be given special non-metallic glasses to wear, or may wear ther own contact lenses if available. It is helpful to know the participant's lens strength prior to participation in the research In some cases, participants with metal in their body (e.g. plates, dental work, pacemakers) may not be suitable for MEG scanning as the collected data would be too noisy.

The ability to measure neural activity in awake, human participants is of great value in the study of several cognitive functions, such as perception, attention, and language processing. MEG provides millisecond time resolution, therefore, like EEG, the technique is particularly well-suited for studying time-courses of brain events. MEG can be used to record neural responses to specific perceptual, cognitive or motor events, or to record on-going neural activity during different types of psychological states, such as during attentive task performance or simply resting.
Unless doing simultaneous EEG-MEG, there is no need to place individual sensors directly on the scalp. The magnetic signals can be recorded with sensors that are simply very close to the head. Preparation requires about half an hour. As eye movements cause large signals in the MEG sensors, eye-movements are monitored by placing up to four electrodes above, below, and to the side of the eyes before the measurement. As the heart can also cause large MEG signals, heart signals are monitored by placing two electrodes on the arms, one on either wrist. Depending on the specific research question, some additional electrodes may be used to record muscular activity.

Simultaneous EEG-MEG may be used when researchers wish to compare the two types of brain signal. The principle of EEG when done with MEG is the same as for standalone EEG; however, MEG compatible equipment must be used. This approved procedure fully covers simultaneous EEG-MEG and so it is not necessary for MEG researchers to also cite the approved procedure for standalone EEG (CUREC_AP_IDREC_03) recording. Conversely, researchers wanting to do standalone EEG without MEG should not cite this approved procedure.

Simultaneous EEG-MEG involves placing a snug fitting elasticated cap, which has electrodes mounted in it, on the participant's head during the set-up procedure. This cap contains MEG compatible electrodes and is designed to integrate with the MEG electronics. The researcher then aims to minimise the impedance between the electrodes and the scalp. To visualise this, the MEG compatible cap is connected to a dedicated computer and specialist software displays the impedance for each electrode. Using abrasive gel and a cotton swab, the researcher moves hair to the side from under each electrode and rubs the scalp to remove dead layers of skin. This may feel unusual to the participant, but should not be uncomfortable. When satisfactory impedances are achieved, each electrode is filled with conductive gel. Preparation with the EEG cap may increase preparation time by an hour.

To monitor the head position in the scanner, five indicator coils are placed on the participant's head (on the forehead and behind the ears) and are spatially digitised. If EEG-MEG is being performed then the spatial location of each electrode is also digitised. The procedure does not cause pain or harm to the participant.

Following this the participant is taken into the scanner room to start the experiment. Researchers are trained to confirm with participants that they are comfortable in the scanner and with the research activities.

2. TRAINING OF RESEARCH STAFF

Training in the use of the equipment and setting up the recording of individual participants should be given by an experienced researcher, and no inexperienced person should be left in sole charge of a MEG study.

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.

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.

The information sheet will explain that the research carries no significant personal risk and that the data will be pseudonymised from the start. Pseudonymised means that the dataset itself does not contain information sufficient to identify the participant. However, the code assigned to the dataset can be linked to the participant's identity through a password protected database that can be accessed by a limited number of approved staff.

The information sheet should explain the procedure that will be followed if abnormal neural activity is suspected.

If researchers require previously acquired MRI scans from WIN, OCMR or OHBA, the information sheet will explain this procedure.

In addition, a verbal explanation will be given to all participants by the researcher conducting the research, and participants will be given the opportunity to ask further questions about the research.

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.

For studies that require MRI scans for participants from previous studies, the consent form will include a statement that the participant agrees data from WIN, OCMR or OHBA may be used in conjunction with this study.

Please refer to the **Consent Form associated with this Approved Procedure.**

Please also see our guidance on the informed consent process.

6. COMPENSATION

Compensation (either financial or in kind) may be offered to participants for their time and inconvenience incurred, as well as reasonable travel expenses. Some studies (for example, those investigating reward processing) may offer a performance-related reward. Individual research proposals will detail the value (if any) of compensation to be offered. The amount may be stated on the Participant Information Sheet, but cannot be disclosed on the advert as this could be coercive.

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

MEG and EEG recording has been used safely for many years. We are aware of no cases of adverse events. It should be stressed that this approved procedure involves purely the recording of weak, magnetic and electric signals: no magnetic field or electric current is applied to the brain, and no magnetic or electrical stimulation is involved. The MEG and EEG equipment comes from a certified supplier of medical equipment, who is 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 also possible to pause the procedure if a participant needs to take a break or, for example, if there is a fire alarm.

Brain signals vary widely from individual to individual. Researchers undertake not to make any judgemental comments on the signals seen in participants, to avoid causing unnecessary anxiety, for example, the researcher should not make a comment such as "you've only got very small brain responses".

Electrodes, EEG caps and instruments used to abrade the scalp are soaked in disinfectant solution after each use. Participants often wash their hair to remove conductive gel at the end of the session, shampoo and freshly laundered towels are provided for this.

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. Researchers should complete a risk assessment for their research if there are particular concerns with their research population and/or research team regarding risk of infection.

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. COMMUNICATION OF RESULTS

It is unlikely that results from MEG or EEG recordings will be meaningful to people other than the researchers. It is made clear on both the participant information sheet, and the consent form, that the MEG or EEG procedure is not for diagnostic purposes.

Results from individual participants should not be fed back to the participants, and this should be stated in the information sheet. However, wherever possible, researchers should provide feedback about the results from the research as a whole.

10. DUTY OF CARE ISSUES / CONFIDENTIALITY

All MEG and EEG studies using this approved procedure are for research only and will not be used to attempt any medical diagnosis. In the very unlikely event that a researcher observes pathological activity there is a standard operating procedure (SOP OHBA_0001) that will be applied.

11. 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.

All MEG (with or without EEG) datasets are collected using the manufacturer's 'Patient' settings (rather than the 'Volunteer' settings which would include the participant's name and date of birth in the dataset). These 'Patient' settings give the dataset the highest available levels of security and confidentiality. Each dataset is identified by a code number generated by the MEG system, e.g.

case_0123, and only this number (also known as the MEG specific participant identifier) appears in the dataset together with the study code. The participant identifier is referenced in a protected database containing the participant name and other details, which can only be accessed by the study's researchers and a limited number of key OHBA personnel.

In summary, the datasets are standalone files that are in effect de-identified. The participant can only be identified through the use of the secure database and this is restricted to key people. The database will be kept indefinitely as identification in the future may be required for medical reasons or if the participant consents to their historical data being linked.

Researchers are provided with information on the UK General Data Protection Regulation (UK GDPR) before starting a study, and are given guidance from members of OHBA to ensure they adhere to the Regulation.

The points below summarise the default data handling procedures:

- MEG (with or without EEG) data is collected as 'Patient'.
- Files that link data to names are password protected and stored on a password protected computer. The MEG database is securely stored indefinitely but any other files are deleted as soon as not required.
- Consent forms and, if used, screening forms, are stored by the researcher in a locked filing cabinet in a room that is locked when not in use. The standard storage of these documents is five years. These forms do not contain the participant's study ID code or MEG system number.
- Participant contact details may be stored in a password protected file on a password protected computer when necessary, for example, if the participant has requested to receive a summary of the combined study results (personal results should not be sent out to participants). These details are not stored with the participant's study ID code or MEG system number.
- Researchers will ensure all participants are fully aware of how their data will be handled.

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.

12. CHANGE HISTORY

Version No.	Significant Changes	Previous Version No.
3.0	Retitled `Approved Procedure' (previously 'Protocol'). Approved by CUREC, 19 November 2015	N/A
3.1	Updated to reflect Current Practice	3.0
4.0	Updated to clarify that the procedure may be combined with that for EEG (AP03) and/or that for Psychophysiological methods with adults (AP18)	3.1
4.1	Updated hyperlinks for new CUREC website	4.0
4.2	Changed references of Functional Magnetic Resonance Imaging of the Brain (FMRIB) to Wellcome Centre for Integrative Neuroimaging (WIN)	4.1
4.3	Updated for General Data Protection Regulation (GDPR)	4.2
5.0	Updated to reflect current practice	4.3
5.1	Administrative revisions for accessibility	5.0
5.2	Revision of section 6 – compensation to reflect text on other procedures. Addition of text to section 7 about infection control. This is to replace an additional supplementary document that had been in place during the COVID-19 pandemic. Administrative revisions. Complete update of data management section – text approved by CUREC Nov 2021	5.1