STUDIES INVOLVING FUNCTIONAL TRANSCRANIAL DOPPLER ULTRASONOGRAPHY TO MEASURE CEREBRAL LATERALISATION IN ADULT VOLUNTEERS

1. SCOPE

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.

Because this method constitutes an ‘invasive procedure’ as defined in the CUREC glossary, such research cannot be approved on the basis of checklist completion alone. This approved procedure is intended to be used for cases where:

- all responses to sections A and B of the CUREC/1 form will be NO, except for question B7
- where the participants are adult volunteers, not recruited via the NHS
- the study does not involve brain stimulation by TMS or TCS, the use of any pharmacological agents, or the collection of biological samples
- where the study involves no deception.

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).

Doppler ultrasound measurements will be undertaken while the participant performs cognitive tasks such as listening to speech or remembering images from a sequence. The total maximum task duration is 2 hours.
Central University Research Ethics Committee (CUREC)

Approved Procedure: IDREC_10_Version 2.1

Title: Studies Involving Functional Transcranial Doppler Ultrasonography to Measure Cerebral Lateralisation in Adult Volunteers

2. TRAINING OF RESEARCH STAFF

Accurate placement of ultrasound probes is a skill that has to be learned, and it is recommended that all those using this method with participants should have sufficient practice, supervised by a researcher experienced in the method, to be able to locate the window in the temporal bone accurately within around 10 minutes or less with the participant.

3. METHODS FOR RECRUITING PARTICIPANTS

Participants for fTCD studies are typically recruited via posters around the University. 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.

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 is 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.

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

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. 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](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**

Functional transcranial Doppler recording has been used safely for many years for the assessment of cerebral vessels in neurological patients, and we are aware of no cases of adverse events. Equipment for measuring fTCD comes from certified suppliers of medical equipment, who are obliged by law to adhere to published guidelines on electrical and mechanical safety (IEC-601). The manual accompanying the equipment stresses that one should use as low ultrasound power as possible to get a good signal, but all equipment automatically limits the power that can be applied to be well within accepted safety standards.

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.

In a small number of individuals (estimated as around 5% or less), it is not possible to obtain a recording, because a measurement ‘window’ is not detectable. In such cases, it may take a while to determine whether there is a probe position that will allow for a signal to be measured, but if no window has been found within 30 minutes, the experiment should be terminated, and the participant paid as usual.

One consideration is hygiene: the probes are cleaned with disinfectant wipes after each use. As only small amounts of gel are applied, this can readily be removed using tissues and wet wipes. The headset is cushioned by removable pads that are changed for each participant. 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 Accident 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 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. There is no time limit on retention of completely anonymised data.

10. **CHANGE HISTORY**

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<td>Hyperlinks updated for new CUREC website. Sections 4 and 5 updated to replace specific list with reference to associated documents</td>
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