

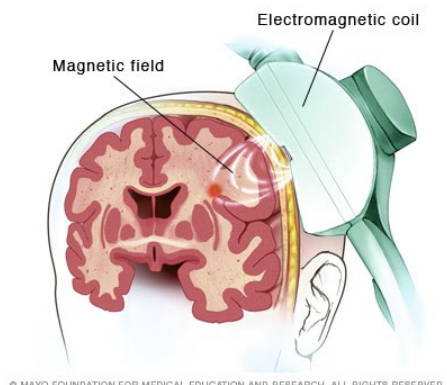


TMS & tDCS Brain Stimulation

Purpose: The purpose of this document is to provide guidance about IRB review and requirements related to TMS and tDCS transcranial brain stimulation used for research purposes at the University of Arizona.

What is TMS?

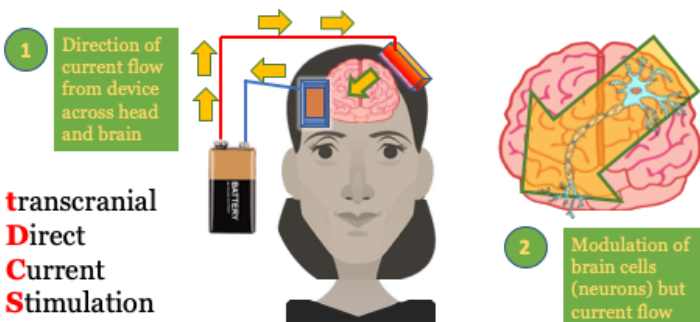
Transcranial Magnetic Stimulation (TMS) is a noninvasive neurological technique that uses an electromagnetic coil that is placed against the scalp near the targeted brain area to deliver a controlled magnetic pulse to stimulate nerve cells in the brain. The pulse passes through the skin and skull, inducing a brief change in the electrical activity in areas lying directly beneath the coil.



What is tDCS?

Transcranial Direct Current Stimulation (tDCS) is a portable, wearable brain stimulation technique that delivers a low fixed electric current to the scalp. tDCS works by applying a positive (anodal) or negative (cathodal) current via electrodes to the brain. The current may be applied in a continuous manner (tDCS) or in an alternating manner (tACS - transcranial Alternating Current Stimulation).

The procedure can produce immediate and lasting changes in brain function, it has also shown the potential to produce broad benefits for people who suffer from cognitive impairments. tDCS is often used for cognitive training and working memory (WM) training.



<https://neuromodec.org/what-is-transcranial-direct-current-stimulation-tDCS/>



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IRB Review and Requirements

Clinical investigations of either TMS and/or tDCS projects are reviewed by the Full IRB Committee, unless the devices are being used in their approved indications. The IRB will make a Significant Risk or Non-Significant Risk determination about the device by reviewing relevant information at a convened meeting. This information includes the description of the device (via the device appendix and device manual), reports of prior investigations conducted with the device, the proposed investigational plan, and the subject selection criteria. The IRB will expect to see the exclusion criteria includes the exclusion of patients with seizure history.

TMS and tDCS procedures can only be performed by qualified staff who have completed training in the safe operation of the equipment and protocol delivery.

If the **Principal Investigator** (PI) of the study is not a physician, a responsible physician must be appointed to the study and be present during the TMS or tDCS procedures. If it is of the professional opinion of the PI that the safety profile of the study does not warrant the presence of a physician during the TMS or tDCS procedures, the IRB Committee will ask to see a Standard Operating Procedure (SOP) that outlines the emergency protocol to be used in the event of a medical emergency. It is at the discretion of the IRB to review each submitted SOP on a case-by-case basis and determine the appropriateness of the physician's presence during the TMS or tDCS procedures. The plan, at minimum, should include the following:

- a. Procedures to be followed during the event of a medical emergency;
- b. acknowledgment the responsible physician will review all potential TMS or tDCS cases prior to the procedure;
- c. the responsible physician will be available by phone during all cases; and
- d. only research personnel with relevant background/training/and expertise will complete the procedure.

References:

- <https://pubmed.ncbi.nlm.nih.gov/24353923/>
- <https://pubmed.ncbi.nlm.nih.gov/9474057/>
- <https://www.mayoclinic.org/tests-procedures/transcranial-magnetic-stimulation/about/pac-20384625>
- https://www.hopkinsmedicine.org/psychiatry/specialty_areas/brain_stimulation/tms/faq_tms.html
- <https://neuromodec.org/what-is-transcranial-direct-current-stimulation-tdcs/>