



**The Ottawa
Hospital**

RESEARCH
INSTITUTE

**L'Hôpital
d'Ottawa**

INSTITUT DE
RECHERCHE



NeuroCognitive Controller: Implanted device for assistive communication for persons with tetraplegia Safety Study

Research Description and Purpose:

Researchers at the Ottawa Hospital and University of Ottawa want to test the safety and usefulness of a new type of assistive communication device. This study is for persons with tetraplegia who are otherwise in good health. Participation in this research is voluntary.

Would this study be a good fit for me?

This study might be a good fit for you if:

- You are tetraplegic due to amyotrophic lateral sclerosis (Lou Gehrig's disease) or cervical spinal cord injury.
- You are otherwise healthy.
- You are able to communicate your wishes, with or without the aid of a caregiver.
- You are willing to have a surgery to temporarily implant electrical sensors in the upper layers of your brain.
- You are willing to travel to a research site or have researchers come to your home several times per week for eight or more months.
- If you have ALS, you already have an advanced directive about ventilation.

Contact Information:

To take part in the NCC research study or for more information, please contact Nella Bianconi at 613-761-5073.

This research study has been approved by the Ottawa Health Science Network Research Ethics Board (OHSN-REB #20170100-01H).

What would happen if I took part in this study?

If you decide to take part in this research study, you would:

- Meet with members of our clinical team who will test your function and suitability for the study.
- Have magnetic resonance images (MRI) and CT Scans taken of your head and brain.
- Have a surgery to temporarily implant electrical sensors in the outer layers of your brain and a connector on your head.
- Stay in the hospital for three days after each surgery.
- After returning home, participate in research sessions three or four times per week. The research sessions can be at your home or at another site.
- In each research session, perform tasks like thinking about making hand movements or making decisions. At the end of each session the researchers will help you to use the device to control different assistive communication devices (e.g. typing or controlling a computer cursor) as you please.
- After 8 or more months, at the end of the study, have another surgery to remove the electrical sensors and connector.

There is no financial compensation for participating in the study. Transportation costs associated with participating in the study (fuel, parking or taxi) will be reimbursed.