Participant Information Sheet for Healthy Control Participants

You will be given a copy of this information sheet to keep.

Title of project: The Back of the Brain project (BoB)
Name of Principal investigator: Dr Alex Leff
REC number: 16/0393 **Version:** 5 **Date:**12/06/2018

Invitation to take part

You are being asked to take part in a research study of how the brain processes the visual world.
Before you decide, it is important that you understand why the research is being done and what it involves.
Please read the information on this sheet carefully.
Discuss it with your family or friends or your GP if you want to.
Please ask us if you need more information.
Take as long as you like to decide whether or not you want to take part.

Why have I been chosen?

We are looking for people with a normal history of reading and visual perception to take part.

Do I have to take part?

You decide whether or not you want to take part.
If you decide to take part, you will be given this information sheet to keep.
You will be asked to sign a consent form.
You can change your mind and stop taking part at any time.
You don't need to give a reason for changing your mind.

What happens if I withdraw from the study?

If you choose to withdraw from the study at any stage, data resulting from your participation up to that point will be retained, unless you request us to delete it.

In the unlikely event that you lose capacity to consent during your participation in the study, you would be withdrawn from the study but we would retain your existing data.

What is the purpose of the study?

In this study, we are interested in how participants with normal history of reading and visual perception development perform on a range of behavioural tests. **We will also ask you to complete an MRI scan (Magnetic Resonance Imaging). This uses a strong magnetic field to take pictures of the brain and will take place at UCL.** This data will be compared to results from patients with reading and visual perception impairments caused as a result of brain injury, such as stroke.

What restrictions do I need to follow during the study?

We ask that you do not drink alcohol for 12 hours before language testing. Otherwise you can eat and drink as normal.
You should take all your medications as usual during the study.

Are there any reasons why I can't take part in the study?

You may not be able to take part in the study if you have:

- A history of reading or language problems
- A history of neurological or psychiatric illness.
- A history of visual perception problems

The MRI scanner contains a large magnet, so metal or electronic objects must be kept out. We will NOT be able to scan you if you have:

- **Certain types of metallic implants such as cardiac pacemakers, aneurysm clips in their brain, ear implants, permanent eye lining, or have been exposed to metallic flakes or splinters travelling at high speed.**
- **If you are pregnant.**
- **If you suffer from claustrophobia.**

What are the possible benefits of taking part?

The study will provide information useful to the study of stroke recovery.

Will I be compensated for my travel expenses and time?

We will pay your travelling expenses, but unfortunately we cannot offer additional payment for taking part in the study.

Are there any risks or side-effects involved?
Brain scanning:
MRI scans are very common, SAFE procedures with no known health risks.

What if new or unexpected information becomes available?
There is a small chance that the MRI scan may show an unexpected brain abnormality.

If this happens, we will discuss this with you.
If further action is necessary, we will write to your GP who may need to arrange further imaging or medical assessment within the NHS.

What will happen if I take part?
We will ask you to complete a number of computer-based tests **and an MRI scan**. This will take **a day** to complete.

What if something goes wrong?
If you have a concern about any aspect of this study you should speak to the researchers who will do their best to answer your questions.

In the event that something does go wrong and you are harmed during the research and this is due someone's negligence then you may have grounds for a legal action for compensation against UCL, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will be available to you.

If you wish to complain, or have any concerns about any aspect of the way you have been approached or treated by members of staff you may have experienced due to your participation in the research, UCL complaints mechanisms are available to you. Please ask a member of the research team if you would like more information on this.

In the unlikely event that you are harmed by taking part in this study, compensation may be available to you. If you suspect that the harm is the result of the Sponsor's (University College London) negligence then you may be able to claim compensation. After discussing with a member of the research team, please make the claim in writing to Dr Alex Leff who is the Chief Investigator for the research and is based at the Institute of Neurology, UCL. Dr Leff will then pass the claim to the Sponsor's Insurers, via the Sponsor's office. You may have to bear the costs of the legal action initially, and you should consult a lawyer about this.

Will my participation in this study be kept confidential?
All information regarding your participation will be treated as strictly confidential and will only be used for research purposes. Dr Alex Leff will be responsible for security of your data.

We will collect basic data from you about your age, sex, and health.
Video or audio recordings may also be made for research or teaching purposes, but only with your agreement.

Your personal data will be safely stored on a University computer with all names removed so that you cannot be identified.

What happens when the research study stops?
You will receive a newsletter outlining the results of the study. The results of the studies will be reported in medical journals or at conferences. None of the study participants will be identified in any report or publication. We will inform you about these publications and how to access them.

Who is organising and funding the research?

This study is organised by the Institute of Cognitive Neuroscience (part of University College London).

It is funded by the Danish Council for Independent Research.

Professor Alex Leff is the principal investigator.

Please contact Alex or any member of the research team if you have any questions, using the contact details below.

Who has reviewed this study?
The Queen Square Research Ethics Committee has reviewed and approved all procedures involved in this study.

Contacts for further information:

Principal Investigator: Alex Leff

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Research Team:

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GDPR requirements

University College London is the sponsor for this study based in the United Kingdom. We will be using information from gathered from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. University College London will keep identifiable information about you for 10 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information by contacting Sheila Kerry (0207 679 1183) or Alex Leff (020 7679 1129).

University College London will collect information from you and your medical records for this research study in accordance with our instructions.

The BOB study team will keep your name and contact details confidential and will not pass this information to University College London. The BOB study team will use this information as needed, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Certain individuals from [sponsor organisation] and regulatory organisations may look at your medical and research records to check the accuracy of the research study. University College London will only receive information without any identifying information.

University College London will keep identifiable information about you for 10 years after the study has finished.

Future use of data

When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research.

This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research, and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.