Participant Information Sheet/Consent Form

Title	Hemispatial neglect, EEG correlates and the effects of short wavelength light on spatial inattention
Protocol Number	14408A
Principal Investigators	Prof Mark Bellgrove, Dr Peter New, Dr Megan O'Neill, Dr Méadhbh Brosnan
Associate Investigator(s)	Prof Jason Mattingley, Dr Dragan Rangelov, Dr Paul Dockree, Dr Nele Demeyere, Dr Rene Stolwyk, Dr Pascal Molenberghs, Dr Redmond O'Connell, Dr Shou-Han Zhou, Nicholas Parsons, Daniel Pearce, Bryce Fleming, Julia [illegible]
Location	Monash Health – Kingston Centre, Casey Hospital, Dandenong Hospital

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project, which is called "Hemispatial neglect, EEG correlates and the effects of short wavelength light on spatial inattention." This is because you have previously experienced a stroke. This research project has a number of aims, but generally we are aiming to investigate what changes to behaviour can result following a stroke. We are particularly interested in what changes occur to how we pay attention to areas of space, and how remaining cognitively, socially and physically active across the lifespan helps the brain protect against damage and dysfunction.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the processes involved with taking part. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or local health worker.

Participation in this research is voluntary. If you don't wish to take part, you don't have to.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- Understand what you have read
- Consent to take part in the research project
- Consent to be involved in the research described
- Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

2 What is the purpose of this research?

The aim of this study is to examine the changes that some people experience following a stroke. Following a stroke, some people experience problems with attention, memory, language or reasoning. We aim to investigate how and why some people experience problems and others do not. We'd particularly like to focus on how and why people develop problems in paying attention to space following a stroke, and how remaining cognitively, physically and socially active over the lifetime interacts with this. This may assist in better characterising stroke-related changes in the brain, and allow improved rehabilitative standards and processes.

3 What does participation in this research involve?

The study will include approximately 50 individuals who have previously experienced a stroke, and approximately 50 healthy control participants. Of the 50 stroke-patients, some may have experienced symptoms of hemispatial neglect symptoms whereas others may have had no problems.

There are two parts to this study. Following the completion of the informed consent process, you will then be invited to participate in Parts A and B. You may choose to participate in some or all parts of this study. Part A involves one session at Monash University, in Clayton, Victoria, while Part B requires two sessions at the same location. In response to the COVID-19 pandemic, Part A will temporarily be conducted over the phone.

Additionally, we understand that activities are often more difficult and tiring following a stroke, and encourage you to pause or stop testing if you experience fatigue or discomfort during the testing process. Each part can be completed across multiple sessions if required.

Part A:

If you decide to take part in the research project, you will first be asked to respond verbally or in writing to questions that test thinking skills such as your attention, memory, language and reasoning. You will also be asked to complete brief questionnaires regarding your performance of daily tasks such as getting dressed and eating, and the amount of fatigue that you experience. This process should not take longer than 90 minutes of your time, and will currently be completed over the phone to minimize the amount of face-to-face contact required.

You will then be asked a range of questions about your life, covering your:

- Occupation history;
- Education;
- Family;
- Social network;
- Leisure activities and hobbies

This interview will take approximately forty minutes and may be recorded with your consent.

We would also like to ask permission to access your medical records, such as date of birth, clinical reports, date of stroke and date of admission. We are also seeking your permission to access your brain scans (CT/MRI) where available, so we can see which part of your brain was affected by the stroke..

Part B:

Part B of this study will involve you completing two similar computerised tasks. While you are completing these tasks, we'll measure the electrical activity in your brain using electroencephalography (EEG). We will also track your eye movements using an eye tracker at Monash University, Clayton Campus.

EEG is commonly used in hospitals in order to test brain activity. Many patients undergo an EEG recording as part of clinical investigations. EEG is non-invasive and is not painful. It is one of the most sensitive techniques available to understand the temporal parameters of brain activity.

EEG is recorded by wearing a cap, which resembles a bathing cap. Electrodes attached to the outside of this cap. In order for the electrodes to record the electrical brain activity that you are generating, conductive gel is inserted into the electrodes using a blunt syringe. Thus, some of the gel will get in your hair but this washes out with water and will be wiped off at the end of the testing procedure. The cap fitting procedure takes about 30-60 minutes.

Each session will take 2-3 hours in total. All efforts will be made to minimise the disruption to your rehabilitation, including scheduling this session on the weekend where appropriate.

4 Other relevant information about the research project

The principal and associate researchers listed above have instigated this research project and the project is being conducted by Monash University in co-operation with Monash Health. This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study investigators or participants jumping to conclusions. The results of this project will be used by associate researcher, Daniel Pearce, to obtain a Doctor of Philosophy (Clinical Neuropsychology) degree.

5 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine care, your relationship with professional staff or your relationship with Monash Health or Monash University.

6 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research. However, results from this study will improve our understanding of how stroke impacts the brain and the person's level of function, and of how lifestyle can help the brain protect against certain forms of impairment. This may allow us to make better recommendations for people, and to rehabilitate individuals who have experienced stroke more effectively and efficiently.

There are no costs associated with participating in the research project, nor will you be paid. You will be reimbursed for any of the following costs that you incur as a result of participating in this research project, including reasonable travel and parking costs associated with research project visits.

7 What are the possible risks and disadvantages of taking part?

The research project is not expected to pose any risks to you. The researchers aim to minimise any discomfort to you during testing, such as tiredness, by offering frequent breaks as required. We have incorporated breaks into the testing sessions to try and avoid this. You will be repeatedly reminded that testing can be stopped at any stage if you are feeling too tired and/or you are unwilling to continue. Someone will be available to talk to you at all times during the task and if you would like you can have someone (a family member or friend) accompany you to the testing sessions.

You may feel that some of the questions we ask are stressful or upsetting. If you do not wish to answer a question, you may skip it and go to the next question, or you may stop immediately. If you become upset or distressed as a result of your participation in the research project, the research team will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the research team. This counselling will be provided free of charge.

This project requires attendance at Monash University, Clayton campus, on two-to-three occasions. Given the current COVID-19 pandemic, there is risk associated with exposure to the virus. Please be assured that we have implemented a number of precautions to ensure your risk of exposure to the COVID-19 virus is minimised, including regular cleaning of equipment, use of PPE by researchers, reducing the number of sessions, symptom screening, and appropriate social distancing. If you are uncomfortable participating at present, however, please inform the researcher. An attempt will be made to reschedule sessions for a time that better suits you.

You should not participate in this research if you have a familial or personal history of epilepsy, a personal history of unexplained fainting or sensitivity to flickering light.

8 What if I withdraw from this research project?

If you do consent to participate, you may withdraw at any time. If you decide to withdraw from the project, please notify a member of the research team before you withdraw. A member of the research team will inform you if there are any special requirements linked to withdrawing. If you do withdraw, you will be asked to complete and sign a 'Withdrawal of Consent' form; this will be provided to you by the research team.

If you decide to leave the research project, the researchers will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected up to the time you withdraw will form part of the research project results. If you do not want your data to be included, you must tell the researchers when you withdraw from the research project.

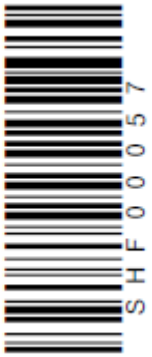
9 Could this research project be stopped unexpectedly?

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as:

- Decisions made by local regulatory/health authorities (e.g. in relation to COVID-19 restrictions).

10 What happens when the research project ends?

Results from the study will be available from July 2021. If you would like to receive a summary of these findings, please email Prof Mark Bellgrove (mark.bellgrove@monash.edu) after this date.



Part 2 How is the research project being conducted?

11 What will happen to information about me?

No information will be shared with any other party, for any other purpose, without your consent. Should you agree to participate in affiliated studies, some deidentified information may be shared with other researchers with your consent. This may include information such as your age, gender, years of education, stroke details, test data, and brain imaging results. We will ensure that private information such as your name and contact details are not included in any information shared with other researchers.

Victorian law

Your collection, use and disclosure of a person's health information is governed by the Health Records Act 2001 (Vic) (HR Act). **Health information** is defined in the HR Act and includes (amongst other things) information or an opinion, whether true or not, about the physical, mental or psychological health (at any time) of an individual about an individual whose identity is apparent, or can reasonably be ascertained, from the information or opinion.

There are eleven Health Privacy Principles (HPPs). HPP 1 and 2 govern the collection, use and disclosure of health information, including for the purposes of research. The HR Act is administered by the Victorian Health Services Commissioner, who may issue or approve Guidelines in relation to the HPPs. The Guidelines in relation to research can be obtained from the Health Services Commissioner's website: www.health.vic.gov.au/hsc.

Any researcher who considers that the HPPs might apply to their research should read these guidelines. It is important to note that this Victorian Act applies generally to private sector organisations when they handle health information in Victoria.

Your collection, use and disclosure of a person's personal information is governed by the Information Privacy Act 2000 (Vic) (IP Act). **Personal information** means information or an opinion (including information or an opinion forming part of a database), that is recorded in any form and whether true or not, about an individual whose identity is apparent, or can reasonably be ascertained, from the information or opinion, but does not include health information.

The IP Act sets out ten Information Privacy Principles (IPPs) that regulate the responsible collection and handling of personal information by organisations in the Victorian public sector, including universities set up by state legislation. IPPs 1, 2 and 10 deal with the collection, use and disclosure of this information for the purposes of research. There are no separate Guidelines issued in relation to the IP Act, which is administered by the Victorian Privacy Commissioner: www.privacy.vic.gov.au.

Commonwealth law and trans-border data flow

The Privacy Act 1988 (Cth) (Privacy Act) applies to Commonwealth and ACT government agencies, and to certain private sector organisations. It applies to private sector health service providers, and to private and ACT universities. It does not apply to State or Northern Territory government agencies, including state and territory public hospitals and health care facilities except in relation to certain records in certain circumstances. It does not cover universities (other than private and ACT universities).

The Privacy Act outlines thirteen Australian Privacy Principles (APPs), which establish requirements for the collection, storage, use and disclosure of **personal information** and **health information**. Sections 16A and 16B of the Privacy Act set out certain circumstances in which it is permissible to collect, use and disclose personal information and health information for the purposes of research.

APP 8.1 requires an organisation, before it discloses personal information to an overseas recipient, to take reasonable steps to ensure that the overseas recipient does not breach the APPs in relation to the information. APP 8.1 applies to the disclosure (APP 8.1 applies to all cross-border disclosures of personal information, unless an exception in APP 8.2 applies), and the overseas recipient is not subject to the APPs, but the act or practice would be a breach of the APPs if they were.

APP 8.2 lists a number of exceptions to APP 8.1, including where:

- the organisation reasonably believes that the recipient is subject to a law or binding scheme that has the effect of protecting the information in a way that is, overall, substantially similar to the APPs; and there are mechanisms available to the individual to enforce that protection or scheme (APP 8.2(a)). The requirement for an overseas jurisdiction to have accessible enforcement mechanisms introduces a higher threshold than the equivalent NPP 9 exception; or where
- an individual consents to the cross-border disclosure, after the organisation informs them that APP 8.1 will no longer apply if they give their consent (APP 8.2(b)).

There are other exceptions to the application of APP8.1 set out in APP 8.2.

Any researcher wishing to obtain information from a Commonwealth agency, and any researcher who considers that the APPs might apply to their research, should read the Guidelines under Section 95, 95A and 95AA of the Privacy Act 1988, issued by the NHMRC (see www.nhmrc.gov.au/publications/synopses/e26syn.htm).

The health information and personal information that you collect about an individual for the purposes of your study MUST be dealt with on a strictly confidential basis and in accordance with the HPPs, IPPs and APPs as applicable.

By signing the consent form you consent to the research team collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. In any publication, information will be provided in such a way that you cannot be identified. Results gathered from your participation in the project will be stored electronically on secure password-protected computers and backed up on password protected hard drives. Any hard copy information collected will be stored in a locked filing cabinet without any personally identifying information attached to them. Although the consent form has your participant information on it, these forms and the research data are stored separately in accordance with ethical guidelines. Raw data collected during this project will only be accessible by the named research team. Information will be retained for up to ten years following final publication of findings. After this period the electronic and paper data will be deleted/destroyed. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

The personal information that the research team collect and use includes medical history, contact details, information from questionnaires and results from this and previous parts of the study.

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to request access to the information about you that is collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please inform the research team member named at the end of this document if you would like to access your information.

Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

12 Complaints and compensation

Where possible, minor complaints or concerns should be raised with the investigator as they arise. All effort will be made to resolve these issues to the satisfaction of all parties involved.

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Name	Ms. Deborah Dell
Position	Manager, Human Research Ethics Committees
Telephone	(03) 9594 4605
Email	Deborah.Dell@monashhealth.org

13 Who is organising and funding the research?

This research project is being conducted by the named principal and associate researchers.

14 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC).

The ethical aspects of this research project have been approved by the HREC of Monash Health and of Monash University.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

15 Further information and who to contact

The person you may need to contact will depend on the nature of your query. If you want any further information concerning this project or if you have any problems which may be related to your involvement in the project, you can contact the research team directly.

Research contact person

Name	Prof Mark Bellgrove
Position	Principal researcher
Telephone	(03) 9902 4200
Email	Mark.Bellgrove@monash.edu

Consent Form – Parts A and B

Title: Hemispatial neglect, EEG correlates and the effects of short wavelength light on spatial inattention
Protocol Number: 14408A
Principal Investigators: Prof Mark Bellgrove, Dr Peter New, Dr Megan O'Neill, Dr Méadhbh Brosnan
Associate Investigators: Prof Jason Mattingley, Dr Dragan Rangelov, Dr Rene Stolwyk, Dr Tarrant Cummins, Dr Pascal Molenberghs, Dr Redmond O'Connell, Mr Daniel Newman, Ms Stefanie Roberts, Nicholas Parsons, Daniel Pearce, Bryce Fleming

Declaration by Participant

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future care.

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to Monash University concerning my condition and treatment that is needed for this project. I understand that such information will remain confidential.

I agree to complete the demographic questionnaire and screening tasks	□
I agree for the research team to access medical notes that are stored on the ward in which I am currently an inpatient	□
I agree for the research team to access my CT/MRI scans	□
I agree to complete the interview about my life	□
I agree to take part in the computerised tasks, including EEG and eye tracking	□
I agree for the research team to contact me in the future regarding participation in additional related studies	□

Name of Participant (please print) _____

Signature _____ Date _____

Declaration by Researcher

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Researcher (please print) _____

Signature _____ Date _____