



**THE BRISBANE
HAND & UPPER LIMB**

RESEARCH INSTITUTE

STUDY PROTOCOL: POCD

Prediction of post-operative cognitive decline following shoulder surgery in the beach chair position: the value of cerebral oximetry.

Version: 4.0, 1 June 2018

Superseded: Version 3, 17 June 2016

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Date: 17/06/2016

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SUMMARY OF CHANGES TO THIS VERSION

Section	Change	Reason for update
Version	Version 3 to version 4.0	Investigator changes
Contents page	Addition of section “Summary of Changes to this Version”	Clarity
1. Clinical investigation plan summary – part one	Addition and deletion of investigators	UQ team leaves project, staff turnover
9. Confidentiality	Change UQ HREC to Bellberry HREC	Error correction
14. Clinical investigation plan summary – part two	Addition and deletion of investigators, reference to “The University of Queensland” deleted	UQ team leaves project, staff turnover
15.8. Recruitment	References to “The University of Queensland” and “UQ School of Psychology” deleted	UQ team leaves project
19 Confidentiality	Change UQ HREC to Bellberry HREC, change the University of Queensland to Brisbane Hand and Upper Limb Research Institute	Error correction, UQ team leaves project
24.2 Participant Information Form	Addition and removal of investigators, change of project contact, references to the University of Queensland deleted	UQ team leaves project, staff turnover
24.2 Participant Information Form	Expected date of study conclusion changed from 2018 to 2019	Updated estimate
24.3 Participant Consent Form	References to the University of Queensland deleted	UQ team leaves project
24.5 Participant Withdrawal Form	Addition and removal of investigators, change of project contact	UQ team leaves project, staff turnover
24.6 Participant survey – STUDY TWO	Change of contact email, expected date of study conclusion changed from 2018 to 2019	UQ team leaves project, updated estimate
24.7 Participant Information Form – STUDY TWO	Addition and removal of investigators, change of project contact, references to the University of Queensland deleted, expected date of study conclusion changed from 2018 to 2019, change of project contact	UQ team leaves project, staff turnover, updated estimate
24.8 Participant Consent Form – STUDY TWO	references to the University of Queensland deleted	UQ team leaves project

1 CLINICAL INVESTIGATION PLAN SUMMARY – PART ONE

TITLE	Prediction of post-operative cognitive decline following shoulder surgery in the beach chair position: the value of cerebral oximetry.
INVESTIGATORS	Principal: Associate Professor Mark Ross, Dr Phillip Duke, Dr David Gilpin, Dr Phil Melksham Associate: Dr Silvia Manzanero, Ms Ruby Strauss, Ms Chelsea Duke, Ms Louise Lee, Mr Glen Russell
OBJECTIVES	<u>Primary aim:</u> To examine the relationship between cerebral desaturation during shoulder surgery in the beach chair position, and post –operative cognitive decline. <u>Secondary aims:</u> 1. To determine the variation in cerebral oxygenation recorded using simultaneous application of the INVOS™ and FORE-SIGHT® oximeters, during shoulder surgery in the beach chair position. 2. Assess the relationship between cerebral oxygen desaturation and mean arterial pressure, incidence of nausea / vomiting, duration of hospital stay, BMI, hypertension and adverse events.
STUDY DESIGN	A prospective cohort study.
SITES	Brisbane Private Hospital.
NUMBER OF SUBJECTS	Approximately 200 participants will be recruited to this study.
TARGET POPULATION	Participants will be adults who require shoulder surgery in the beach chair position.
LENGTH OF CLINICAL INVESTIGATION	It is anticipated that this study will require 27 months from commencement of recruitment to final data collection phases (24 month recruitment period). The primary end point of the study will be 3 months post-surgery. Participants will be assessed 1 day prior to surgery (baseline), at day 1 post-surgery (early), between 10 & 14 days (mid), at 1 month (late) and at 3 months post –surgery (late).
OUTCOMES	Primary Post- operative cognitive decline will be defined as a drop of 1 standard deviation or more from baseline on 2 or more neuropsychological indices (Tournay-Jette et al., 2011). The following neuropsychological tests will be used; <ul style="list-style-type: none">• Logical memory test• Trail making test: Delis-Kaplan Executive Function System• Single letter verbal fluency• Stroop test: Victoria’s version• List Learning: Rey Auditory Verbal Learning Test• Letter-Number Sequencing (from Wechsler Adult Intelligence Scale, 4th edition).

	<p>Secondary Frequency of cerebral desaturation events (CDE) measured (INVOS™ vs FORE-SIGHT®). Cerebral desaturation will be defined as a decrease in rSO2 greater than, or equal to 20% from baseline or a fall below 50% absolute (after Murphy et al., 2010; Salazar et al., 2013). Variables associated with this outcome include:</p> <ul style="list-style-type: none"> • Mean Arterial Pressure (mmHg) • BMI • Hypertension • Nausea and Vomiting – within 48 hours • Duration of hospital stay • Adverse Events
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2 INTRODUCTION

The “beach chair position” (BCP) has been used to perform shoulder surgery since the early 1980s and has several cited advantages compared to alternative positions. These include; reduced strain on the brachial plexus, less risk of neurovascular injury compared to a lateral decubitus approach and excellent intra-articular visualization (Murphy et al., 2010). However, despite these advantages and the widespread use of this position during shoulder surgery, the BCP has also been associated with some rare but severe adverse clinical outcomes. These have included; ischaemic brain and spinal cord injury, stroke, visual loss and ophthalmoplegia (Pohl & Cullen, 2005; Murphy et al., 2010). This has highlighted the need to routinely monitor cerebral oxygenation during shoulder surgery in the beach chair position and has prompted the development of clinical protocols to minimise the effect of cerebral desaturation events (CDE) (Closhen et al., 2013; Salazar et al., 2013).

It has been hypothesized that a combination of factors may contribute to the increased risk of CDE occurring in the BCP. Normal physiological changes associated with sitting upright are magnified in the context of a general anaesthetic. Venous return is reduced by the effect of gravity and compromised further by vasodilation and the myocardial depressant effect of anaesthesia. In the non- anaesthetised patient, changes in the sympathetic nervous system produce an increase in systemic vascular resistance to counteract the effect of gravity. This modulation of haemodynamics via the autonomic nervous system is lost in the anaesthetised patient increasing the risk of cerebral hypoxia (Pohl & Cullen, 2005).

The relationship between CDE and post- operative cognitive decline (POCD) is not well understood (Lopez et al., 2013). Little is known about the significance of the type and duration of CDE and whether or not this has any bearing on cognitive outcome. Some authors continue to question the relationship between CDE and subsequent cognitive impairment (Parra et al., 2011; Zheng et al., 2013; Kok et al., 2014). Salazar et al., (2013) provide the only study that examines the relationship between CDE in shoulder surgery using the BCP and subsequent cognitive impairment. These authors did not find a statistically significant relationship between CDE and cognition as assessed using the “Repeatable

Battery for Assessment of Neuropsychological Status “(RBANS) with either composite scores or using the sub-indices. They attribute this lack of significant findings to insufficient study power. The incidence of cerebral desaturation in their study was 18% (9/50 participants). In contrast, de Tournay-Jette et al, (2011) found a significant relationship between CDE and POCD in elderly patients following coronary artery bypass graft surgery. These authors used a detailed battery of neuropsychological assessments and highlight the need for sensitive assessments of cognitive function.

This difficulty in clarifying the relationship between CDE and POCD may be further compounded by our ability to accurately measure cerebral perfusion. To date, no clear definition of cerebral ischaemia exists and little is known about individual patient factors (e.g. pre-existing cerebral vascular disease) that may influence cognitive outcome (Murphy et al., 2010). Additionally, changes in the proportion of venous versus arterial components of blood pressure will vary with changes in body position. This is not necessarily reflected in the observed change in overall oxygen concentration (Murphy et al., 2010). Individual variation in acceptable mean arterial blood pressure has also been reported. Whilst 50mmHg is generally the accepted level, the required level in some cases has been found to be as high as 70-80mmHg (Murphy et al., 2010). Hence, the conditions leading up to a CDE associated with cognitive impairment may vary from one patient to another and are influenced by patient specific characteristics (Murphy et al., 2010).

A number of cerebral oximeters are commercially available. Douds et al. (2014) completed a systematic review of devices commonly used in cardiac surgery and concluded that there were only a very limited number of high quality papers available. Most of these papers were based on the INVOS™ system. These authors highlighted the need for further RCTs to investigate the role of cerebral oximetry and the efficacy of devices currently available. Hessel et al., (2014) examined cerebral oxygenation in newborns using both the FORE-SIGHT® and INVOS™ monitors. They found that the FORE-SIGHT® monitor demonstrated greater repeatability and hypothesised that this may indicate a lower responsiveness to change in oxygen saturation. In contrast, Closhen et al., (2013) compared the use of the INVOS™ and FORE-SIGHT® monitors to detect oxygen saturation in the beach chair position and found no significant difference according to monitor type. The study by Bickler et al., (2013) compared the performance of several cerebral oximeter devices including the FORE-SIGHT® and INVOS™ monitors. It compares the performance of different cerebral oximetry devices using an invasive reference standard and a common sample population (health adult volunteers), simultaneous testing methodology and data analysis. It is important that the monitors are being used within their approved indication for and that care must be taken to avoid optical cross-talk between the sensors of different manufacturers. In addition, the sensors will be placed randomly on the forehead in terms of superior and inferior in the same position to avoid sequential bias. Both the FORE-SIGHT® and INVOS™ cerebral oximetry measurements have been assessed and shown to be valid surrogates for true cerebral oxygenation .

Monitoring cerebral oxygenation in the BCP is an area of evolving attitudes in regards to standard of care. There are many hospitals in Australia who have now adopted cerebral oximetry as a standard of care for monitoring patients in the beach chair position. It is the feeling of all of the surgeons involved in the investigation that in fact, cerebral oxygenation monitoring is part of an adequate standard of care for patients in the beach chair position and it is routinely utilised currently in all beach chair position surgeries. It is not expected that there will be any significant alteration to operative time by placing two oxygen monitors and there is certainly no risk to the surgeon, anaesthetist or the nursing team. Data is recorded using monitors that output the data digitally and all of the data will be compared using standard timestamp methods so that they can be directly compared. The oximetry and MAP data will be simultaneously digitally recorded for the research data collection and analyses.

In conclusion, the relationship between shoulder surgery in the BCP and cerebral oxygenation is suggestive and requires further investigation. In addition, factors associated with cerebral desaturation and the incidence of POCD are not well understood. The value of cerebral oximetry in predicting CDE and POCD remains unclear. Further research in these areas is indicated and the proposed study aims to address the issues raised here.

2.1 KEY TERMS

BCP – beach chair position

POCD – post operative cognitive decline

CDE – cerebral desaturation event

rSO₂ – regional cerebral oxygen saturation

MAP – mean arterial pressure

BMI – body mass index

2.2 LAYMAN'S SUMMARY

Surgery to the shoulder may be performed with patients seated upright in a position known as the “Beach Chair Position (BCP).” This position has certain advantages compared to alternative surgical positions (eg side lying) in some situations. However, it has been found that surgery in the BCP can temporarily decrease the amount of oxygen in the brain as a result of the combined effects of gravity and anaesthesia. This can result in complications following surgery such as some memory loss and confusion. Rarely, more serious complications have been reported in the past including death and stroke.

Due to these reported complications the use of “cerebral oximetry” during shoulder surgery in the BCP has become more common. Before and during surgery, a monitor placed on the patients forehead measures the amount of oxygen present in the brain to help control this to an acceptable level. A number of monitors are now commercially available. Two monitors are commonly discussed in the literature; the INVOS™ 5100 and the FORE-SIGHT® machines. However, the actual relationship between the supply of oxygen to the brain

during surgery and the chance of later developing problems with memory and thinking (known as “post operative cognitive decline” – POCD) is not clear. It is also not known if one monitor is more accurate than another at predicting these complications.

Therefore, the main aim of this study is to examine the relationship between cerebral oxygen levels during shoulder surgery and the incidence of POCD (i.e. problems with memory and thinking). A second aim is to compare the INVOS™ 5100 and FORE-SIGHT® monitors ability to measure cerebral oxygen and CDE as well as the importance of other key clinical variables (e.g. blood pressure, nausea, body fat etc).

3 PURPOSE OF THE INVESTIGATION

The purpose of this investigation is to generate evidence about cerebral oxygenation during shoulder surgery and the incidence of POCD. Currently, evidence relating to POCD following surgery is conflicting and relates mostly to outcomes following cardiac surgery. There is a strong need to explore this relationship in the specific context of shoulder surgery in the BCP.

3.1 INTERVENTION GROUPS

The first study, hereby named STUDY ONE will involve a single prospective cohort. Patients who meet the selection criteria will be recruited to the study following voluntary informed consent . Cerebral

3.2 STUDY ONE

3.3 AIM OF THE STUDY

This study has three aims;

- (i) To examine the relationship between cerebral desaturation during shoulder surgery in the BCP, and the incidence of POCD.
- (ii) To determine the variation in cerebral oxygenation recorded using randomised (for superior/inferior) simultaneous application of the INVOS™ and FORE-SIGHT® oximeters, during shoulder surgery in the beach chair position.
- (iii) Assess the relationships between cerebral oxygen desaturation during shoulder surgery in the BCP and variables including mean arterial pressure, incidence of nausea/vomiting, duration of hospital stay, BMI, hypertension and adverse events.

3.4 RESEARCH QUESTION

There are three research questions correlating with the three research aims;

- (i) Is cerebral desaturation during shoulder surgery associated with POCD?
- (ii) Do the FORE-SIGHT® and INVOS™ 5100 devices vary in their measurement of cerebral oxygenation during shoulder surgery in the BCP?

- (iii) Is there a relationship between cerebral desaturation events during shoulder surgery in the BCP and variables including mean arterial blood pressure, post-operative nausea/vomiting, length of hospital stay, BMI, hypertension and any adverse events?

3.5 NULL HYPOTHESES

The three null hypotheses are;

- (i) Cerebral desaturation as measured using cerebral oximetry is not related to POCD after shoulder surgery in the BCP.
- (ii) There is no significant difference between the INVOS™ 5100 and the FORE-SIGHT® monitors assessment of cerebral oxygenation during shoulder surgery in the BCP.
- (iii) There is no relationship between cerebral desaturation events during shoulder surgery in the BCP and variables including mean arterial blood pressure, the frequency of post-operative nausea/vomiting, length of hospital stay, BMI, hypertension and any adverse events.

3.6 PRIMARY HYPOTHESES

The primary research hypotheses are;

- (i) Cerebral desaturation events during surgery in the BCP will be related to POCD.
- (ii) The INVOS™ 5100 and the FORE-SIGHT® monitors will show no significant difference in their ability to measure cerebral oxygenation.
- (iii) Cerebral desaturation events experienced during shoulder surgery in the BCP are related to a drop in mean arterial blood pressure, an increased likelihood of post-operative nausea and vomiting, greater length of hospital stay, a higher BMI, hypertension and greater frequency of adverse events.

4 INVESTIGATOR RESPONSIBILITY

The investigators will be responsible for:

- Obtaining ethical clearance prior to the commencement of the study;
- Recruitment;
- Providing participants with informed consent prior to allocation of intervention;
- Provision of intervention;
- Concise and comprehensive collection of medical history, baseline demographic data, intra-operative measures and cognitive assessments;
- Ensuring confidentiality of data collection forms and results;
- Ensuring data is kept in a safe, secure and lockable location, and electronic copies have been backed up on a secure server;

- Ensuring the study is conducted in a safe and ethical manner in line with Queensland Health policies and procedures, National Health and Medical Research Council (NHMRC) guidelines and relevant laws;
- Maintaining the confidentiality of participant records and data collected, and abiding by the NHMRC guidelines for Human Research;
- Data input from paper into electronic format;
- Paper preparation and submission;
- Adherence to the Good Clinical Practice Guidelines.

A statistician will assist with the power calculation, data analysis and interpretation.

The Primary Investigators will be responsible for monitoring the implementation of the study and study processes in line with the study protocol. Any adverse events will be reported to the ethics committee.

5 STUDY DESIGN AND METHODS

5.1 GENERAL

This study aims to examine the relationship between cerebral desaturation measured via oximetry during shoulder surgery in the BCP, and POCD. Patients treated by the Principal Investigators who meet the selection criteria, will be invited to participate in this prospective study. The investigation will be conducted at the Brisbane Hand and Upper Limb Research Institute at the Brisbane Private Hospital, Brisbane, Australia.

5.2 DESIGN

A prospective cohort design will be implemented.

5.3 PARTICIPANT ELIGIBILITY CRITERIA

5.3.1 INCLUSION CRITERIA

Patients meeting the following inclusion criteria will be invited to participate in the study (see 15.1);

- Receiving treatment primarily by, but not restricted to, one of the Primary investigators for a shoulder condition that requires surgery in the BCP.
- Over 18 years of age
- Able to read and speak English

5.3.2 EXCLUSION CRITERIA

Patients will be excluded from the study for the following reasons (see 15.1);

- Under 18 years of age
- Pregnant women

- Pre- operative Mini-Mental State Examination (MMSE) < 24
- Pre-existing cerebrovascular disease as reported by the assessing medical consultant and recorded in patient charts
- Orthostatic hypotension
- ASA physical status IV and V*
- History of drug and/or alcohol abuse
- Neurological disease (e.g. previous stroke)
- Significant mood and anxiety disorders as determined by treating consultant.
- Any other condition, which in the opinion of the investigators, would render the patient unsuitable for participation in the study

* ASA = the American Society of Anaesthesiologists physical status classification system. Level IV indicates the presence of severe systemic disease that is a threat to life. Level V is a moribund person who is not expected to survive without some form of surgery.

5.3.3 WITHDRAWAL OF PARTICIPANTS DURING TRIAL

Participants may decide not to proceed with their surgery for personal reasons. We will, however, record any other type of intervention they have chosen to have at this stage (e.g. physiotherapy, injection). Those who withdraw during the follow up period will be noted and this will be reported in the final report. The sample size calculation in the study has allowed for dropouts. Dropouts will be compared to study participants according to their baseline characteristics as part of the final analysis in order to assess for differential attrition.

5.4 RECRUITMENT

The study patient population will be recruited primarily from the private consulting practices of the Principal investigators at the Brisbane Hand and Upper Limb Clinic at the Brisbane Private Hospital. All patients who are undergoing surgery in the beach chair position will be approached by a member of the research team or a research assistant employed by BHULI after they have indicated to the consultant their interest in participating in the study after the decision to undertake surgery has been made. Indeed all patients who are undergoing shoulder surgery in beach chair position by any of the surgeons involved the study would be undergoing surface cerebral oximetry anyway. There is no question that the discussion regarding participating in the study would not happen until it was already established that the patient was undergoing shoulder surgery in the beach chair position. It has nothing to do with the clinical discussion regarding the patient's treatment.

5.5 SAMPLE SIZE

Approximately 200 participants will be recruited to the study. Based on historical patient presentation rates for this group, it is anticipated that recruitment will take approximately 24 months. This allows for 75% recruitment rate and 30% loss to follow up.

6 SCREENING /ENROLMENT

Patients will be screened according to the selection criteria (see 5.3.1 and 5.3.2) and the eligibility checklist completed (24.1). Those who meet the selection criteria will be invited to participate in the study. After reviewing the Participant Information form (24.3) and acknowledging that they have understood the purpose of the study, their involvement, risks and benefits, they will be asked to provide written consent (24.3). Any participant who refrains from participation will not be disadvantaged in any way. Any participant who wishes to withdraw during the study of his/her own accord and for whatever reason is entitled to do so without obligation and prejudice. In the event of this occurring, the investigator will record this clearly on the Data Collection Form (24.4).

6.1 STUDY INTERVENTIONS

Following recruitment to the study participants will be booked for surgery. An initial assessment (pre-operative screening test) will be conducted one day prior to surgery. Demographic information will be collected and the initial cognitive screen will be conducted at this assessment. Cognitive assessment will then be repeated at day 1, 10 days post-surgery and at one month and 3 months post-surgery. These time points coincide with standard follow-up intervals post shoulder surgery. Minor changes in the timing of these assessments will be made if necessary to accommodate pre and post-operative surgery schedules.

The intra- operative procedure will be as follows;

1. The patient's bed will be inclined between 30-70 degrees, with the angle being measured by an inclinometer.
2. The anaesthetic and surgical procedure will continue as usual whilst the oximeters record cerebral oxygenation.
3. Any CDE will be recorded on the data collection sheet. Additionally, a digital record will be obtained of mean arterial pressure and also oxygenation from the oximeters until surgery is complete and the patient has regained consciousness. This will allow more detailed analysis by the statistician.
4. Intraoperative drug administration data will be recorded on the data collection sheet (24.4). This will allow for analysis of potential confounding effects.
5. The type of surgical procedure and the duration of surgery will be recorded (24.4) to again reduce further confounding affects.
6. Any variations from the usual surgical/anaesthetic protocol or adverse events will be recorded on the data collection form (24.4).
7. Post-operative analgesia data will be recorded in the data collection form (24.4).

7 DATA COLLECTION

7.1 DATA COLLECTION INTERVALS

Data Collection Interval	Review Method
Baseline (approx. 24 hours prior to surgery)	In person at the clinic
Day 1	In person on the ward
Between 10 and 14 days	In person at the clinic
1 month	In person at the clinic
3 months	In person at the clinic

Data will be collected by an independent assessor who is not involved in the provision of treatment. These data collection points have been chosen to assess both the immediate and longer term effects of cerebral desaturation on cognitive function.

The follow-up period for this study is 3 months. Assessment of cognitive function will be conducted 1 day pre-operatively and as part of routine follow-up appointments at approximately 1 day and 10 days post-op, 1 month and 3 months. In this way we hope to maximise study retention by avoiding the necessity for participants to return for additional appointments beyond those required for normal care.

7.2 DATA COLLECTION FORMS FOR PRIMARY AND SECONDARY OUTCOMES

Clinical and demographic data collection forms will be completed for each participant, and will be performed as per the standard care of the study site. The investigators will perform all of the assessments. Data will be collected on the appropriate paper data collection forms as described below, and later transcribed into electronic databases.

7.2.1 ELIGIBILITY CRITERIA CHECKLIST

An Eligibility Criteria Checklist will be completed prior to seeking informed voluntary consent (24.3).

7.2.2 DEMOGRAPHIC AND MEDICAL INFORMATION FORM

Demographic and medical information will be obtained from each participant who is recruited to the study (see 15.4). This information will include, but is not limited to:

- Age
- Gender
- Occupation

- Information pertinent to surgery and/or neuropsychological assessment (e.g. recreational activities)
- Current medical status (e.g. diagnosis, side of injury) and co-morbidities (e.g. diabetes mellitus)
- Medical History e.g. cerebrovascular disease, hypertension
- History of current and previous medication, supplements

7.2.3 DATA COLLECTION FORMS FOR PRIMARY AND SECONDARY HYPOTHESES

Primary and secondary outcomes will be recorded for each participant on their data collection form. This form will include demographic, clinical and outcome data (24.4). The primary outcome to be measured is the incidence of Post-operative Cognitive Decline. This has been defined as a drop of 1 standard deviation or more from baseline on 2 or more of the neuropsychological indices included. The secondary outcome to be measured is the incidence of cerebral desaturation as well as the importance of other key clinical variables (e.g. blood pressure, nausea, body fat etc).

8 OUTCOME MEASURES

8.1 COGNITIVE ASSESSMENT TOOLS

8.1.1 NEUROPSYCHOLOGICAL TESTS

Logical Memory (5 minutes) - impairment in perceptions of and/or psychometrically determined, immediate and delayed recall and recognition memory following surgery has been frequently noted in research examining POCD (Krenk et al., 2010; Salazar et al., 2013). Commonly used psychometrically viable tests are prose story memory recall and recognition tests. The prose story is administered at the beginning of the session and the immediate recall occurs straight after. Delayed recall for the story occurs after 20-30 minutes. The test-retest reliability, construct and convergent validity of this test has been proven time again, commonly rendering an adequate to good coefficient (Sullivan, 2005).

Trails: Delis-Kaplan Executive Function System (10 minutes) - The D-KEFS was designed to detect even mild forms of executive dysfunction (Strauss et al., 2006). Executive dysfunction has been inadvertently linked with significant post-operative cognitive declines following surgery (Krenk, et. al., 2010). The D-KEFs Trails subtest has four trials; visual scanning, number sequencing, letter sequencing and letter number sequencing. The internal and test-retest reliability, and convergent and predictive validity of the D-KEFS is consistently adequate to high, and this subtest in particular renders a good to high coefficient (Strauss, et al., 2006).

Single Letter Verbal Fluency (1 minute) - Performance on brief verbal fluency tasks have been found to change pre- to post- surgery following cerebral desaturation events (Salazar et al., 2013). Aside from being a suitable assessment of both premorbid and current intellectual performance, tasks of verbal fluency examine spontaneous production of language and verbal associations. The task requires the individual to spontaneously generate a list of words in 60 seconds, where the words cannot be name of places, people or other proper nouns. A one-letter task is administered per package and has been found to be as valid as a three-letter fluency task (i.e. FAS or PGH;

Strauss, et al., 2006). Verbal fluency tasks have been found to have high internal and test-retest reliability and adequate to high content, construct and predictive validity (Strauss, et al., 2006).

Stroop Test Victoria's Version (5 minutes) - The stroop task has three components. The first examines colour discrimination, selective attention and visual scanning. The second assesses word discrimination and selective attention. The third examines the ability to inhibit responses and cognitive flexibility, it requires an individual to verbalise the colour the word is written in, when the words are colours. This version of the Stroop test was selected for the purposes of large font size, a brief amount of items in comparison to other versions thus requiring less administration time. The reliability of the test is adequate and the test itself has been found to be sensitive enough to detect changes from baseline (Strauss, et al., 2006).

List Learning – Rey Auditory Verbal Learning Test (RAVLT; 5-10 minutes) - Performance on a brief list-learning task has been found to change pre- to post- surgery following cerebral desaturation events (Salazar et al, 2013). Due to the poor validity and reliability of such a brief task, however, a full list-learning task is designed to be more sensitive to change as well as having a greater validity and reliability (Strauss, et al., 2006). The RAVLT assesses immediate and delayed auditory memory recall and recognition. The task consists of 15 nouns learned over 5 trials with a free recall after each presentation. The order of presentation remaining fixed across trials (List A). At the end of the 5th trial an interference list of 15 words is presented (List B), following a free recall of that list. Immediately after this, delayed recall of the first list is tested. Following a 20-minute delay, delayed recall and recognition of the first word list is assessed.

Letter-Number Sequencing (from Wechsler Adult Intelligence Scale, fourth edition subtest (WAIS-IV), 5-10 minutes) - This particular subtest of the WAIS-IV assesses attention and concentration. The examinee is verbally presented with a combination of numbers and letters or increasing amounts. The examinee is required to recall the numbers in ascending order then letters in alphabetical order. The WAIS-IV as an overall measure is one of the most widely used tests of intelligence and has consistently rendered highly valid and reliable results. This subtest of the WAIS-IV has high internal consistency and adequate test-retest reliability (Strauss, et al., 2006; Wechsler, 2008).

8.1.2 PSYCHOLOGICAL MEASURES

The following measures capture different aspects of psychological functioning including perceptions of cognitive impairment, mood and social participation. Psychological and social distress are known to influence performance on cognitive tests over and above that of any effects of POCD (e.g. Kizilbash, A. H., Vanderploeg, R. D., & Curtiss, G. (2002). Including these variables allows us to control for their influence in statistical analysis. There is evidence of increased risk of social disconnection when people face life changes and periods of vulnerability (Jones et al., 2011; Jetten, Haslam & Haslam, 2012). Surgery involves a period of such vulnerability, which is why two very brief validated measures of this construct are included within the study (i.e., n=3 items). These have the capacity to be delivered face-to-face or online using iPad that will be provided.

European Brain Injury Questionnaire (EBIQ) (10-15 minutes)- The European Brain Injury Questionnaire (EBIQ), is a self-report and relative-report measure of the subjective experience of cognitive, emotional and social difficulties experienced by people with any form of acquired brain injury (Teasdale et al., 1997). It is a clinically reliable measure that assesses change in subjective concerns in these areas over time (Sopena et al., 1997). In the present study it will serve as a subjective index of cognitive change. The measure comprises 66 items rated on a 3-point scale (1=not at all to 3=a lot).

Depression Anxiety and Stress Scale-21 (DASS-21; 3 minutes) - Depression, anxiety and stress both pre- and post- surgery have been shown to hinder recovery and increase the risk of

short- term and long-term complications (Tully et al., 2008). The DASS-21 has 21 questions that index the level of depression, anxiety and stress an individual has experienced in the pre- ceding week. It is a valid and reliable measure that is frequently used in clinical practice and research alike (Henry & Crawford, 2005).

Social Relationships and Support (2 x 4-item scales; 3 minutes) - There is a vast epidemiological and medical evidence base showing the important role that social connectedness with others plays in health and recovery (Holt-Lunstad et al., 2010; Marmot, 2005;). Recent evidence shows that the nature of social participation with individuals and groups of others can make differential contributions to these outcomes. The social support measures we propose are those that been used more extensively in previous research to address the issues of social process in a range different clinical populations (e.g., Gleibs et al., 2011; Haslam et al., 2014; Jetten et al., 2010; Morton et al., 2015).

Loneliness Scale (3 minutes) - People who are less connected socially also experience higher perceived loneliness and social isolation. To capture this, the study incorporates a standardised 3-item Loneliness scale (Hughes et al., 2004) comprising items from the well-validated UCLA Loneliness scale (Russell et al., 1980).

Total expected time for all cognitive assessment tools (including Pain 7.3 below): 45-60 minutes. All neuropsychological tests will be given in a counterbalanced order; with four different packages, randomly assigned at the four time points comprising the alternate versions of specific tests to manage practice effects.

8.2 CEREBRAL DESATURATION

The incidence of cerebral desaturation events using both the INVOS™ and FORE-SIGHT® machines will be recorded on the data collection form. Cerebral desaturation will be defined as a decrease in rSO₂ greater than, or equal to 20% from baseline or a fall below 50% absolute (after Murphy et al., 2010; Salazar et al., 2013).

We will use data capture software that will simultaneously provide a record from which we can determine the number, severity and length of CDEs from both INVOS and Foresight sensors plus MAP. Subanalyses performed on these may attempt to ascertain whether or not any of these factors are important.

8.3 PAIN

Pain is a common occurrence with any injury and a highly predominant outcome post-surgery (Mitchell, Adebajo, Hay, & Carr, 2005). To capture this; the study will incorporate a validated, analogue global pain scale (0-100; Williamson & Hoggart, 2005). Each increment is a Likert-type scale of 0-100, where “0” is no pain, “50” is moderate pain and “100” is the worst imaginable pain. The participant will be asked to label which increment at which their current pain is falling.

8.4 ADVERSE EVENTS

Any adverse events arising during the trial will be closely monitored and followed up until the resolution of symptoms. These will be checked at each assessment stage and recorded on the data collection form (24.4).

9 CONFIDENTIALITY

Information about study subjects will be kept confidential and managed accordingly to the requirement of Human Research as determined by the NHMRC, and the local ethics review board, in this case, the Bellberry Human Research Ethics Committee.

All raw data forms will be kept in an individually identifiable format. The data collection forms and the master participant list with patient names; contact details and a study specific number will be kept in a secure lockable cabinet at the Brisbane Hand and Upper Limb Research Institute. All data will be transcribed in a re-identifiable format and analysed and reported in a non-identifiable format.

10 DATA ANALYSIS

Data will be transcribed from the participants data collection forms into excel spreadsheets in a re-identifiable format. Analysis will be performed with the assistance of a statistician and the statistical package used will be SPSS.

10.1 STATISTICAL METHODS

Baseline demographic and clinical data will be examined using descriptive statistics (means, standard deviations [SDs], and percentages). Dropouts will be compared to those who complete the study. For initial data screening, descriptive statistics (means, standard deviations [SDs], and percentages) will be completed for all predictor and outcome variables. Based on the findings of de Tournay - Jette et al. (2011), we assume that 62% of patients will not experience desaturation, and that the probability of postoperative cognitive dysfunction in these patients is 29%. To observe an increased risk of cognitive dysfunction of 1.75 times in patients who experienced desaturation (i.e. to 50%) we will be required to collect postoperative data on 193 participants, assuming $\alpha=0.05$ and $\text{power}=80\%$. For the secondary outcome, which is the concordance between the INVOS™ 5100 and FORE-SIGHT® devices during shoulder surgery, the agreement between these pairs of observations will be assessed using intra-class correlation (ICC 3,1) (Portney & Watkins, 1993).

A number of statistical analyses will be used to explore the relationship between CDE and other study variables to allow for use of continuous and categorical data (e.g. linear & logistic regression). With an anticipated sample size of 200 this should provide adequate numbers for our analysis (Portney & Watkins, 1993). Prior to the use of a regression analysis, exploratory bivariate analyses (e.g. correlation, chi square, one-way ANOVA) will be conducted among all predictor variables to identify multi-collinearity. Bivariate analyses between each predictor and outcome variable will then be conducted. Significant predictor variables identified from bivariate analyses will be entered into the regression model. A process of backward elimination will then be used to identify the best model considering main effects and two-way interactions at $p \leq 0.05$. Data analysis will be conducted using SSPS version 23. Any complication rates will be reported in terms of frequency and analysed. The potential contribution of type of surgery, the length of surgery and the nature of the anaesthetic agents

used are recorded as standard practice and will be included in analyses to assess whether or not they represent confounding factors. The final multivariable model will include the main effects of interest and variables identified as potential confounders.

The type and duration of anaesthesia is being recorded (see 15.4). Although the choices of anaesthetic medications and techniques may affect the incidences of cerebral desaturation event, they do not have any impact on correlating cerebral desaturation events, should they occur, and the postoperative metrics we are seeking to measure other than the secondary outcomes of pain and postoperative nausea and vomiting. By recording these additional data sets we will seek to ascertain any confounding effects they may have on the pain and postoperative nausea and vomiting but they will not be relevant to cerebral desaturation events since we are looking at the effects of the cerebral desaturation events rather than their incidence.

11 RISK ANALYSIS

Shoulder surgery in the BCP is routinely used in clinical practice. Participants who agree to be part of the trial will experience no additional risks above those normally associated with this routine procedure. X-ray imaging is performed for some surgical procedures as the normal course of intraoperative patient care. Suspected adverse neurological outcomes associated with the surgery may require further imaging in the form of cerebral CT / MRI as is standard practice. Such imaging would be unrelated to the monitoring of cerebral oximetry.

If a participant is found to be experiencing psychological distress (i.e. depression, anxiety or suicidality) or is found to have a significant cognitive impairment, the following procedures will be put in place. Psychological distress will be monitored initially through the psychological measures being used and will be administered by a clinical psychology trainee or other health professional. These measures are standardised and have recognised clinical cut-off criteria. The medical consultant in the project team will be informed of anyone meeting the criteria for at least mild to moderate levels of distress. As the medical consultant is responsible for the care of all patients, he will take responsibility for any onward referral or medical management as per standard clinical practice. A similar procedure will be followed in the case of significant cognitive impairment. The neuropsychological tests are standardised with norms provided to indicate possible impairment. The medical consultant will be informed of anyone meeting the criteria for mild to moderate impairment and this will be managed as per standard clinical practice with referral for further assessment. Additionally, any mood- or cognitive-related concerns raised by participants will be brought to the attention of the medical consultant.

12 BUDGET AND FUNDING IN-KIND SUPPORT

	Item	Source	Details	Costs to BHULRI & UQ
1	Investigator time & Research assistant	BHULRI & UQ	Protocol development, ethics, study assessments, participant follow-up, data entry, analysis, writing paper for publication, submission.	In Kind
2	INVOS™ monitors/sensors	Supplier	Standard monitors/sensors used at Brisbane Private Hospital for this population	Nil
3	FORE-SIGHT® monitors/sensors	Supplier	Sufficient monitors/sensors to be provided for purpose of research	Nil

13 DISSEMINATION

Findings from this investigation will be disseminated locally through existing state and nation wide clinical networks and in-service education amongst relevant clinical teams (e.g. multi-disciplinary upper limb teams in hospital facilities).

Research outcomes will also be disseminated widely through peer-reviewed publications as well as through local, national and/or international conferences. The proposed dissemination of these findings is likely to guide models of healthcare both nationally and internationally.

14 CLINICAL INVESTIGATION PLAN SUMMARY- PART TWO

TITLE	Health professionals' experiences of post-operative cognitive decline
INVESTIGATORS	Principal: Associate Professor Mark Ross, Dr Phillip Duke, Dr David Gilpin, Dr Phil Melksham Associate: Dr Silvia Manzanero, Ms Ruby Strauss, Ms Chelsea Duke, Ms Louise Lee, Mr Glen Russell
OBJECTIVES	The general aim of the study is to understand what professionals experience and understand of POCD, and/or what they might expect to experience.
STUDY DESIGN	Descriptive Survey
SITES	Brisbane Private Hospital
NUMBER OF SUBJECTS	Approximately 200 participants will be recruited to this study.
TARGET POPULATION	Participants will be currently practicing medical, nursing and allied health practitioners.
LENGTH OF CLINICAL INVESTIGATION	It is anticipated that this study will require 6 months from commencement.
OUTCOME	Demographic data and outcome variables will be examined using descriptive statistics (means, standard deviations [SDs], and percentages). Factors examined will be: <ul style="list-style-type: none"> • Whether each individual clinician has encountered POCD in practice • What cognitive functions were affected or what they would expect to see • The duration seen or expected • Whether there were any emotional symptoms or whether they would expect emotional symptoms • How it was managed or how they would expect it to be managed • What else could be done to manage POCD

15 INTRODUCTION

There are no published studies on the experiences of POCD from a health professionals' perspective. With so many debates surrounding the nature and duration of POCD in the literature (e.g. Berger et al., 2015), an understanding of experiences and expectations from the treating clinician's perspectives would be an important supplement to the current research base. As a result the nature, duration, prevention techniques and management of POCD from a practicing clinicians' perspective particularly, require further investigation. Further research in these areas indicated and the proposed study aims to address the issues raised here.

15.1 LAYMAN'S SUMMARY

As there is no existing literature base, it would be invaluable to examine POCD from a clinicians perspective, particularly surrounding the duration, current prevention techniques and management in a clinical setting.

15.2 PURPOSE OF THE INVESTIGATION

The purpose of this investigation is to gain clinicians' perspectives regarding the experience of POCD in Australian practice. Currently, there is no existing literature base to suggest what clinicians encounter day to day in clinical practice and what is actually being done to manage POCD and possible psychological sequela. A clinician's perspective would provide practical implications for the clinical stakeholders and their patients as well as for the management of POCD and potential for services.

15.3 INTERVENTION GROUPS

The study will involve a descriptive survey. Clinicians who meet eligibility criteria will be able to complete the survey.

15.4 GENERAL AIM OF THE STUDY

The general aim of the study is to understand what professionals experience and understand of POCD, and/or what they might expect to experience.

15.5 RESEARCH QUESTIONS

STUDY TWO has five research questions, based on the perspective of practicing clinicians;

- (i) How many times has POCD been seen in a clinical setting?
- (ii) How often are psychological symptoms seen comorbidly with POCD?
- (iii) How POCD is currently managed in clinical practice?
- (iv) What are clinician perspectives on how POCD should be managed?
- (v) Does the experience of POCD differ between professions and clinical populations?

15.6 HYPOTHESES

As this is a descriptive study no specific hypotheses have

15.7 STUDY TWO PARTICIPANT ELIGIBILITY CRITERIA

15.7.1 INCLUSION CRITERIA

Participants meeting the following inclusion criteria will be invited to participate in the study (see 15.1);

- Over 18 years of age
- Able to read and speak English
- A clinician currently practicing in the fields of medicine, nursing or allied health

15.7.2 EXCLUSION CRITERIA

Participants will be excluded from the study for the following reasons (see 15.1);

- Under 18 years of age
- Not currently registered with Australia Health Practitioner Regulation Association

15.8 RECRUITMENT

The survey population will be recruited from The Brisbane Private Hospital. A link to complete the survey will be emailed through existing email lists associated with BHULRI.

15.9 SAMPLE SIZE

As this is a descriptive study examining practicing clinicians perspectives of POCD no power analyses can be conducted.

16 SCREENING /ENROLMENT

Patients will be screened according to the selection criteria. Those who meet the selection criteria will be invited to complete the survey. After reviewing the Participant Information form (24.7) and acknowledging that they have understood the purpose of the study, their involvement, risks and benefits. Any participant who refrains from participation will not be disadvantaged in any way.

17 DATA COLLECTION

17.1 DATA COLLECTION FOR PRIMARY AND SECONDARY OUTCOMES

Demographic data and survey data will be completed by each participant on an online database QUALTRICS.

17.1.1 DEMOGRAPHIC AND MEDICAL INFORMATION FORM

Demographic information will be obtained from each participant who agrees to participate in the survey. This information will include, but is not limited to:

- Age
- Gender
- State
- Profession
- Level within that profession
- Years in Clinical Practice
- Client groups the participant works with (e.g. adult internal medicine, geriatric neurology)
- Based in hospitals (e.g. public or private) or private practice.

18 OUTCOME MEASURES

18.1 SURVEY

A survey has been designed and developed on Qualtrics to examine each individual clinician's experiences of POCD in practice (24.6). The participant information sheet and consent form will be provided online at the beginning of the survey (24.7 & 24.8). The questions will identify whether each individual clinician has encountered POCD or not in practice. If they have encountered POCD in clinical practice follow up examination includes how many times they have encountered POCD, what cognitive functions were effected, the duration of POCD, were there any emotional symptoms, how it was managed and what else could have been done to manage POCD. If they have not previously encountered POCD in clinical practice follow up examination includes what cognitive functions they expect to be effected, would they expect emotional symptoms and how they might manage a patient experiencing POCD. The survey is expected to take 10 minutes to complete.

19 CONFIDENTIALITY

Information about study subjects will be kept confidential and managed accordingly to the requirement of Human Research as determined by the NHMRC, and the local ethics review board, in this case, the Bellberry Human Research Ethics Committee.

All data will be downloaded in non-identifiable format from the Qualtrics Database and stored on securely on electronically on password-protected computers by the research team based at the Brisbane Hand and Upper Limb Research Institute, for purposes of analysis.

20 DATA ANALYSIS

Data will be downloaded directly from Qualtrics into an SPSS datasheet. Analysis will be performed with the assistance of a statistician and the statistical package used will be SPSS.

20.1 STATISTICAL METHODS

As this is a descriptive study, demographic data and outcome variables will be examined using descriptive statistics (means, standard deviations [SDs], and percentages).

21 RISK ANALYSIS

This is a low risk study with no foreseeable risks.

22 BUDGET AND FUNDING IN-KIND SUPPORT

	Item	Source	Details	Costs to BHULRI & UQ
1	Investigator time & Research assistant	BHULRI & UQ	Protocol development, ethics, data entry, analysis, writing paper for publication, submission.	In Kind

23 DISSEMINATION

Dissemination will be the same as study one (13).

24 REFERENCES

- Berger, M., Nadler, J. W., Browndyke, J., Terrando, N., Ponnusamy, V., Cohen, H. J., . . . Mathew, J. P. (2015). Postoperative Cognitive Dysfunction. *Anesthesiology Clinics*, 33(3), 517-550.
doi:10.1016/j.anclin.2015.05.008
- Bickler, P. E., Feiner, J. R., Eilers, H., & Rollins, M. (2013). Factors affecting the performance of 5 cerebral oximeters during hypoxia in healthy volunteers. *Anesth Analg*. 117(4):813-23.
- Closhen, D., Berres, M., Werner, C., Engelhard, K., & Schramm, P. (2013). Influence of beach chair position on cerebral oxygen saturation: A comparison of INVOS and FORE-SIGHT cerebral oximeter. *Journal of neurosurgical anesthesiology*, 25(4), 414-419.
- Douds, M. T., Straub, E. J., Kent, A. C., Bistrick, C. H., & Sistino, J. J. (2014). A systematic review of cerebral oxygenation-monitoring devices in cardiac surgery. *Perfusion*, 0267659114544713.
- Gleibs, I., Haslam, C., Jones, J., Haslam, S.A., McNeil, J., & Connolly, H. (2011). No country for old men? The role of a Gentlemen's Club in promoting social engagement and psychological well-being in residential care. *Aging and Mental Health*, 15, 456-466
- Haslam C Cruwys T Haslam SA. "The we's have it": Evidence for the distinctive benefits of group engagement in enhancing cognitive health in ageing. *Soc Sci Med*. 2014; 120: 57-66.
- Henry, J. D., & Crawford, J. R. (2005). The short-form version of the Depression Anxiety Stress Scales (DASS-21): Construct validity and normative data in a large non-clinical sample. *British Journal of Clinical Psychology*, 44(2), 227-239.
- Hessel, T. W., Hyttel-Sorensen, S., & Greisen, G. (2014). Cerebral oxygenation after birth—a comparison of INVOS® and FORE-SIGHT™ near-infrared spectroscopy oximeters. *Acta Paediatrica*, 103(5), 488-493.
- Holt-Lunstad, J., Smith, T. B., & Layton J. B. (2010) Social Relationships and Mortality Risk: A Meta-analytic Review. *PLoS Med*; 7: e1000316.
- Jetten, J., Haslam, C., Pugliese, C., Tonks, J., & Haslam, S.A. (2010). Declining autobiographical memory and the loss of identity: Effects on well-being. *Journal of Clinical and Experimental Neuropsychology*, 32, 408-416.
- Jetten, J., Haslam, C., & Haslam S. A. (Eds.) (2012). *The social cure: Identity, health and well-being*. London: Psychology Press.
- Jones, J. M., Haslam, S. A., Jetten, J., Williams, W. H., Morris, R., & Saroyan, S. (2011). That which doesn't kill us can make us stronger (and more satisfied with life): The contribution of personal and social changes to well-being after acquired brain injury. *Psychology and Health*, 26(3), 353-369.
- Kizilbash, A. H., Vanderploeg, R. D., & Curtiss, G. (2002). The effects of depression and anxiety on memory performance. *Archives of clinical neuropsychology*, 17(1), 57-67.
- Kok, W. F., Harten, A. E., Koene, B. M. J. A., Mariani, M. A., Koerts, J., Tucha, O., & Scheeren, T. W. L. (2014). A pilot study of cerebral tissue oxygenation and postoperative cognitive dysfunction among patients undergoing coronary artery bypass grafting randomised to surgery with or without cardiopulmonary bypass*. *Anaesthesia*, 69(6), 613-622.

- Krenk, L., Rasmussen, L. S., & Kehlet, H. (2010). New insights into the pathophysiology of postoperative cognitive dysfunction. *Acta anaesthesiologica Scandinavica*, 54(8), 951-956.
- Lopez, O. D., Gollaher, T., & Riddle, D. (2014). Cerebral oxygen desaturation monitored by intraoperative near-infrared spectroscopy and incidence of post-operative cognitive dysfunction: a systematic review. *The JBI Database of Systematic Reviews and Implementation Reports*, 12(8), 145-192.
- Marmot M. (2005). Social determinants of health inequalities. *Lancet*. 365:1099-104.
- Mitchell, C., Adebajo, A., Hay, E., & Carr, A. (2005). Shoulder pain: diagnosis and management in primary care. *Bmj*, 331(7525), 1124-1128.
- Morton, T.A., Wilson, N.A., Haslam, C., Birney, M., Kingston, R., & McCloskey, L.-G (2015). *Activating and Guiding the Engagement of Seniors through social media: Findings from the UK arm of the AGES 2.0 project*. Manuscript under review.
- Murphy, G. S., Szokol, J. W., Marymont, J. H., Greenberg, S. B., Avram, M. J., Vender, J. S., & Nisman, M. (2010). Cerebral oxygen desaturation events assessed by near-infrared spectroscopy during shoulder arthroscopy in the beach chair and lateral decubitus positions. *Anesthesia & Analgesia*, 111(2), 496-505.
- Parra, V. M., Sadurni, M., Donate, M., Rovira, I., Roux, C., Ríos, J., & Fita, G. (2011). [Neuropsychological dysfunction after cardiac surgery: Cerebral saturation and bispectral index: A longitudinal study]. *Revista medica de Chile*, 139(12), 1553-1561.
- Pohl, A., & Cullen, D. J. (2005). Cerebral ischemia during shoulder surgery in the upright position: a case series. *Journal of clinical anesthesia*, 17(6), 463-469.
- Portney, L. G. & Watkins, M.P. (1993). *Foundations of clinical research. Applications to practice*. Appleton & Lange, Stamford.
- Russell, Dan; Peplau, Letitia A.; Cutrona, Carolyn E. The Revised UCLA Loneliness Scale: Concurrent and Discriminant Validity Evidence. *Journal of Personality and Social Psychology* 1980;39:472–80.
- Salazar, D., Sears, B. W., Aghdasi, B., Francois, A., Tonino, P., & Marra, G. (2013). Cerebral desaturation events during shoulder arthroscopy in the beach chair position: patient risk factors and neurocognitive effects. *Journal of Shoulder and Elbow Surgery*, 22(9), 1228-1235.
- Sopena S., Dewar B.K., Nannery R., Teasdale T.W. & Wilson B.A. (2007). The European Brain Injury Questionnaire (EBIQ) as a reliable outcome measure for use with people with brain injury. *Brain Inj.* 21(10):1063-8.
- Strauss, E., Sherman, E. M., & Spreen, O. (2006). *A compendium of neuropsychological tests: Administration, norms, and commentary*. Oxford University Press, USA.
- Sullivan, K. (2005). Alternate forms of prose passages for the assessment of auditory-verbal memory. *Archives of Clinical Neuropsychology*, (20): 745-753.
- de Tournay-Jetté, E., Dupuis, G., Bherer, L., Deschamps, A., Cartier, R., & Denault, A. (2011). The relationship between cerebral oxygen saturation changes and postoperative cognitive dysfunction in elderly patients after coronary artery bypass graft surgery. *Journal of cardiothoracic and vascular anesthesia*, 25(1), 95-104.

- Tully, P. J., Baker, R. A., Turnbull, D., & Winefield, H. (2008). The role of depression and anxiety symptoms in hospital readmissions after cardiac surgery. *Journal of behavioral medicine, 31*(4), 281-29.
- Wechsler, D. (2008). Wechsler adult intelligence scale–Fourth Edition (WAIS–IV). *San Antonio, TX: NCS Pearson.*
- Williamson, A., & Hoggart, B. (2005). Pain: a review of three commonly used pain rating scales. *Journal of Clinical Nursing, 14*(7), 798-804. doi: 10.1111/j.1365-2702.2005.01121.x
- Zheng, F., Sheinberg, R., Yee, M. S., Ono, M., Zheng, Y., & Hogue, C. W. (2013). Cerebral Near-Infrared Spectroscopy (NIRS) monitoring and neurologic outcomes in adult cardiac surgery patients and neurologic outcomes: a systematic review. *Anesthesia and analgesia, 116*(3)



24.1 Eligibility Checklist

Does the patient meet the following inclusion criteria?

1. Able to read and speak English
2. Over 18 years of age
3. Requires shoulder surgery in the Beach Chair position

Does the patient have any other clinical characteristics requiring exclusion from the study?

Exclusion Criteria	Yes	No
Under 18 years of age		
Pre- operative Mini-Mental State Examination (MMSE) < 24		
Pre-existing Cerebrovascular Disease		
Orthostatic hypotension		
ASA physical status IV and V*		
History of drug and/or alcohol abuse		
Unstable mental health condition		
Neurological disease (e.g. previous stroke)		
Currently pregnant or suspected to be pregnant		

ASA = the American Society of Anaesthesiologists physical status classification system. Level IV indicates the presence of severe systemic disease that is a threat to life. Level V is a moribund person who is not expected to survive without some form of surgery.

24.1.1 PARTICIPANT ELIGIBILITY CRITERIA

INCLUSION CRITERIA

Patients meeting the following inclusion criteria will be invited to participate in the study (see 14.1);

- Have a shoulder condition for which surgery in the BCP is appropriate.
- Over 18 years of age
- Able to read and speak English

EXCLUSION CRITERIA

Patients will be excluded from the study for the following reasons (see 14.1);

- Under 18 years of age
- Pregnant women
- Pre- operative Mini-Mental State Examination (MMSE) < 24

- Pre-existing cerebrovascular disease as reported by the assessing medical consultant and recorded in patient charts
- Orthostatic hypotension
- ASA physical status IV and V*
- History of drug and/or alcohol abuse
- Neurological disease (e.g. previous stroke)
- Significant mood and anxiety disorders as determined by treating consultant
- Any other condition, which in the opinion of the investigators, would render the patient unsuitable for participation in the study

* ASA = the American Society of Anaesthesiologists physical status classification system. Level IV indicates the presence of severe systemic disease that is a threat to life. Level V is a moribund person who is not expected to survive without some form of surgery.



24.2 Participant Information Form

Participant Information Form Brisbane Private Hospital

Project Title: *Prediction of cognitive decline following shoulder surgery in the beach chair position: the value of cerebral oximetry.*

You are being advised of this research because you have decided to undergo shoulder surgery in the Beach Chair Position (BCP). You are being asked to take part in a study evaluating the use of cerebral (brain) oxygen monitors in shoulder surgery to predict and potentially prevent what is known as post-operative cognitive decline (i.e. memory and thinking problems) that occurs in a very small number of people. This Study is being conducted by The Brisbane Hand & Upper Limb Research Institute in conjunction with the University of Queensland.

Who is doing the Research?

Primary Investigators:

Associate Professor Mark Ross	Orthopaedic Surgeon
Dr Phillip Duke	Orthopaedic Surgeon
Dr David Gilpin	Orthopaedic Surgeon
Dr Phillip Melksham	Anaesthetist

The primary investigatory team comprises staff of the Brisbane Private Hospital (BPH) and the University of Queensland (UQ). The including consultant orthopaedic surgeons, A/Prof Ross (BPH, UQ) and Dr's Duke and Gilpin, and an anaesthetist, Dr Melksham.

Associate Investigators: Dr Silvia Manzanero, Ms Ruby Strauss, Ms Chelsea Duke, Ms Louise Lee, Mr Glen Russell

Contact:

Dr Silvia Manzanero
Research Manager
Phone: (07) 3834 7069
Email: researchmanager@upperlimb.com

What does this form tell me?

This is an important form. Please read it carefully. This form tells you about the research project. It explains the procedures involved. Knowing what is involved will help you decide if you want to take part in the research. If you agree to take part in this study, you need to sign this form. Your signature means that you have been told about the study and what the risks are. Your signature on this form also means that you want to take part in this study. This form or the consent form may contain words that you do not understand. Please ask the study doctor or study staff to explain any words or information that you do not clearly understand. Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether you take part or not. 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 participate in the research processes that are described;
- consent to the use of your personal and health information as described.

What is the purpose of this research project?

Surgery to the shoulder may be performed with patients seated upright in a position known as the "Beach Chair Position (BCP)." This position has certain advantages compared to other surgical positions (e.g. side lying) in some situations. However, it has been found that surgery in the BCP can temporarily decrease the amount of oxygen found in the brain as a result of the combined effects of gravity and anesthesia. Occasionally, this has been associated with some mild memory loss and confusion. As a result, the use of a "cerebral oxygen monitor" (a machine that measures oxygen content in the brain) during shoulder surgery in the BCP has become part of standard care. Before and during surgery, a monitor placed on the your forehead measures the amount of oxygen present in the brain to help control this to an acceptable level. A number of monitors are now commercially available. However, the actual relationship between the supply of oxygen to the brain during surgery and the chance of later developing problems with memory and thinking (known as "post operative cognitive decline" – POCD) is not clear. It is also not known if one monitor is more accurate than another at predicting these. Therefore, this study will examine the relationship between brain oxygen levels during shoulder surgery and the incidence of POCD (problems with memory and thinking). A second aim is to compare two commonly used oxygen monitors as well as the importance of other key clinical variables (e.g. blood pressure, nausea, body fat etc). Two sets of adhesive sensors, (one set from each of the two monitors we are comparing), will be placed on your forehead to allow us to compare them.

What does participation in this research project involve?

We aim to recruit approximately 200 people for this study. Your part in the project will involve you an assessment of emotional status, memory and concentration using pen and paper and verbal tasks. The measures of your emotional status are being taken, as this too can sometimes be associated with changes memory and concentration. These tasks take approximately an hour of your time to complete and you will be asked to complete them at five time points (the day before surgery, day one, between ten and fourteen days post-surgery, at one month post-surgery and at 3 months). Should you agree to participate in the project, we will organize for these post-operative assessments to take place alongside your usual follow up visits with your Orthopaedic surgeon. You will not be paid to take part in this research. You will not be required to pay for any time spent completing the tests involved in this study, specifically there will be no extra costs to you outside of what would be normal for your usual follow up assessment. It is important for you to understand that there will be questions relating to your mood and feelings including sensitive information about possible depression and suicidality. As participation is voluntary, you do not have to answer these questions if you find them upsetting.

What are the possible benefits?

We cannot guarantee or promise that you will receive any benefits from this research. However, you will be provided with feedback about the results of the assessments should you wish. The findings from this research will add to our existing knowledge base and may benefit patients in the future.

What are the possible risks?

There are no anticipated risks involved with participating in this study beyond the inconvenience associated with time required to complete the assessments.

If you have any concerns about possible cognitive changes after surgery, these will be brought to the immediate attention of your medical consultant for management (which could involve an appointment with your consultant and in some cases, the possibility of referral for further investigation).

Do I have to take part in this research project?

Participation in the research project is voluntary. If you do not wish to take part you don't have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage. Your decision whether to take part or not to take part will not affect your ongoing treatment in any way at The Brisbane Private Hospital.

How will I be informed of the results of this research project?

You can be informed of the final results of the research if you wish. Your individual results will not be provided to you. If you would like to learn the outcome of the study, a summary of results from the study will be published on our website (www.upperlimb.com) at the conclusion of the study which is expected to be in 2019.

What will happen to information about me?

Any information obtained in connection with this research project, which can identify you, will remain confidential and will only be used for the purpose of this research project. It will only be disclosed with your permission, except as required by law. Your data will be stored securely on-site at the Brisbane Hand and Upper Limb Research Institute Office, Brisbane Private Hospital. The investigators in this study will also use information from your medical records.

Data from this study may be published in journals or books and may be used for educational purposes or presentations. However, your name and other identifying information will not be used.

How can I access my information?

In accordance with relevant Australian privacy laws, you have the right to access the information collected and stored by the researchers about you. You also have the right to request that any information, with which you disagree, be corrected. Please contact one of the researchers if you would like to access your information.

Is this research project approved?

The ethical aspects of this research project have been approved by Bellberry HREC. This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)* produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies.

COMPENSATION for Injury

If, as a result of your participation in this study, you become ill or injured, immediately advise your study doctor of your condition. In the first instance your study doctor will evaluate your condition and then discuss treatment with both you and your regular treating doctor. Since you are participating in a non-sponsored study any question about compensation must initially be directed to your study doctor who should advise their insurer of the matter. It is the recommendation of the independent ethics committee responsible for the review of this study that you seek independent legal advice.

Advice and Information

If you have any further questions regarding this study please do not hesitate to contact Dr Silvia Manzanero on (07) 38347069. If you have any questions regarding ethics, please contact Bellberry HREC on (08) 8361 3222.



Participant Informed Consent Form - Brisbane Private Hospital

Project Title: Prediction of cognitive decline following shoulder surgery in the beach chair position: the value of cerebral oximetry.

- I am over 18 years old.
- I have read this document and I understand the purposes, procedures and risks of this research project.
- I have given permission for access to my medical records, for the purpose of this research.
- I give permission for my GP to be informed of my participation in the study and be provided with any relevant clinical information.
- I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to the Brisbane Hand and Upper Limb Research Institute concerning my treatment that is needed for this project. I understand that such information will remain confidential and will be safe-guarded.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- I understand that my results will remain confidential, and that my data will be kept at the Brisbane Hand and Upper Limb Research Institute.
- I freely agree to participate in this research project.
- I understand that I am free to withdraw at any time.
- I understand that if I do withdraw or decline to participate, this will have no impact on the treatment I receive.
- I understand that I will be given a signed copy of this document to keep.

Participant's name (printed)	
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.	
Researcher's name (printed)	
Signature	Date



Data Collection Form – Cerebral Perfusion Beach Chair Position

Patient Identifier:

Surgeon:

Date of Surgery:

Investigator to Complete		
Date of Assessment: <i>Pre-op:</i> <i>Day 1:</i> <i>Day 10-14:</i> <i>1 month:</i> <i>3 months:</i>		
Gender: Male <input type="checkbox"/> Female <input type="checkbox"/>	Date of Birth:	Age:
Height: (cm)	Weight: (kg)	BMI:
Operative Side: Left <input type="checkbox"/> Right <input type="checkbox"/>		
Dominance: Left <input type="checkbox"/> Right <input type="checkbox"/> Ambidextrous <input type="checkbox"/>		
Occupation:(Please note previous occupation of retired participants)		
Current work status: Part time <input type="checkbox"/> Full time <input type="checkbox"/> Other (e.g. voluntary work):		
Recreational activities (including sports):		

<p><i>Primary Diagnosis (check one)</i></p> <p><input type="checkbox"/> OA</p> <p><input type="checkbox"/> Trauma a) Mechanism -</p> <p style="padding-left: 40px;">b) Date of Injury –</p> <p><input type="checkbox"/> Chronic Condition</p> <p><input type="checkbox"/> Other, specify –</p>	<p><i>Presenting Symptoms (select yes or no)</i></p> <table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <thead> <tr> <th style="width: 10%;"></th> <th style="width: 15%;">Pain</th> <th style="width: 15%;">Weakness</th> <th style="width: 15%;">Decreased motion</th> <th style="width: 15%;">Instability</th> <th style="width: 15%;">Impaired sensation</th> <th style="width: 15%;">Other</th> </tr> </thead> <tbody> <tr> <td>Yes</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>No</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>		Pain	Weakness	Decreased motion	Instability	Impaired sensation	Other	Yes							No						
	Pain	Weakness	Decreased motion	Instability	Impaired sensation	Other																
Yes																						
No																						

Current treatments:

- Therapy –
- Medications –
- Other (including supplements)-

Co-morbidity

- | | |
|--|--|
| <input type="checkbox"/> Current smoker
<input type="checkbox"/> Past smoker
<input type="checkbox"/> Type 1 Diabetes
<input type="checkbox"/> Type II Diabetes
<input type="checkbox"/> Osteoporosis
<input type="checkbox"/> High blood pressure
<input type="checkbox"/> Low blood pressure | <input type="checkbox"/> Genitourinary disorder _____
<input type="checkbox"/> Haematological disorder _____
<input type="checkbox"/> Cardiovascular disorder _____
<input type="checkbox"/> Gastrointestinal Disorder _____
<input type="checkbox"/> Respiratory Disorder _____
<input type="checkbox"/> Mental Health Condition _____
<input type="checkbox"/> Endocrine/metabolic disorder _____
<input type="checkbox"/> Other (please specify) _____ |
|--|--|

Medical/Surgical history:

--

Cognitive Testing

<i>Assessment</i>	<i>Pre-op</i>	<i>Day 1</i>	<i>Day 10-14</i>	<i>1 month</i>	<i>3 months</i>
MMSE (pre-op only)	x				
Logical memory test	x	x	x	x	x
Trail making test	x	x	x	x	x
Single letter verbal fluency	x	x	x	x	x
Stroop test	x	x	x	x	x
List learning	x	x	x	x	x
Letter-number sequencing	x	x	x	x	x
EBIQ	x	x	x	x	x
Depression anxiety stress	x	x	x	x	x
Social support	x	x	x	x	x
Loneliness scale	x	x	x	x	x

Surgical Record

--

Type of Shoulder Surgery	BCP: <input type="checkbox"/> Other: <input type="checkbox"/>
Duration of Surgery	Time (hh:mm)
Beach Chair Angle	<p>What angle was used? <input type="text"/></p> <p>Was this altered at all during surgery? Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>If so how? _____</p>
Cerebral O ₂	<p>1. What was baseline cerebral O₂? <input type="text"/></p> <p>2. Did cerebral O₂ drop >20% from baseline? Yes <input type="checkbox"/> No <input type="checkbox"/> If yes how many occasions and duration/occasion? _____</p> <p>3. Did cerebral O₂ drop < absolute value of 50%? Yes <input type="checkbox"/> No <input type="checkbox"/> If yes how many occasions and duration/occasion? _____</p> <p>4. What was the <i>average</i> cerebral O₂ over the entire procedure? _____</p>
Mean Arterial Blood Pressure	<p>What was the mean arterial blood pressure range during surgery? _____</p> <p>Did the mean arterial blood pressure drop significantly during surgery? Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>If yes how much did this drop? _____</p>
Adverse Events	<p>Were any complications experienced during surgery? Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>If yes please specify _____</p> <p>_____</p>
Duration of Anaesthetic	<p>How long was the patient anaesthetised? hh:mm</p> <p>_____</p>
Anaesthetic medication	<p>What medications were used during surgery and what doses were given?</p> <p>1.</p> <p>2.</p> <p>3.</p> <p>4.</p>
Intraoperative Drug Record	<p>What medications (other than anaesthetics) were used during the surgery and what doses were given?</p> <p>1.</p> <p>2.</p> <p>3.</p>

	4.
Perioperative Drug Record	<p>What medications (other than anaesthetics) were provided before and/or after the surgery and what doses were given?</p> <p>1.</p> <p>2.</p> <p>3.</p> <p>4.</p>

Post -Operative Record	
Analgesic Protocol	Medications used:-
Nausea	Yes <input type="checkbox"/> No <input type="checkbox"/>
Vomiting	Yes <input type="checkbox"/> No <input type="checkbox"/> Frequency _____
Length of Hospital Stay	

INVESTIGATOR SIGNATURE

24.5 Participant Withdrawal Form



Participant Withdrawal Form - Brisbane Private Hospital

Project Title: Prediction of cognitive decline following shoulder surgery in the beach chair position: the value of cerebral oximetry.

Protocol Number: HREC2015-12-832

Primary Investigators: Associate Professor Mark Ross, Dr Phillip Duke, Dr David Gilpin, Dr Phil Melksham

Associate Investigator: Dr Silvia Manzanero, Ms Ruby Strauss, Ms Chelsea Duke, Ms Louise Lee, Mr Glen Russell

Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with Brisbane Hand & Upper Limb Research Institute.

Name of Participant (please print) _____
Signature _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.

--

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of Study Doctor/ Senior Researcher† (please print) _____
Signature _____ Date _____

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.

24.6 Participant Survey – STUDY TWO

HEALTH PROFESSIONALS' EXPERIENCES OF POST OPERATIVE COGNITIVE DECLINE

PROFESSIONAL BACKGROUND

The following questions are about you and your profession.

Age: _____

Gender:

Male

Female

State:

Queensland

New South Wales

Victoria

South Australia

Canberra

Western Australia

Tasmania

Other:

What is your profession?

Medical

Area: _____

Nursing

Psychology

Neuropsychology

Occupational Therapy

Speech Pathology

Physiotherapy

Other

What level are you currently in your profession? _____ (e.g. interns, registrar, fellow, professor)

How senior is your position in your current organization:

Very senior

Senior

Intermediate

Junior

Very junior

How many years have you been in clinical practice (years)?

≤1

1-3

4-7

8-10

≥10

How long have you worked for your *current* organisation? _____ (weeks/months/years)

Who is your employer?

- Public Sector
- Private Sector
- Private Practice
- University
- Multiple

What population(s) do you currently work with?

- Paediatric
- Adult
- Geriatric

In which areas (e.g. surgical, neurology, internal medicine, allied health): _____

Postoperative cognitive dysfunction (POCD) is a decline in cognitive function more typically seen after a few days to several months following surgery, but can last for several years.. It is distinct from delirium, which only occurs within the first few days. The decline in cognitive function is not attributed to any adverse complications and occurs peri-operatively. What we would like to know is your experiences of POCD in a *clinical setting*.

1. Have you encountered POCD before?

- YES
- NO

If you answered yes please complete questions 2 to 9. If you answered no please go to question 10.

2. How many times have you encountered it? _____ (number)

3. What cognitive functions were impacted? If you have seen more than one case of POCD, identify all the areas that were affected across the people you have seen:

- Short Term Memory
- Long Term Memory
- Attention/ Working Memory
- Planning/Organisation
- Inhibition
- Initiation
- Self-monitoring
- Emotional Control
- Gross and Fine Motor Control
- Language
- Learning

4. For the problems you identified, please number them in order of the general impact you felt this had on the person's (or people, if you have encountered more than one case) everyday functioning from 1= least impactful to 5 = most impactful.

- Short Term Memory
- Long Term Memory
- Attention/ Working Memory
- Planning/Organisation
- Inhibition
- Initiation
- Self-monitoring
- Emotional Control

- Gross and Fine Motor Control
- Language
- Learning
- 5. How long did the POCD last?
- 3-7 days
- 8-28 days
- 4-6 weeks
- 6 weeks to 3 months
- >3 months
- >12 months
- Unknown

6. Did people experience any associated emotional changes? Please tick all that apply

- Low mood
- Nervousness/Worry
- Panic
- Stress
- Fatigue
- Change in sleep
- Irritability
- Weight gain/loss
- Change in appetite
- Excessive crying
- Poor concentration
- Restlessness
- None

7. How was the POCD and/or emotional changes managed?

- No additional intervention to treatment-as-usual
- It was monitored
- Assessment
 - Brief screen (e.g. MMSE)
 - Full Cognitive Battery
- Referral
 - Clinical Psychologist
 - Neuropsychologist
 - Speech Therapist
 - Occupational Therapist
 - Neurologist
 - Other professional
- Other: _____

8. In your opinion could anything else have been done to manage the cognitive and/or mood symptoms? _____

9. If you have any additional information you would like to share about POCD or to provide comments on the survey, please do so here. _____

10. Given the nature of POCD as described above, what cognitive functions do you feel might be vulnerable? Please rank these in order from the 1=most likely to 5= least likely:

- Short Term Memory
- Long Term Memory
- Attention/ Working Memory
- Planning/Organisation
- Inhibition
- Initiation
- Self-monitoring
- Emotional Control
- Gross and Fine Motor Control
- Language
- Learning

11. Would you anticipate changes to emotional functioning? If so, what might you expect to see? Please rank these in order from the 1=most likely to 5= least likely

- Low mood
- Nervousness/Worry
- Panic
- Stress
- Fatigue
- Change in sleep
- Irritability
- Weight gain/loss
- Change in appetite
- Excessive crying
- Poor concentration
- Restlessness
- None

12. In your opinion, how do you feel POCD should be managed?

- No additional intervention to treatment-as-usual
 - Monitor the POCD
 - Provide Assessment
 - Brief screen (e.g. MMSE)
 - Full Cognitive Battery
 - Further Referral
 - Clinical Psychologist
 - Neuropsychologist
 - Speech Therapist
 - Occupational Therapist
 - Neurologist
 - Other professional
- Other: _____

9. Any other comments _____

Thank you for your participation. If you would like to know the outcome of the survey please email researchmanager@upperlimb.com otherwise a summary of results from the study will be finalized and published on our website (www.upperlimb.com) in 2019.

24.7 Participant Information Form – STUDY TWO

Participant Information Form

Project Title: ***Health professionals' experiences of post operative cognitive decline***

You are being advised of this research, as you are a provisional or qualified professional who are currently employed within the field of medicine, nursing or allied health. You are being asked to take part in a study exploring health professionals' experiences of post operative cognitive decline in a clinical setting.

Who is doing the Research?

Primary Investigators: Associate Professor Mark Ross, Ms Sarah Graham, Dr Phillip Duke, Dr David Gilpin, Dr Phil Melksham, Professor Catherine Haslam

Associate Investigators: Dr Silvia Manzanero, Ms Ruby Strauss, Ms Chelsea Duke, Ms Louise Lee, Mr Glen Russell

Contact:

Dr Silvia Manzanero
Research Manager
Phone: (07) 3834 7069
Email: researchmanager@upperlimb.com

What does this form tell me?

This is an important form. Please read it carefully. This form tells you about the research project. It explains the procedures involved. Knowing what is involved will help you decide if you want to take part in the research. If you agree to take part in this study, you need to sign this form. Your signature means that you have been told about the study and what the risks are. Your signature on this form also means that you want to take part in this study. This form or the consent form may contain words that you do not understand. Please ask the study doctor or study staff to explain any words or information that you do not clearly understand. Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether you take part or not. 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 participate in the research processes that are described;
- consent to the use of your personal and health information as described.

What is the purpose of this research project?

Postoperative cognitive dysfunction (POCD) is a decline in cognitive dysfunction more typically seen after a few days to several months following surgery, but can last for several years. It is distinct from delirium, which only occurs within the first few days. The decline in cognitive function is not attributed to any adverse complications and occurs peri-operatively. There are a number of debates however, within the POCD literature, particularly where the duration of decline and assessment are concerned. What we would like to know is a health professional's experiences of POCD in a clinical setting.

What does participation in this research project involve?

Your part in the project will involve completing an online survey, which will take approximately 10

minutes of your time. You will not be paid to take part in this research. There will be no cost to you if you decide to complete this study.

What are the possible benefits?

We cannot guarantee or promise that you will receive any benefits from this research. However, you will be provided with feedback about the results of the assessments should you wish. The findings from this research will add to our existing knowledge base and may benefit patients in the future.

What are the possible risks?

There are no anticipated risks involved with participating in this survey beyond the inconvenience associated with time required to complete the assessments.

Do I have to take part in this research project?

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

How will I be informed of the results of this research project?

You can be informed of the final results of the research if you wish. Your individual results will not be provided to you. If you would like to learn the outcome of the study, a summary of results from the study will be finalized in 2019.

What will happen to information about me?

Any information obtained in connection with this research project, which can identify you, will remain confidential and will only be used for the purpose of this research project. Your data will be stored securely on-site at the electronically on password-protected computers by the research team based at the Brisbane Hand and Upper Limb Research Institute, for purposes of analysis. Non-identifiable data from this study may be published in journals or books and may be used for educational purposes or presentations.

How can I access my information?

In accordance with relevant Australian privacy laws, you have the right to access the information collected and stored by the researchers about you. You also have the right to request that any information, with which you disagree, be corrected. Please contact one of the researchers if you would like to access your information.

Is this research project approved?

The ethical aspects of this research project have been approved by Bellberry HREC. This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)* produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies.

Advice and Information

If you have any further questions regarding this study please do not hesitate to contact Dr Silvia Manzanero on (07) 38347069. If you have any questions regarding ethics, please contact Bellberry HREC on (08) 8361 3222.

24.8 Participant Consent Form – STUDY TWO

Participant Informed Consent Form

Project Title: *Health professionals' experiences of post-operative cognitive decline*

- I am over 18 years old.
- I have read this document and I understand the purposes, procedures and risks of this research project.
- I understand that my results will remain confidential, and that my data will be kept at the Brisbane Hand and Upper Limb Research Institute for the Duration of this Study.
- I freely agree to participate in this research project.
- I understand that I am free to withdraw at any time.

YES