Participant Information Sheet/Consent Form

Non-Interventional Study - *Adult providing own consent*

A **Non-Interventional** research project involves clinical research where no interventional treatment is given to participants other than their routine care. It does not involve the administration of an investigational product, treatment or procedure. Examples include observational research and monitoring of participants.

Instructions for Creating a Participant Information Sheet/Consent Form

- **This template is a guide only.** Non-Interventional research is a very broad area; the template should be adapted to suit the particular research project.
- For projects that involve trialling a clinical drug, procedure or device, one of the other participant information and consent form templates should be used.
- If more than one Participant Information Sheet/Consent Form is required for your research project, please label the different forms clearly for the different participant groups. Please note that if there is a sub-study, a separate form is required.
- There are 20 numbered sections in this template. Please ensure that all relevant sections are included and numbered appropriately in your final document. These headings are included to ensure that all the National Statement and ICH/GCP elements are addressed.
- You should delete any headings and sections that are not relevant to your study and/or modify paragraphs so that they are relevant to your study.
- In this template, there are prompts for the content of your Participant Information Sheet/Consent Form (in *orange italics*) and instructions regarding the format of your document (in *blue italics*). Please ensure that you delete all prompts (*orange italics*) and instructions (*blue italics*) from the final document.
- **Preferred language** recommendations for use in your Participant Information Sheet are in black text with a border around paragraphs. Ensure that the border is removed from the 'Preferred language' sections in the final document. Note that this formatting does not apply to section 20 or to the Consent Form.
- If institutional letterhead/logo is to be used, leave space for the letterhead/logo in accordance with the institution's requirements.
- Include the version date of the document in the footer of each page. Do not use the 'automatic' date insertion function.
- Use the '1 of X' pagination option. Ensure that all references to version date or pagination in the text are correct and consistent with the information in the footer.
- Do not include a place for initialling the document on each page.
- Study participants should be referred to as 'participants' and not 'subjects' or 'patients'.
- References to the National Statement (NS) and ICH/GCP Guidelines are noted in relevant sections as footnotes for your information only and do not need to be included in the final document.
- This guide proposes preferred language for some sections of the Participant Information Sheet/Consent Form. This preferred language may be the totality of what is required for the section or it may be a series of suggested phrases to be used along with other information in the section, as indicated by the guidelines pertaining to the section.
- The reviewing institution may have additional preferred language or standard clauses that you are required to include. Please check with the relevant HREC administration to determine whether additional requirements apply.
- Language used should be readily understandable by the participant (Grade 8 reading level or below) and include Australian spelling of words.
- If translated Participant Information Sheet/Consent Forms are to be used, please check with the relevant HREC administration in case additional requirements apply.
- You should state whether an interpreter will be used in the consent process and/or during the collection of data.
- Text should be at least font size 11 in an easily readable font style.

- Ensure that all font styles and sizes, bolding, italicisation and underlining are intended and that any variations are consistent throughout the document.

- **Please ensure that your final document is proofread.**

This space is reserved for use by jurisdictions or institutions for instructions regarding version control of Participant Information and Consent Forms or other matters specific to jurisdictions or institutions.

St Vincent's Clinic Diagnostic Endoscopy Centre

Participant Information Sheet/Consent Form

Non-Interventional Study - *Adult providing own consent*

Diagnostic Endoscopy Centre

Title	*Motor and cognitive recovery post propofol-only anaesthetic*
Short Title	*anaesthetic*
Protocol Number	*[Protocol Number]*
Project Sponsor	*[Project Sponsor in Australia]*
Coordinating Principal Investigator/ Principal Investigator	*Dr. Drew Heffernan/ Dr. Jenny Stevens*
Associate Investigator(s)	*Mr. Harry Jones and Mr. James Kelly*
Location	*St Vincent's Diagnostic Endoscopy Centre*

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project, *Motor and Cognitive Recovery post Propofol-only Anaesthetic.* This is because you are undergoing an endoscopic procedure or are accompanying someone undergoing an endoscopic procedure. The purpose of this study is to look at the impact of an anaesthetic drug (propofol) which is commonly used for sedation and anaesthesia during endoscopic procedures. This study aims to test participant's cognitive abilities before and after administration of propofol using cognitive testing computer software, and compare the results with participants who have received no propofol (i.e. those accompanying someone having an endoscopy). The results from this study will be used to determine if there are any lasting effects of the propofol anaesthetic used.

The study will involve you reading and signing this consent form and providing us with some baseline demographic information before undergoing two computer-based cognitive tests. The tests will each take around ten minutes to complete.

- If you are undergoing an endoscopy procedure today, you will take the first test immediately before your procedure. After your procedure, an investigator from the study will conduct the second computer-based test.
- If you are not undergoing a procedure today, you will complete the first and second tests with at least one hour in between tests. This will allow us to account for any learning improvement that participants may experience.

Your scores from the computer-based cognitive tests will be de-identified and stored securely with other de-identified information.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and research involved. 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 doctor.

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 or not you take part.

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 the tests and research that are 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 demonstrate the effect, if any, of propofol-only anaesthetic on participant's cognition and motor skills (ability to think and move). Currently, we know that people recover quickly from propofol anaesthetics but there is little existing research to demonstrate this with specific testing of cognition. The computer tests used in this study have been validated in other research looking at the impact of alcohol on people's cognitive and motor skills. As such, our research aims to fill the gap in our knowledge in order to have good evidence that we are discharging people after endoscopic procedures at an appropriate point in the recovery phase following propofol anaesthetic. This audit of current practices in the endoscopy suite will ensure that we are able to provide the best level of care and safety for patients undergoing procedures here.

This research has been initiated by the study doctor, Dr. Drew Heffernan.

3 What does participation in this research involve?

Before proceeding any further, you must read and sign this consent form. If you have any questions at any time after doing so, do not hesitate to ask one of the study investigators.

We will then need to collect some baseline demographic data from you, including things such as your age, gender, height and weight.

Following this, you will be asked a series of questions to determine your eligibility to be included in the study.

Both groups of participants (those having an anaesthetic for endoscopy and those who are not) will then complete the first set of cognitive testing. This testing will be completed using a computer and will take approximately 10-15 minutes to complete.

If you are due to have a procedure today, you will then be taken to where this is to be performed. There will be no change to standard operating procedures during your endoscopy. We will, however, need to be informed if certain situations arise during your procedure. This may occur if one of the doctors looking after you decides that you require additional medications in addition to the propofol during your endoscopy. It is important for us to know about this as it may affect the results of our research. We would like to stress that any and all required treatment and medication will be given as per current best practice and this study will impose no restrictions or modifications to standard procedure for endoscopy.

Following your endoscopy, you will be brought around to recovery in the recovery bay. At one hour after your last dose of propofol, you will complete the second set of cognitive tests.

If you have not had a procedure today then you will also complete the second set of testing at a time approximately one hour after completing the first set. This is to allow us to account for any effect of participants 'learning' the computer programs, potentially improving scores on the second run.

After the second set of testing is finished, your involvement in the study will be complete. There will be no need for us to follow up with you at any time after today.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions.

There are no costs associated with participating in this research project, nor will you be paid.

4 What do I have to do?

In order to participate in this study, you will have to complete the two sets of computer testing as outlined above. There are no restrictions upon your lifestyle, diet, regular medications, or ability to donate blood.

There are a few criteria that you must meet in order to participate in this study:

- You **must** be over the age of 18
- You **must** have an English-speaking background (this is because the instructions for the computer testing program are reliant on English language skills)
- You **must not** have any history of dementia or any other significant cognitive impairment

If you meet these criteria and sign this consent form then you are eligible to participate in this study. It is your responsibility to give us accurate and current information to ensure the quality of the data obtained from this study.

5 Other relevant information about the research project

610 people will be recruited to participate in this study, which will be completed entirely at the St Vincent's Diagnostic Endoscopy Centre. 305 participants will be in each of the groups (i.e. 305 receiving anaesthetic and 305 accompanying and acting as a control group). This study is a stand-alone project and is being carried out by the anaesthetic department of St Vincent's Hospital.

6 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 treatment, your relationship with those treating you or your relationship with the Diagnostic Endoscopy Centre or St Vincent's Hospital.

7 What are the possible benefits of taking part?

There will be no clear benefit to you from your participation in this research. The data obtained from this study will hopefully provide us with information that will allow us to better care for people undergoing endoscopic procedures in the future.

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

This study will not present any material risks to you as a participant. There will be an imposition on your own personal time of approximately 20-30 minutes whilst you complete the testing, with additional time required to transport you from where the computer tests take place and where your endoscopy will take place (approximately 5 minutes). There are material risks associated with the administration of your anaesthetic and endoscopy procedure, but these do not form part of our study protocol and the risks related to these should be explained to you by the doctors performing them.

9 Can I have other treatments during this research project?

As previously outlined, there will be no change to any medications that you are currently taking, or to any medications that you may require as part of your endoscopic procedure.

10 What if I withdraw from this research project?

If you decide to withdraw from this research 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 your consent during the research project, the study doctor and relevant study staff 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 by the sponsor up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

11 What happens when the research project ends?

As previously outlined, your involvement in this research will end once you have completed all testing. There will be no further follow up required. We will use the data from the computer testing to allow us to determine if there is a significant effect of propofol upon your test scores and compare these results with people in the control group.

Part 2 How is the research project being conducted?

12 What will happen to information about me?

By signing the consent form you consent to the study doctor and relevant research staff 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. All baseline demographic data collected from you will be connected to your test scores, but will be de-identified and stored in a secure location. 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.

Information about you may be obtained from your health records held at this and other health services for the purpose of this research. By signing the consent form you agree to the research team accessing health records if they are relevant to your participation in this research project.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission. All data and test score will remain de-identified in any such publication or presentation.

Information about your participation in this research project may be recorded in your health records.

In accordance with relevant Australian and/or NSW privacy and other relevant laws, you have the right to request access to the information collected and stored by the research team about you. You also have the right to request that any information with which you disagree be corrected. Please contact 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.

13 Complaints and compensation

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

14 Who is organising and funding the research?

This research project is being conducted by the Anaesthetics department of St. Vincent's Hospital.

The study investigators declare that they have no conflicts of interest in conducting this research.

15 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 St Vincent's Hospital.
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.

16 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 medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the principal study doctor on *[phone number]* or any of the following people:

Clinical contact person

Name	*Dr. Drew Heffernan*
Position	*Coordinating Investigator*
Telephone	*[Phone number]*
Email	*[Email address]*

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Complaints contact person

Name	*[Name]*
Position	*[Position]*
Telephone	*[Phone number]*
Email	*[Email address]*

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:

This person should be someone independent of the research, such as the Executive Officer of the reviewing HREC that approved the project. Contact your local HREC administrator for the requirements at your institution.

Reviewing HREC name	*[Name of HREC]*
HREC Executive Officer	*[Name]*
Telephone	*[HREC Executive Officer Phone number]*
Email	*[HREC Executive Officer Email address]*

Reviewing HREC approving this research and HREC Executive Officer details

Local HREC Office contact (Single Site -Research Governance Officer)

Name	*[Name]*
Position	*[Position]*
Telephone	*[Phone number]*
Email	*[Email address]*

Consent Form - *Adult providing own consent*

Title	*Motor and cognitive recovery post propofol-only anaesthetic*
Short Title	*anaesthetic*
Protocol Number	
Project Sponsor	
Coordinating Principal Investigator/ Principal Investigator	*Dr. Drew Heffernan/Dr. Jenny Stevens*
Associate Investigator(s)	*Mr. Harry Jones and Mr. James Kelly*
Location	*Diagnostic Endoscopy Centre*

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 health care.

I understand that I will be given a signed copy of this document to keep.

Name of Participant (please print) _____

Signature _____ Date _____

Declaration by Study Doctor/Senior 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 Study Doctor/
Senior Researcher[†] (please print) _____

Signature _____ Date _____

[†] A senior member of the research team must provide the explanation of, and information concerning, the research project.

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

Form for Withdrawal of Participation - *Adult providing own consent*

Title	*Motor and cognitive recovery post propofol-only anaesthetic*
Short Title	
Protocol Number	
Project Sponsor	
Coordinating Principal Investigator/ Principal Investigator	*Dr. Drew Heffernan/Dr. Jenny Stevens*
Associate Investigator(s)	*Mr. Harry Jones and Mr. James Kelly*
Location	*Diagnostic Endoscopy Centre*

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 the Diagnostic Endoscopy Centre.

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.