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**Participant Information Sheet/Consent Form**

**Interventional Study** -*Adult providing own consent*

The Queen Elizabeth Hospital

|  |  |
| --- | --- |
| **Title** | A pilot study to assess patient understanding in surgical consultations. |
| **Protocol Number** | [Protocol Number] |
| **Principal Investigator** | Professor Guy Maddern |
| **Associate Investigator(s)** | Jessica Reid  Jesse Ey |
| **Location** | The Queen Elizabeth Hospital |

**Part 1 What does my participation involve?**

**1 Introduction**

You are invited to take part in a research project, entitled “A pilot study to assess patient perspective and utility of a patient prompting document in surgical consultation”. This is because we are trying to improve surgical outpatient consultation efficiency and enhance the efficacy of patient-doctor communication with the use of a patient prompting document. The research aims to investigate the effect of using a patient prompting document during the outpatient surgical consultation.

This Participant Information Sheet/Consent Form tells you about the research project and explains the intervention 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 colleague or the research team.

This is a research project and you do not have to be involved. If you do not wish to participate, your medical care will not be affected in any way. Also, you may withdraw from the project at any time after you have commenced. Participation in this research is voluntary. If you don’t wish to take part, you don’t have to.

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

• Understand what you have read

• Consent to take part in the research project

• Consent to being video recording during your surgical consultation

• Consent to the potential use of the intervention as described

• Consent to the use of your personal information as described.

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

**What is the purpose of this research?**

Aim: To identify whether the use of a patient prompting document affects patient empowerment regarding their health decisions, aids in appropriate and complete informed consent process, affects patient understanding of their health situation and aids in recall of conversations, to improve patient outcomes

Literature shows that the interventions that increase patient involvement in the consultation process such as question prompt lists and audio-visual tools increase the amount of questions asked, reduce patient anxiety and increase perceived involvement in health care decisions. Prompting documents have been extensively researched in the fields of palliative medicine and oncology but less so in the field of surgery.

The aim of this study is to investigate the effect providing participants with a patient prompting document has on the outpatient surgical consultation from the patient’s perspective.

Findings from this study may contribute to future patient prompting document design to improve patient empowerment, self-health advocacy, and the patient experience to aid in better patient outcomes.

**3 What does participation in this research involve?**

If you choose to participate you will first need to complete and sign the consent form as described in section 1.

You will be participating in a randomised controlled research project. We do not know if the use of our intervention is beneficial or not beneficial for participants. To find out we need to compare participants who have access to the patient prompting document with participants who do not. The results are compared to see if one is better. To try to make sure the groups are the same, each participant is put into a group by chance (random). The patients you consult will have a 50% chance of receiving the patient prompting document, or one in two chance.

If the patient is given a patient prompting document, it is their decision whether or not to use it during the surgical consultation. They may wish to use it to give them some ideas about what they may wish to discuss with you. The patient prompting document is theirs to take home and keep if they so choose. Your surgical consultation will otherwise occur as normal.

Your surgical consultation will be videotaped by small cameras. The recording will be reviewed at a later stage by the research team. The recording will allow the researcher to identify whether the patient prompting document was useful to the success of the consultation and help the researcher to determine how consultations can be better in the future. Your face and everything that is discussed during the consultation will be captured on the video recording. Your role is to ensure that any physical examinations or reasons for the patient to undress does not occur in an area of the room where the camera would record.

All results from this study will be combined and analysed to help decide whether the patient prompting document is a useful tool for facilitating a successful consultation.

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

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

**4 What do I have to do?**

As a participant you do not need to do anything more than what you would normally do during the surgical consultation. If your patient is provided with a patient prompting document it is their choice whether or not they use it, and in what manner they use it.

**5 Other relevant information about the research project**

The research team are trialling the use of a patient prompting document to see if it is a useful tool. If it is shown to be effective, other sites may undertake a similar activity

**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. Your decision to take part or not to take part will not affect your employment position in any way. If you decide to take part and later change your mind, you are free to withdraw from the study at any stage. Participation or non-participation, or participation and then withdrawal will not affect your employment.

**7 What are the possible benefits of taking part?**

There will be no clear benefit to you from your participation in this research.

the study will allow us to gain a better understanding of the utility of providing patients with prompting documents in the outpatient department. If shown to be useful, future patients as well as other surgeons’ patients may benefit from your involvement.

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

There is a minimal chance that your privacy may be breached; however, this is mitigated by rigorous security protocol discussed below in part 2 section 13

**9 What if new information arises during this research project?**

Sometimes during the course of a research project, new information becomes available about the intervention that is being studied. If this happens, the research team will tell you about it and discuss with you whether you want to continue in the research project. If you decide to continue in the research project you will be asked to sign an updated consent form.

**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.

If you do withdraw your consent during the research project, the study doctor and relevant study staff will not collect any further information from you, although information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law.

**11 Could this research project be stopped unexpectedly?**

Whilst it would be extremely uncommon in a study of this nature, it remains possible that this project could be terminated unexpectedly prior to completion

**12 What happens when the research project ends?**

When the project ends the information that has been provided will be analysed. Depending on the results of this analysis, the study may be published in a medical journal and/or presented at medical conference(s).

Should you wish to learn about the study’s findings prior to this, the study investigators will be available to discuss the results when sufficient information is available to them

**Part 2 How is the research project being conducted?**

**13 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 videos and information about you for the research project. Any videos or information obtained in connection with this research project that can identify you will remain confidential. In particular, the recording of your clinic appointment will remain confidential. The recordings will be labelled with a code, so that only the research team can identify your involvement if needed in the future. Research policy at this hospital requires that the study doctors retain all information obtained from this and other studies, including the recordings, for a period of time (up to fifteen years). All documents and recordings from this study will therefore be kept in a locked area, accessible only to the research team, in the Department of Surgery, at The Queen Elizabeth Hospital. At the end of the storage period, all documents and recordings related to this study will be confidentially destroyed. Your information and videos 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.

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.

Any information or videos obtained during the research project are subject to inspection for the purpose of verifying the procedures and the data. This review may be done by the relevant authorities who are part of the institution relevant to this Participant Information Sheet, that is The Queen Elizabeth Hospital, or as required by law. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant research personnel and regulatory authorities as noted above.

The study doctors have developed this study for the purpose of improving knowledge in this area and potentially improving the effectiveness of outpatient consultations which may benefit patients in the future. The information gathered during the study may also be utilised by a member of the research team to obtain further educational qualifications.

It is expected 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.

Any information or videos obtained for the purpose of this research project, and for any future research related to it, 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

Students from the University of Adelaide Medical School may review your data. They will be under the guidance of CALHN researchers, Professor Guy Maddern and Dr Jessica Reid.

**14 Complaints and compensation**

If you have concerns relating to your participation in this research study, the study investigators are available to discuss these with you (see below for contact details). If you wish to lodge a complaint about any aspect of the study TQEH complaints officer is available for this purpose. If you wish to express any concerns to an independent body, it is recommended that you contact the HREC Executive Officer (see below for contact details).

**Your participation in this study shall not affect any other right to compensation you may have under common law.**

**15 Who is organising and funding the research?**

The research is being conducted by Professor Guy Maddern, from Division of Surgery at The Queen Elizabeth Hospital.

The investigators have not received external funding or sponsorship for the purpose of this study. The investigators have developed this study for the purpose of advancing knowledge in this field. This study, and the data obtained, will be used by a member of the research team to obtain further educational qualifications or a higher degree. No member of the research team will receive a personal financial benefit from either their involvement, or your participation in this research project (other than their ordinary wage). The study investigators have no conflicts of interest to declare.

**16 Who has reviewed the research project?**

All research in Australia involving humans is reviewed by an independent group called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the CALHN HREC..

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

**17 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 study you can contact the principal study doctor (Professor Guy Maddern) on 8222 6000 or any of the following people:

**Clinical contact person**

|  |  |
| --- | --- |
| Name | Dr Jessica Reid |
| Position | Study Coordinator |
| Telephone | 8222 7779 |

The study has been approved by the Central Adelaide Local Health Network Human Research Ethics Committee. If you wish to speak to someone not directly involved in the study about your rights as a volunteer, or about the conduct of the study, you may also contact the CALHN HREC Chair, on 7117 2229 or 8222 6841.

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:

**Complaints contact person**

|  |  |
| --- | --- |
| Name | Central Adelaide Local Health Network Human Research Ethics Committee (CALHN HREC) |
| Position | Executive Officer |
| Telephone | (08) 7117 2229 |
| Email | [Health.CALHNResearchEthics@sa.gov.au](mailto:Health.CALHNResearchEthics@sa.gov.au) |

**HREC executive officer details**

|  |  |
| --- | --- |
| Name | Central Adelaide Local Health Network Human Research Ethics Committee (CALHN HREC) |
| Position | Executive Officer |
| Telephone | (08) 87117 2229 |
| Email | Health.CALHNResearchEthics@sa.gov.au |



**Consent Form -** *Adult providing own consent*

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| **Title** | A pilot study to assess patient understanding surgical consultations. |
| **Protocol Number** | *[Protocol Number]* |
| **Principal Investigator** | Professor Guy Maddern |
| **Associate Investigator(s)** | Jessica Reid  Jesse Ey |
| **Location** | The Queen Elizabeth Hospital |

**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 give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to The Queen Elizabeth Hospitalconcerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential.

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 study without affecting my future health care.

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

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|  | | | | | | |
|  | 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.

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|  | | | | | | |
|  | 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.