

**Appendix** Click here to enter Appendix identifier.

**DEPARTMENT OF** Click here to enter your Department name.

**RESEARCH STUDY INFORMATION LETTER**

**REC 11.0**

Click here to enter the date.

**Good Day**

My name is Click here to enter your first name and surname. **I WOULD LIKE TO INVITE YOU TO PARTICIPATE** in a research study on Click here to enter a single-sentence description of the topic of your research, or your research title if appropriate.

Before you decide on whether to participate, I would like to explain to you why the research is being done and what it will involve for you. **I will go through the information letter with you and answer any questions you have.** This should take about 10 to 20 minutes. The study is part of a research project being completed as a requirement for a Click here to enter your degree (e.g. Master’s or Doctoral). Degree in Click here to your discipline. through the University of Johannesburg.

**THE PURPOSE OF THIS STUDY** is to Click here to enter a description of the purpose of the study..

Below, I have compiled a set of questions and answers that I believe will assist you in understanding the relevant details of participation in this research study. Please read through these. If you have any further questions I will be happy to answer them for you.

1. **DO I HAVE TO TAKE PART?** No, you don’t have to.It is up to you to decide to participate in the study. I will describe the study and go through this information sheet. If you agree to take part, I will then ask you to sign a consent form.
2. **WHAT EXACTLY WILL I BE EXPECTED TO DO IF I AGREE TO PARTICIPATE?** Click here to enter a detailed description of what the participant will be expected to do, in simple language understandable by a lay person.

**NB:** The section below (3) is only applicable to clinical research with an intervention. Please delete the section if this does not apply.

1. **WHAT IF NEW INFORMATION BECOMES AVAILABLE?** Sometimes new information may become available about the treatment you will be receiving. If this is the case, I will tell you about this and discuss it with you. You can then decide whether you would like to continue participating in the research. If you decide not to continue, there will be no other consequences for you. If you do decide to continue, I will ask you to sign an updated consent form.
2. **APPROXIMATELY HOW LONG WILL MY PARTICIPATION TAKE?** Your participation will take approximately Click here to enter an estimate of how long participation in the research will take (in total).
3. **WHAT WILL HAPPEN IF I WANT TO WITHDRAW FROM THE STUDY?** If you decide to participate, you are free to withdraw your consent at any time without giving a reason and without any consequences. If you wish to withdraw your consent, you should inform me as soon as possible.

**NB:** The section below (6) is only applicable to clinical research with an intervention. Please delete the section if this does not apply.

1. **ARE THERE ANY OTHER POSSIBLE REASONS WHY MY PARTICIPATION MIGHT BE STOPPED?** It may happen that, due to your health or other treatments that you may receive or for safety reasons, I will need to stop your participation in this research. I will discuss this with you beforehand if it becomes necessary.
2. **IF I CHOOSE TO PARTICIPATE, WILL THERE BE ANY EXPENSES FOR ME, OR PAYMENT DUE TO ME?** Click here to enter the relevant information. If there is no expense or payment, a suggested entry is: “You will not be paid to participate in this study and you will not bear any expenses.” Please clearly indicate that participants will be responsible for their own medical expenses if they are accidentally injured while participating in research, if such a risk of injury is possible.
3. **IF I CHOOSE TO PARTICIPATE, WHAT ARE THE RISKS INVOLVED?** Click here to enter a description of the possible risks. If there are no anticipated risks, please state this.
4. **IF I CHOOSE TO PARTICIPATE, WHAT ARE THE BENEFITS INVOLVED?** Click here to enter a description of the possible benefits. Clearly differentiate between direct benefits to the participant and other more general benefits to future patients etc.
5. **WILL MY PARTICIPATION IN THIS STUDY BE KEPT CONFIDENTIAL?** All reasonable efforts will be made to keep your personal information confidential and respect your right to privacy. This includes replacing your identifying personal information with a number that only I and my research supervisor will know. You will not be identified in any research reports that are published. Under some circumstances, such as when required to do so by a court of law, I may have to disclose your personal information. In addition, it may happen that your information will need to be reviewed by another organisation for quality assurance purposes. I will tell you about this if it happens.

Click here to enter any other information about confidentiality specific to your research, if applicable.

1. **WHAT WILL HAPPEN TO THE RESULTS OF THE RESEARCH STUDY?** The results will be written into a research report that will be assessed. In some cases, results may also be published in a scientific journal. In either case, you will not be identifiable in any documents, reports or publications. You will be given access to the results of this if you would like to see them, by contacting me.
2. **WHAT WILL YOUR RESPONSIBILITIES BE, AS THE RESEARCHER?** Click here to enter a summary of researcher responsibilities in this research study.
3. **WHO IS ORGANISING AND FUNDING THIS RESEARCH STUDY?**  The study is being organised by me, under the guidance of my research supervisor at the Department of Click here to enter your Department name. at the University of Johannesburg. Click here to enter details about funding of the study. If there are none, a suggested entry is: “This study has not received any funding.”
4. **WHO HAS REVIEWED AND APPROVED THIS STUDY?** Before this study was allowed to start, it was reviewed in order to protect your interests. This review was done first by the Department of Click here to enter your Department name., and then secondly by the Faculty of Health Sciences Research Ethics Committee at the University of Johannesburg. In both cases, the study was approved.
5. **WHAT IF THERE IS A PROBLEM?** If you have any concerns or complaints about this research study, its procedures or risks and benefits, you should ask me. You should contact me at any time if you feel you have any concerns about being a part of this study. My contact details are:

Click here to enter your first name and surname.

Click here to enter your contact telephone number.

Click here to enter your email address.

You may also contact my research supervisor:

Click here to enter your supervisor’s title, first name and surname.

Click here to enter our supervisor’s email address.

If you feel that any questions or complaints regarding your participation in this study have not been dealt with adequately, you may contact the Chairperson of the Faculty of Health Sciences Research Ethics Committee at the University of Johannesburg:

Prof. Christopher Stein

Tel: 011 559-6564

Email: cstein@uj.ac.za

**FURTHER INFORMATION AND CONTACT DETAILS:** Should you wish to have more specific information about this research project information, have any questions, concerns or complaints about this research study, its procedures, risks and benefits, you should communicate with me using any of the contact details given above.

*Researcher:*

Click here to enter your name and surname.

<Signature>



**DEPARTMENT OF** Click here to enter your Department name.

**RESEARCH CONSENT FORM**

**REC 11.0**

Click here to enter the title of your research study.

Please initial each box below:

I confirm that I have read and understand the information letter dated Click here to enter the date, as is appears on the information sheet. for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

 I understand that my participation is voluntary and that I am free to withdraw from this study at any time without giving any reason and without any consequences to me.

 I agree to participate in the above research.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Participant Signature of Participant Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Researcher Signature of Researcher Date



**DEPARTMENT OF** Click here to enter your Department name.

**RESEARCH CONSENT FORM OR INTERVIEWS TO BE AUDIO-TAPED**

*(Please delete this entire page if your research does not involve audio-recording)*

Click here to enter the title of your research study.

Please initial each box below:

I hereby give consent for my interview, conducted as part of the above study, to be audio-taped.

 I understand that my personal details and identifying data will be changed in order to protect my identity. The audio tapes used for recording my interview will be destroyed two years after publication of the research.

 I have read this consent form and have been given the opportunity to ask questions.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Participant Signature of Participant Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Researcher Signature of Researcher Date