



## Community Participant Information Sheet

**STUDY TITLE:** Adverse outcomes of pregnancy

**Hello!**

**Introduction:**

My name is ..... I am a member of a team of people working for the National Institute for Occupational Health (NIOH) and the University of Witwatersrand. We are doing research on the adverse outcomes of pregnancy which occur in women in your district area. *Adverse outcomes of pregnancy includes maternal complications as well as foetal complications during pregnancy (like miscarriage), during child birth (like stillbirth) and after delivery (like neonatal death).* It is important that you read and understand the following explanation of the study. Also please ask questions about any thing you do not understand.

**Invitation to participate:**

We are inviting you to participate in our research, which looks into adverse outcomes of pregnancy. Your participation in this study is entirely voluntary.

**What is involved in this study?**

We will be recruiting about 2000 women from three communities in the Potchefstroom district area, including yours, over the next few weeks. You have been contacted to take part in this research because you live in the community. If you agree to participate you will be asked to answer questions related to your pregnancies, child birth (*including sensitive topics such as abortions, miscarriages and sexual history*), your health and the health of your babies, work and

environmental factors. This interview should take about 40 minutes. We might also ask for access to your maternity records at the clinic when necessary.

### **Risks**

Please note that there are no physical risks involved in this study. You might experience some emotional discomfort. If the interview proves to be emotionally traumatizing for you, the interviewer will try to provide emotional support and refer you to the nearest public health facility for psychological counselling when necessary.

### **Benefits**

You can request a private report of your research results. Apart from the policies and interventions which may be developed, for the greater good of the community in general, from the findings of this study, there are no direct benefits to you for taking part in this study.

### **Participation is voluntary**

Remember that your participation in this study is entirely voluntary. After you have decided to participate, you still have a right to withdraw from this study at anytime and this will not affect you in any way i.e. there is no penalty or loss of any benefit as a participant or a community member if you refuse to participate or if you withdraw from the study after enrolling.

### **Confidentiality**

All the information you share with us is very important to ensuring that we have accurate data, any personal information obtained during the study will be kept confidential. Absolute confidentiality cannot be guaranteed. Your name and any material identifying you as a study participant will never be released. Only your research number will be used during analysis of the information collected. No one outside of the research team will be able to trace any information back to you, unless required by law.

All collected information will remain confidential at all times. A summary result from this study can be presented to your community if agreed

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Finally, the study has been approved by the University of the Witwatersrand, Human Research Ethics Committee (HREC) and the Department of Health. If you feel that the study was conducted unfairly or your rights have been violated at any stage, please contact the chair or the administrator of the Human research Ethics committee at the following contact details:

Anisha Keshav (Wits ethics committee administrator)

Tel: (011) 717-1234

Thank you once again for your assistance in the collection of this valuable information.

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Protocol ..... English Informed Consent  
Version..... 24/02/2007  
Approved by Wits HREC  
Date approved: \_\_\_\_\_

Participant Initials: \_\_\_\_ \_\_\_\_ \_\_\_\_

Participant Number: \_\_\_\_\_

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