Consent for Photograph

1. INTRODUCTION

* This consent is to ask permission for us to take a photograph of your baby for research purposes.
* This consent form gives information about the research study. The study team will discuss it with you. Once you understand the study, and if you agree to take part, we will ask you to put a thumbprint on this consent form. We will offer you a copy to keep.
* It is important that you understand the following:
* Your taking part in the study is completely voluntary.
* You may refuse to take part in the study without losing other benefits to you.
* Your decision will not affect your future medical care or your ability to take part in other studies.

**2. WHY IS THIS STUDY BEING DONE?**

* We are conducting research at maternities throughout Botswana. We plan to identify and correctly categorize congenital abnormalities. Congenital abnormalities are when a baby is born with a problem with their development in the womb.
* The purpose of the research is to find out if some medications taken during pregnancy might lead to an increase in congenital abnormalities. To do this, we are trying to identify all congenital abnormalities, whether a woman took medications during pregnancy or not.
* We are requesting a photograph of your baby. We will send it to a doctor who is an expert at classifying congenital abnormalities.

**3. OVERVIEW OF THE STUDY**

* The study will look at medication use and pregnancy outcomes for about 410,000 deliveries in Botswana.If congenital abnormalities are identified, we will take a photograph of the baby so that an experienced doctor can examine the photograph. The doctor will determine what type of abnormality it is. The doctor will not know your name or your child’s name. Other than one photograph of your baby, there is nothing else required for participation in the study at this time.

**4. WHAT DO I HAVE TO DO IF I AM IN THIS STUDY?**

* To be in this study, we will ask your permission to take a picture of your baby. We will make every effort to have this picture be physically anonymous when possible. We will not put the name of the baby or your name on this picture. Even though your baby`s picture will not have any identifying information, there will be an identification number created that links the picture to the coded information collected about your pregnancy history, but neither your name nor your baby’s name will be put/written on the photograph.

**5. HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?**

* About 6,000-6500 photographs will be taken as part of this study.

**6. HOW LONG WILL I BE IN THIS STUDY?**

* Your participation in the study only requires this one photograph. It is possible we may contact you in the future to ask if you are interested in another part of the study. We may ask for your phone number for this purpose, but you do not have to do this unless you want to.

7. CAN I CHANGE MY MIND?

* You may change your mind and ask us to destroy this photograph at any time if you keep a copy of the coded number. All photographs will be destroyed at the end of the study, unless you choose to give permission to allow the photograph to be used for training or research purposes.

**8. WHAT ARE THE RISKS OF THE STUDY?**

* There are no risks to a photograph being taken. A very minor risk to your baby would be if other people could learn about your baby’s medical history. This is unlikely because no name will be on the photograph.

**9. ARE THERE BENEFITS TO TAKING PART IN THIS STUDY?**

If you keep the Participant Study Number that we give you, in about 3-4 months you may return or call us to ask the study staff for the result of the expert’s review of the photograph. This result may help your baby’s doctors here in Botswana care for your baby**. You are, however, encouraged to take your child to the clinic or hospital for medical care even before the results are out. The study will not be providing direct medical care as such it is important that your child receives appropriate care for their abnormality from the local health facilities. Furthermore, the photographs taken are not part of your baby’s standard clinical care but for research purposes.**

Your participation may help other mothers during pregnancy and benefit their babies in Botswana in the future.

**10. WHAT OTHER CHOICES DO I HAVE BESIDES THIS STUDY?**

* You may choose not to take part in the study and no photograph will be taken.

**11. WHAT ABOUT CONFIDENTIALITY?**

* We will do everything we can to keep your personal information confidential. We cannot guarantee complete confidentiality, but we will try to protect it by:
1. Not putting a name on the photograph (it will be linked to medical records only by a code number)
2. Not photographing the child’s face unless required for identification of the congenital abnormality. If the anomaly is on the face, we will make every attempt to mask facial details that might be identifiable
3. Keeping the photograph in a secure research database
4. Destroying the photograph at the end of the study, unless you choose to give permission to allow the photograph to be used for training or research purposes

**12. WHAT ARE THE COSTS TO ME?**

* There is no cost to you.

**13. WILL I RECEIVE ANY PAYMENT?**

* You will not be paid for agreeing to have your child’s photo taken for the study. You will however receive a P50 airtime voucher for you to be able to call us for the results when available.

**14. WHAT HAPPENS IF I AM INJURED?**

* There is no chance of injury from this study.

**15. WHAT ARE MY RIGHTS AS A RESEARCH PARTICIPANT?**

* Taking part in this study is completely voluntary. You may choose not to take part in this study or leave this study at any time. You will be treated the same no matter what you decide. If you want the results of the study, please ask the study staff.

**16. WHAT IF I HAVE QUESTIONS OR PROBLEMS?**

* If you have any questions about this study or your rights as a participant, either while participating or after you have completed the study, you should contact:
* Dr. Joseph Makhema: Tel: 3902671; Cell: 72100846
* Ms Modiegi Diseko: Tel:3101120: Cell: 71848453
* Chief Research Officer at Ministry of Health Botswana (for rights as a participant): Tel: 3632775

 **Consent for Photograph**

 **STAFF:**

Check the box below to confirm participant is 18 years old or above

**Overall Study Participation**

The purpose of the study, procedures to be followed, and risks and benefits have been explained to me. By placing my fingerprint below, I am agreeing to allow a photograph of my baby to be taken. I understand that my fingerprint is being used to protect confidentiality. I understand that I can keep a copy of the Participant Study Number, and using this number, I may ask that the photograph be destroyed at any time without affecting my rights or those of my baby to receive medical care.

**Participant's fingerprint:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Participant’s Study Number from maternity surveillance:**

##### Date:\_\_\_\_/\_\_\_\_/\_\_\_\_ (dd/mm/yy)

**Use of Photo**

 By checking this box, I agree to allow the photo to be used in training materials or research publications, so that health care providers can learn more about this issue.  I understand that there will be no identifying information about myself or my infant on the photo, in the event that the photo is used in training or published material.

 By checking this box, I do NOT agree to allow the photo to be used in training materials or research publications.  I understand that I can still be a part of this study and checking this box will not limit my participation in this study in any way.

**Participant's fingerprint:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

##### Date:\_\_\_\_/\_\_\_\_/\_\_\_\_ (dd/mm/yy)

**Witness**: (*for use**when a participant is illiterate, in addition to the participant’s thumbprint; when possible, witness should not be study staff).*

The purpose of this study and the procedures, risks and benefits to her and her baby have been explained to the participant. To the best of my knowledge she understands the purpose, procedure, risks and benefits to her and her baby.

**Witness’s signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Witness’s name (first - last) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date of signature** **\_\_\_\_/\_\_\_\_/\_\_\_\_ (dd/mm/yy)**

I have explained the purpose of the study to the participant. To the best of my knowledge, she understands the purpose, procedures, risks and benefits to her and her baby.

**Health officer's name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Health officer's signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date of signature** **\_\_\_\_/\_\_\_\_/\_\_\_\_ (dd/mm/yy)**