

**DRAKENSTEIN CHILD HEALTH STUDY**  
**CONSENT AND INFORMATION SHEET FOR MOTHERS – MAIN COHORT**  
Oct 2016

**CONSENT FORM AT YEAR 3**

You and your child are invited to take continue to take part in a study that is being done in the Drakenstein sub-district, in collaboration with the Universities of Cape Town and Stellenbosch. We would like to thank you and your child for taking part in this study, we hope to impact child health and your participation will help us achieve that. The following information describes the study and you and your child's role for the next year. Please read this carefully and feel free to ask any questions.

**Why is this study being done?**

Lung infections and chest problems are common in young children. This study is being done to find out the effect of chest infections in the early years of life on the development of lung disease in children. The study will also look at a number of other factors that may affect your child's health.

You and your child will continue to attend occasional scheduled visits at your primary health care clinic and at Paarl Hospital. During these visits, we will assess the health of you and your child by using questionnaires and doing tests. Should your child get sick with a chest infection, then he/ she will be carefully investigated to try and find out the cause of this infection. This study will help us to better understand why children get chest illness and may help to improve child health.

Cognition and social emotional development are important parts of a child's overall health. By cognition we mean the way a child thinks, learns, plans and pays attention. Social emotional and social cognitive development refer to how a child learns to understand their own and others' emotions, and to reason about what other people think, believe and feel. We want to see how these factors develop over time. This study will help us understand how various other factors we look at in the main study impact on this development, and also how this development affects overall health.

**What must I do if I agree to continue in the study?**

If you agree to continue in this study, we will follow you and your child regularly to assess his/ her health. We will see you and your child at Paarl hospital when your child is about 3 years of age and again at about 4 years of age. We will also schedule a visit at 3 years of age and at 42 months at the primary health care clinic. We will ask you some questions about your child's health, nutrition, growth and development, and any chest illnesses. We will do regular tests to watch these.

At study visits in the next year, you will be asked some questions about you and your child's health. Your child will be examined. Tests will be done on you and your child to assess whether there is any chest problem. The tests that may be done on your child are:

1. Blood tests - these will be to test for allergies or blood problems.
2. A test of the mucus from the nose (nasopharyngeal swab) to test for infection.
3. Saliva will be collected to check for germs which may cause pneumonia
4. A skin test for tuberculosis infection.
5. A urine test for smoke exposure.
6. A stool test to check what germs are in the stool.
7. At 3 years and 4 years of age a breathing test will be done, to measure the air moving in and out of his/her lungs.
8. A skin test if your child has a rash
9. An eye tracking test at 3 and 5 years of age where your child will look at a computer screen showing cartoons and pictures to see how his/her attention and development occurs.
10. A hearing test to see if your child may have any hearing problems

The tests YOU will be asked to complete are:

1. Questionnaires about your socioeconomic status and your levels of emotional distress, stress, life events, social support, exposure to community violence, assessment of maternal parenting styles, your and your child's emotional style, bonding and empathy and drug and alcohol use. If a mental health condition or abuse is suspected, you will be referred to the appropriate local services.
2. An eye-tracking test where you will look at a computer screen showing different baby facial expressions.
3. Neurocognitive and socioemotional assessment at 3.5 years. We will take a short video of you playing with your child, and of your child playing. We will then ask you to answer some questions about your child's feelings and behaviors, and about your own feelings and behaviors as well as any trauma or violence that you or your child may be exposed to. While you are doing this, we will be doing some tasks, games and puzzles with your child.
4. A test of the mucus from the nose (nasal swab) to test for the germs you may carry in your nose when your child is 3 or 4 years of age.
5. A blowing test to check how healthy your lungs are, when your child is 3 or 4 years of age.
6. A discussion about your study experience and the things you like and do not like about being involved in the study.

We will only share your test results with primary health care staff if it indicates that you or your child require treatment or further follow up. For some assessments, study staff may follow up with you and provide you with information on where you can seek help, if necessary.

Should your child get sick with a chest infection, then additional tests will be done to try and find out the cause of your child's illness. The tests that will be done will depend on how sick your child is and what the illness is. These tests may include:

1. Blood tests to test for infections, at the time of the illness, and again 4-6 weeks afterwards
2. A test of the mucus from the nose (nasopharyngeal swab) to test for infection
3. A skin test for tuberculosis infection.
4. A test of the mucus from the lungs (induced sputum test) for chest infection.
5. A urine test for smoke exposure
6. Chest X-ray
7. Breathing test
8. A ultrasound test of the lungs
9. A stool test to check what germs are in the stool.

If your child is enrolled in the study and is admitted to hospital, he/she will be followed up in hospital by a member of the study team. The study member will ask you questions about your child's illness, and some tests may be done, including a nose swab and an induced sputum. All of these tests are usual for investigating the cause of pneumonia.

#### **What are the benefits of my child being in the study?**

You and your child will be closely followed for the first few years of your child's life. Any medical illness or problem should be found soon after it develops. Your child's growth and development will be carefully followed. If an illness or problem is found then your child will be promptly referred for treatment. If your child gets sick you will be able to take him/ her to your usual health facility, where additional tests to find out the cause of your child's illness may be done, depending on how sick your child is. If your child requires hospitalisation, then he/ she will be hospitalised at Paarl hospital as is usually done. If your child is hospitalised, then one of the study staff will see your child in hospital and additional investigations may be done to try and find out the cause of the illness. Therefore the study offers an opportunity for your child to receive appropriate medical care. The study will also help us to better understand the causes of illness in children, and identify the things that may harm their health. We hope that this will lead to improvements in child health. When the study is finished or if you choose to withdraw from the study, you and your child will continue to go to your usual health facility for care and study staff will no longer be involved with you or your child.

#### **What are the risks to my child?**

There are no major risks to your child. Your child may also become tired during the tasks, games and puzzles. To minimize this risk, we will take breaks whenever it seems your child is getting tired. There may also be some discomfort associated with some of the tests we will do. These tests are listed below:

##### **(1) Blood tests**

Your child may feel sore when blood samples are taken with a needle. Where possible an anaesthetic cream will be used to dull the pain from the needle. Some bruising may occur, but this is not harmful and will disappear. Only a

small amount of blood (not more than 3 teaspoons) will be taken from your child at any time

**(2) Nasopharyngeal swab**

A sample of mucus will be taken from your child's nose, to test for germs that can cause chest infections and to monitor which germs are usually in your child's nose. Your child may experience minor discomfort when the nasal swab is done. Occasionally it can cause bleeding from the nose, but this is not serious, and usually stops by itself.

**(3) TB skin test**

A small injection is made on your child's arm. This is to test whether your child has TB or not, and will be done at regular visits. Your child will experience minor discomfort due to the needle, with the skin test. There may also be irritation of the skin if the test is positive (reactive). This test will need to be checked 2-3 days after the injection is given.

**(4) Induced sputum**

Your child will be given salt-water through a nebulizer to loosen the mucous in the lungs. Then a sample of that mucus will be suctioned, or your child will be asked to cough up the mucus. Your child may experience a little discomfort while the sputum test is done. He/ she may develop some coughing or have a small amount of bleeding from the nose after this. These are not serious. Occasionally this test can cause the airways of the lungs to close. If this occurs your child will be given medicine through an inhaler/nebulizer to open the airways.

**(5) Breathing test**

This test is done after a child recovers from pneumonia, and at the 3 year and 4 year visits at Paarl Hospital and should not cause any discomfort. A mask will be put on his/ her face and the air going in and out of his/ her lungs while breathing will be recorded.

**(6) Stool test**

This test may be done monthly on your child and then every 6 months after 1 year. Study staff will collect stool from your child's nappy if passed during a study visit. If there is no stool available, a small tube will be inserted into your child's bottom and some stool will be sucked out with a syringe. The tube is thin and bendable and is only put in 1-2 centimeters to reach stool. There is a very small chance of bleeding at the rectum right where the tube goes is.

**(7) Ultrasound test of the lungs**

This test will be done if your child develops pneumonia so as to better see how the infection is affecting your child's lungs. This is a very safe procedure and there are no side effects.

**(8) Eye tracking**

This test will involve your child watching a series of images to better understand their attention and development. This is a very safe test and there are no risks or side effects.

**(9) Neurocognitive and socioemotional assessment at 3.5 years.**

We will take a short video of you playing with your child, and of your child playing. This will take 5 – 10 minutes. We will then ask you to answer some

questions about your child's feelings and behaviors, and about your own feelings and behaviors as well as any trauma or violence that you or your child may be exposed to. This will be very safe, though you or your child may become tired. We will take lots of breaks so your child can relax and play in between these tasks. We will provide you both with refreshments. In total, this visit will probably last about 2 hours.

**(10) Hearing test**

This test will assess whether your child may have hearing problems. This will be very short and there will be no pain or risk.

**What are the risks to you?**

There are no major risks to you. Some of the questionnaires ask for sensitive information relating to mental health and this may cause some emotional distress or discomfort. Where significant issues are identified, and if you agree, study staff will offer referral to mental health support. You may also choose not to answer certain questions and still remain in the study. You will be able to take breaks, if you need to, and you will be free to terminate or reschedule the interview should the need arise.

**(1) Nasal swab**

A sample of mucus will be taken from your nose, to test for germs that can cause chest infections and to monitor which germs are usually in your nose. Your child may experience minor discomfort when the nasal swab is done.

This is a very safe procedure and there are no side effects

**(2) Lung function test**

This test will be done at each visit to Paarl Hospital. You will be asked to blow into a machine that tests how healthy your lungs are. You will then be given an inhaler with medicine that opens up the chest, and asked to blow into the machine again. You should not experience any discomfort during this procedure. You may feel shaky after the medicine, and your heartbeat may be faster, but this will only last for a short while.

**What happens if I get hurt taking part in this study?**

This research study is covered by an insurance policy taken out by the University of Cape Town. If you suffer a bodily injury because you are taking part in the study, the insurer will pay for all reasonable medical costs required to treat your bodily injury, according to the SA Good Clinical Practice Guidelines 2006. The insurer will pay without you having to prove that the research was responsible for your bodily injury. You may ask the study doctor for a copy of these guidelines.

The insurer will *not* pay for harm if, during the study, you:

- Do not take reasonable care of yourself

If you are harmed and the insurer pays for the necessary medical costs, usually you will be asked to accept that insurance payment as full settlement of the claim for medical costs. However, accepting this offer of insurance cover does not mean you give up your right to make a separate claim for other losses based on negligence, in a South African court.

**Will I be paid to participate in the study?**

No, you will not be paid to participate in this study. If you agree to take part, we will reimburse your transport costs for visits that are not part of your well child clinic visits.

**Will there be any cost to participate in the study?**

No, there will be no cost to you.

**How long will my child be in the study?**

This consent form is for permission for you and your child to participate in the study from 3 to 4 years of age. We hope to continue the study for many years; each year we will ask you again to sign permission for you and your child to continue in the study for another year.

**Will my child's participation in the study be confidential?**

All information that you provide will be considered confidential, and no mention of you or your child's name will appear on the stored samples or in any publication in connection with this study. No persons other than the health care workers overseeing your child's care and the study nurses and doctors will have access to any information that identifies your child personally. All your test results will not be disclosed to anyone other than for the purpose of treating you if there is a problem.

The video material will be securely stored, and only researchers directly involved in this part of the study will have access to it. This material will also be treated as very strictly confidential. Your names will not be attached to the video. The video will give us information about how you and your child interact, and about your child's behavior.

**Mandatory reporting of abuse and/or deliberate neglect**

The researcher(s) may not be able to keep confidential, information about known or reasonably suspected incidents of deliberate neglect or physical, sexual or emotional abuse of an adult or a child. If a researcher is given such information, he or she may report it to the authorities such as child welfare.

**Does my child have to be in the study?**

You can choose not to take part in the study. This will not affect the quality of care your child receives. You will be able to decline to participate at any time should any part of the study be unacceptable to you, you may still take part in the rest of the study.

**What do I do if I have any questions?**

If you have any questions about this study, you can ask study staff, the Principal Investigator, Professor Heather Zar, or the lung study doctor, Dr. Attie Stadler, at: - 021 860 2802. The UCT's Faculty of Health Sciences Human Research Ethics Committee can be contacted on 021 406 6338 in case you have any ethical concerns or questions about your rights or welfare as a participant on this research study

## Informed Consent

1. I, \_\_\_\_\_ understand the information contained in this consent form, as explained to me in a language that I understand. I am prepared to participate in this study and give consent for my child to participate in this study.

I agree to allow study staff to access my medical and hospital records as well as those of my child during the course of the study.

I give consent for the filming interaction between me and my child and consent to its use for the duration of the study.

☐ YES

☐ NO

### 2. To be completed by mother:

Child's Name: \_\_\_\_\_

Mother's Name: \_\_\_\_\_

Mother's Signature: \_\_\_\_\_

Date: \_\_\_\_\_

### 3. Study staff providing information:

Name: \_\_\_\_\_

Role in Study: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

### Study staff confirming consent:

Name: \_\_\_\_\_

Role in Study: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

**4. If the mother is unable to read or write the entire counselling process must be observed by an independent witness who can then confirm the procedure once the mother has given consent.**

**Fingerprint of mother:**

**Witness: I confirm that I am independent of the study and that I witnessed the entire enrolment counselling process in the home language of the mother.**

Name: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

