

## **PARENT/GUARDIAN INFORMATION STATEMENT**

**HREC Project Number:** 30049

**Research Project Title:** *ChocHealth for Kids!* The effects of dark chocolate on children's blood pressure – pilot randomised trial.

Thank you for taking the time to read this Information Statement. This Information Statement is 5 pages long. Please make sure you have all the pages. Your child is invited to participate in a research project that is explained below.

### **What is an Information Statement?**

These pages tell you about the research project. It explains to you clearly and openly all the steps and procedures of the project. The information is to help you to decide whether or not you would like your child to take part in the research.

Please read this Information Statement carefully. You can ask us questions about anything in it. You may want to talk about the project with your family, friends or health care worker.

You can choose whether or not to take part in this project. If you don't want your child to take part, you don't have to. You can withdraw your child from the project at any time without explanation. This will not ever affect their access to the best available treatment options and care from The Royal Children's Hospital Melbourne.

---

### **1. What is the research project about?**

You probably know that many adults have high blood pressure. High blood pressure isn't good for health - it can lead to health problems like heart disease and stroke.

It may surprise you that children can also have high blood pressure. Like adults, this puts them at risk of later health problems. Lowering blood pressure, even in the normal range, can have benefits. There are no school-based programs that aim to lower blood pressure in children.

In adults, a single piece, about 7 grams, of dark chocolate every day helps blood pressure. It makes blood vessels more elastic, which lowers blood pressure. No one knows if it has the same effect in children.

This pilot study aims to find out if schools can deliver a small daily dose of chocolate, and if children, teachers and families are happy with the program. We will also look for any effects of dark chocolate on blood pressure and body weight in children. If the pilot study goes well, we hope to plan a larger study. This will find out if dark chocolate truly lowers children's blood pressure.

We hope around 200 Grades 5 and 6 students from 2-3 different schools will take part. For about 8 weeks during Term 4, teachers in two of three recruited classes will give each child two pastilles of dark chocolate each day before lunch. The other classes will not get any chocolate. At the beginning and at the end of the study, we will visit the school to check children's blood pressure; height and weight; waist; and quality of life.

## 2. Who are the researchers?

The project is based at the Centre for Community Child Health, at The Royal Children's Hospital Melbourne and the Murdoch Childrens Research Institute. The team members are:

- Professor Melissa Wake, a paediatrician (children's doctor) and Director of Research at the Centre for Community Child Health. She is responsible for the study.
- Dr Eunice Chan, a doctor who has nearly finished training as a paediatrician. This project forms part of her training.
- Dr Jon Quach, who conducts research with children in primary schools. His PhD was about children's sleep problems.
- Dr Valerie Sung, a paediatrician and PhD scholar.
- Dr Michael Cheung, a paediatric cardiologist (children's heart specialist).
- Fiona Mensah, a statistician.

## 3. Who is funding this research project?

The Centre for Community Child Health at The Royal Children's Hospital Melbourne.

## 4. Why is my child being asked to be in this research project?

Your child is in Grade 5 or 6 at one of the primary schools taking part.

## 5. What do I need to do to be in this research project?

If you decide to take part, you need to:

- **Complete the questionnaire** (provided in pack). It will take about 15-20 minutes. It asks about your child's health, usual chocolate intake and physical activity. There are also some general questions about you and your family. It is private and your individual answers will not be shared with anyone.
- **Sign both the white and green consent forms** (provided in pack).
- Please keep the white consent form for your own records.
- Put the questionnaire and the **green** consent form in the envelope provided. **Send them back to school with your child** as soon as possible. The teacher will keep all the envelopes until we collect them in about 2 weeks' time. The other consent form is for you to keep for your records.

Once all parents have decided whether to take part, we will put each class into a "Chocolate" or "No chocolate" group. Classes are randomly picked for each group. This is done by chance, like picking a number out of a hat. This is the best way of finding out whether a new program really works or not.

## 6. What does my child need to do to be in this research project?

Once we know who has agreed to take part, two *ChocHealth* researchers will **visit your child's class**. We will see each child separately for about 10-15 minutes. The school will provide somewhere private for this. All our researchers have Working With Children and Police Checks. The researchers will not know which group your child is in.

At the visit we will:

- weigh and measure your child, and check their waist circumference. They don't need to undress – just need to take off their shoes and any heavy outer clothes, like jumpers.
- check their blood pressure twice, using an automated blood pressure machine. You've

probably had your own blood pressure checked at some stage. A cuff is placed around the upper arm and squeezes it quite tight for about 30 seconds. This can be a little uncomfortable, although it doesn't hurt. Sometimes children can be apprehensive – if this is the case, we can let them experiment until they feel comfortable. We will not proceed if they are not comfortable.

- ask your child to complete a short questionnaire about their own health and well-being. This will take about 5 minutes.

We will send home a record of your child's weight, height and blood pressure for your records.

- **If your child is in a “Chocolate” class:** For the first 8 weeks of Term 4, the teacher will give your child two pastilles of dark chocolate (about 7 grams) each school day just before lunch. A researcher will deliver the chocolate to the school each week.
- **If your child is in a “No chocolate” (control) class:** Your child will not get the chocolate.

Near the end of Term 4, two *ChocHealth* researchers will **visit your child's class again**. This visit will include the same measures as at the first visit. We will also:

- ask your child what they thought about the chocolate and the program (if they are in a “Chocolate” class).
- do a test called Pulse Wave Analysis. This tells us about the health of the blood vessels by measuring the shape of the pulse wave at the wrist. Even if the chocolate doesn't improve blood pressure, it could still improve how the blood vessels function. We will ask your child to sit down with their arm resting on a table. We then gently hold a special pressure sensor (shaped like a pen, and connected to a laptop computer) over their pulse on the inside of their wrist. Once we can see the waves on the computer screen, it takes about 12 seconds to take a recording of the pulse wave. We will try to take three recordings. We don't expect your child to have any discomfort during this test.

## **7. What are my child's alternatives to being in this study?**

You can choose to take part or not. You don't have to take part if you don't want to. If you don't want to take part:

- we will not collect any research information from your child.
- your child can still have a piece of chocolate each day if they want – just mark the box on the consent form.

If you or your child decide to take part and later change your mind, you can withdraw at any stage without saying why. We will still keep and use the information already collected, unless you tell us not to.

If you don't take part, or if you withdraw, it will never affect your access to the best available treatment options and care from The Royal Children's Hospital Melbourne.

## **8. What are the possible benefits for my child?**

There may be no benefits for you or your child.

Many parents get a sense of satisfaction from taking part in studies like this. They enjoy the chance to reflect on their child and their own role in their child's health.

Children of this age usually enjoy being in a research project from The Royal Children's Hospital Melbourne.

We will be able to tell you:

- if your child has unusually high blood pressure. Your doctor can re-check it later. Very

rarely, we find blood pressure so high it needs investigation and treatment. This is almost always unexpected, because high blood pressure doesn't usually cause symptoms. If this happens, treatment can help your child's health.

- your child's weight, height, and blood pressure, for your records.

If your child is in the "Chocolate" group, their blood pressure may fall a little. However, we can't guarantee this. This is what the study is trying to find out. You and your child would not notice any obvious changes even if this happens.

### **9. What are the benefits for other people in the future?**

We hope that dark chocolate lowers children's blood pressure. If average blood pressure is even a little bit lower in many children, future health problems like heart disease and stroke can be reduced. Governments, councils and schools can recommend dark chocolate as a healthy choice for children.

This pilot study won't give a final answer about this, but it will give an indication. We will know at the end whether to plan a bigger study that can really test the effects of dark chocolate on children's blood pressure.

### **10. What are the possible risks, side-effects and/or discomforts?**

We do not think the study will harm you or your child.

When we visit, your child may not want to be weighed or measured, or may not like the blood pressure measurement. We won't go ahead in that case.

Some children don't like the taste of dark chocolate. They don't have to eat it if they don't like it. This is one of the things the pilot study is trying to find out.

The amount of chocolate each day is very small (2 pastilles, about 7 grams). This is about a quarter of the size of a two-finger Kit Kat, or one seventh of the size of a standard Mars Bar. We do not think this will cause weight gain, but we will check for this at the end of the program. A similar amount each day did not lead to weight gain in a study of adults.

The dark chocolate doesn't contain nuts. However, chocolate manufacturers usually can't guarantee that there are no traces of nuts in their chocolate. **Therefore, we suggest that children with anaphylaxis do not take part.** These children usually carry an EpiPen.

Dark chocolate is sometimes called 'bittersweet' because it contains sugar. Sugar can cause tooth decay. We don't think this will be a problem because *ChocHealth for Kids!* gives the chocolate immediately before lunch.

If you have concerns, you can talk with a study team member, other professional, or The Royal Children's Hospital Melbourne Consumer Liaison (see below) at any time.

### **11. What are the possible inconveniences?**

The study will take around 15-20 minutes of **your time** to complete the questionnaire and consent form.

**Your child** will have the measurements listed above. If in a "Chocolate" class, he/she will be given two pastilles of dark chocolate to eat each day.

Your child's **teacher** will need to give out the chocolate.

**12. What will be done to make sure my child's information is confidential?**

We keep your information in a special database that needs a password. This is stored on a computer in a locked office at the Centre for Community Child Health. Only members of the research team can use the database.

We will keep your surveys in a locked filing cabinet in the same office. If we write or talk about the study, you cannot be identified. Your questionnaires will be kept securely until your child is 25 years old. After this time, we will destroy them with a secure shredder/protected waste at The Royal Children's Hospital Melbourne. Database files will be deleted.

**13. Will you tell me the results when the study is finished?**

After the pilot study ends, we will send you a summary of the overall results. We are happy to talk with you about the study's progress at any time. We will also put a report on the Centre for Community Child Health's website.

---

If you would like more information about the study or if you need to speak to a member of the research team in an emergency please contact:

**Name:** Dr Eunice Chan or Professor Melissa Wake  
**Contact telephone:** (03) 9313 5026 or (03) 9345 5937

If you have any concerns about the study, or the way it is being conducted, and would like to speak to someone independent of the study, please contact:

Head of Department  
Ethics and Research Department  
Human Research Ethics Committee  
The Royal Children's Hospital  
Telephone: (03) 9345 5044