Government of **Western Australia**
Department of **Health**
Child and Adolescent Health Service

PARTICIPANT INFORMATION SHEET

Is it acceptable to screen children for Familial Hypercholesterolaemia?

Why are we doing the study?
Familial Hypercholesterolaemia (FH) is a genetic disorder affecting approximately 8,000 individuals (1,500 children) in Western Australia (WA). It results in very high levels of LDL (bad) cholesterol from birth. Untreated individuals with FH have a 100-fold increase in the risk of coronary artery disease, with 50% of male and 20% of female patients suffering a heart attack or stroke by age 60. While statins (a type of drug) are a highly effective treatment and are recommended for children with FH from 8 years of age, more than 95% of children with FH in WA remain undiagnosed. Despite a statewide FH cascade-screening program (FHWA) running since 2009, our current pick up rate of only 4% of children with FH (60 out of 1,500) is similar to that in the United Kingdom. Thus we need to find a better way to diagnose FH during childhood. Universal screening of the population is the most effective way of detecting most individuals with FH and would allow treatment to start at the recommended age. However, universal screening also has some potential risks. These include the anxiety generated by identifying some children who require a second blood test to definitively exclude FH but who end up not having FH, as well as the over-diagnosis of children with very mild FH who may never have come to medical attention. Thus careful consideration of the benefits and potential risks of universal screening is needed before a screening program can become established. This study will explore whether the general public thinks it is acceptable to screen children for FH.

Who is carrying out the study?
Doctors from the FH clinics at Princess Margaret and Royal Perth Hospitals, General Practitioners and experts in health policy from the Department of Health.

What will the study tell us?
The study will provide us with important information on the views of the general public as to whether screening children for Familial Hypercholesterolaemia at the time of a scheduled immunisation is considered an acceptable thing to do. We will also determine the preference on whether to screen children at aged 4 or 12 years.

Do I have to take part?
No, there is absolutely no obligation to take part in the study.

What will you be asked to do if you decide to take part in this study?
You will be sent some background information on screening children for FH to read. You will then need to attend a 1-day workshop with approximately 15-20 other members of the general public, to first hear about different perspectives on the pros and cons of screening children for FH. With the guidance of a facilitator you will then work in small groups to try and reach a consensus opinion. Following the workshop you will be sent a report summary, to validate as being an accurate record of the final decisions made by the participants during the workshop.

What do I need to do to be in the study?
You will need to read the background information on FH before the workshop and then attend the workshop to participate in the discussions.

Is there likely to be a benefit to me?
No.

Is there likely to be a benefit to other people in the future?
If the results of this study suggest that universal screening of children for FH is a reasonable option, we will then proceed with another study to test whether it is possible to effectively introduce screening of children for FH in WA.

What are the possible risks and/or side effects?
There are no known risks to your participation in this study.

What are the possible discomforts and/or inconveniences?
You will need to complete the pre-reading and attend a 1-day workshop. You will be paid $150 for attending the workshop to cover any inconveniences related to your participation.

Where is your information kept?
Details of all participants will be stored electronically on a password-protected computer. These details will be destroyed once the study is completed. A record of the key points from the workshop will be entered directly onto that computer.

What about my privacy?
All participants in the study will be de-identified and referred to using an identification code. Results of the study will not be displayed or published with any identifying characteristics.

Who has approved the study?
The study has been approved by the Princess Margaret Hospital Human Ethics Committee.

Who to contact for more information about this study:
If you would like any more information about this study, please do not hesitate to contact one of the research team: Dr Andrew Martin (Paediatrician at PMH) on (08) 9340 8917, or Caron Molster (Office of Population Health Genomics) on (08) 9222 6871. They are very happy to answer your questions.

Who to contact if you have any concerns about the organisation or running of the study?
If you have any concerns or complaints regarding this study, you can contact the Director of Medical Services at PMH (Telephone No: (08) 9340 8222). Your concerns will be drawn to the attention of the Ethics Committee that is monitoring the study.

What to do next if you would like to take part in this research:
If you would like to take part in this research study, please read and sign the consent form provided.

THANK YOU FOR YOUR TIME