

D-HEALTH TRIAL BLOOD COLLECTION PARTICIPANT INFORMATION SHEET

1. ABOUT THE D-HEALTH TRIAL BLOOD COLLECTION

Each year we are randomly selecting about 600 people who are taking part in the trial and inviting them to give a blood sample. This is mainly to monitor the difference in blood vitamin D levels between the two groups of people in the trial but we may also use your samples for other studies related to vitamin D.

You have been selected this year to take part in this important component of the D-Health Trial. While we would be very grateful for your help, you do not have to do this. **You can still continue participating in D-Health if you choose NOT to give blood.**

There may be no direct benefit to you from taking part in the blood collection component of the D-Health Trial. **THERE WILL BE NO COST TO YOU** and if you choose not to take part this will not affect your future medical care.

2. WHAT DO I NEED TO DO TO PARTICIPATE?

You need to

1. Complete the **CONSENT FORM** and return it to us with your survey in the reply-paid envelope.
2. Take the **D-HEALTH PATHOLOGY COLLECTION FORM** to one of the pathology collection centres with which we have an agreement. A list is on the reverse of the collection form. They will collect two tubes of blood from you (approximately 16 ml) and send them to us for processing. You will not be charged for this.

PLEASE DO NOT EAT FOR 8 HOURS PRIOR TO HAVING YOUR BLOOD SAMPLE TAKEN

3. IF I GIVE A BLOOD SAMPLE, WHAT WILL IT BE USED FOR?

Vitamin D is converted in the liver to a substance called 25 hydroxy vitamin D (25D). This then circulates in the blood and is the best marker of your vitamin D status. We will send your sample, without your name on it, to a specialist laboratory for measurement of 25D.

We may also use your sample to understand more about the way vitamin D affects health. For example, we might investigate whether taking a vitamin D supplement influences cholesterol or blood sugar.

We will also store some of your genetic material (DNA) for studies of vitamin D and health (see section 4).

4. WHY DO YOU WANT TO COLLECT MY DNA?

Genes can influence people's health and the way they respond to things in the environment. DNA is the genetic molecule of life and it carries the information that underlies the characteristics of all living things. DNA is organised into units called genes. We can obtain some DNA from your blood sample and we would like to do this for two purposes:



- (1) **To examine the effect of vitamin D supplementation on DNA.** While your genetic 'code' does not change over your life, changes can occur that influence the way your DNA works. These are called 'epigenetic' changes and they may affect people's health. We would like to see if vitamin D influences these 'epigenetic' changes.
- (2) **To study the influence of the genetic code on the response to vitamin D.** By comparing DNA from thousands of people we can see whether differences in DNA affect whether or not people respond differently to taking a vitamin D supplement.

5. HOW IS MY PRIVACY PROTECTED?

- All your samples will be stored securely and without your name on them. They will be labelled with a unique identifier so that they do not get confused with samples from somebody else.
- Any identifying information will be stored securely and separately, away from your samples.
- **No** information that could identify you or your family will be included in any report on the results of the study.

It is possible that samples may be given to other scientists in Australia or overseas for studies of vitamin D and health. If this occurs, these studies will have to be approved by relevant ethics committees. We may provide some data with your samples (for example, your age and smoking history) but no information that could be used to identify you will be included with your samples.



6. WILL I FIND OUT THE RESULTS OF MY BLOOD TESTS?

If you have very low serum 25D levels (<25nmol/L) we will tell you about this in writing and recommend that you discuss this with your doctor. This may not occur for some months after you give your sample, because we have to analyse the blood samples in large batches.

If we do studies of factors that may be clinically important (such as cholesterol or glucose) we will do our best to contact you to ask you if you would like to receive your results. If you say that you would, we will give your results to your nominated general practitioner.

The type of genetic research that we will do as part of the D-Health Trial is extremely unlikely to have any relevance for your health, so we will not routinely give you back any information about your genes. If we decide to study genetic factors that are known to be important for health we will contact you to ask for your consent for your sample to be used in this way.

7. ARE THERE ANY RISKS OF TAKING PART IN THE D-HEALTH TRIAL BLOOD COLLECTION?



When the blood is taken you may feel a little discomfort as the needle goes through the skin. It is possible that you may have some bruising where blood is taken and it is also possible that you will feel light headed or faint. If you feel this way please tell the person taking your blood and they will help you until the feeling goes away.

Currently in Australia genetic research does **NOT** affect your ability to obtain private health insurance. Genetic information may be taken into consideration when you apply for insurance such as cover for death or income protection. However, information from research studies only has to be declared if you are informed about your individual genetic results. **You can choose not to receive any genetic results if we offer this to you in the future.**

The QIMR Berghofer Medical Research Institute has taken out insurance to cover the D-Health Trial. If you would like to see a copy of the indemnity provided, please contact the D-Health helpline on 1300 735 920.

8. ARE THERE ANY BENEFITS TO TAKING PART IN THE D-HEALTH TRIAL BLOOD COLLECTION?

Other than the possibility that we might give you some results of blood tests, there are no direct benefits of taking part in the blood collection component of the D-Health Trial.

There is a chance that information derived from the samples that you are donating under this study may, in the future, have some commercial value. You will not be compensated for your participation in the study or for any future value that the samples you have given may be found to have. However, if money is generated as a result of research using your samples, some will be put into a special fund to be used for future research.

9. CAN I WITHDRAW FROM THE BLOOD COLLECTION COMPONENT OF THE D-HEALTH TRIAL?

You may withdraw from the blood collection component of the D-Health trial at any time and still continue in the D-Health trial. Your decision on whether or not to give a blood sample as part of the D-Health Trial will not disadvantage you or affect your future health care in any way.

You can request for your sample or any results arising from it to be destroyed by contacting us on 1300 735 920.

10. WHO DO I CONTACT IF I HAVE QUESTIONS OR COMMENTS?

If you have any questions, comments or complaints about the study you can:

- Contact the D-Health helpline on 1300 735 920
- Email us at dhealth@qimrberghofer.edu.au
- Write to: A/Professor Rachel Neale
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This study has been approved by the Human Research Ethics Committee of the QIMR Berghofer Medical Research Institute in accordance with the National Health and Medical Research Council's guidelines.

If you would like to speak to an officer of the QIMR Berghofer Medical Research Institute not involved in the study you may contact the Ethics Officer on 07 3362 0117 (HREC Number 1519)