



## Internet-based Cholesterol Assessment Trial (I-CAT)

### **Would you like to be part of a trial exploring how health information provided on the Internet can help people manage their cholesterol levels?**

High cholesterol (the amount of fat in the blood) is one of the things that can cause serious health problems like heart attack and stroke. This is a major problem in Australia. Fortunately if high cholesterol is discovered early there are a number of simple things that can be done to reduce the risk of these health problems, such as changing diet or taking tablets. One problem is that lots of people who have high cholesterol do not find out early enough.

#### **The purpose of the trial**

The purpose of this trial is to find out if a special website might help people discover if they have high cholesterol and then enable them to manage their cholesterol more appropriately.

#### **What the trial involves**

If you agree to take part in this trial, you will be asked to visit a website on 2 or 3 occasions to answer a brief list of questions (each visit should take no more than 5 minutes). On the first visit you will be asked to fill in your contact details and complete a short questionnaire. We will then ask you to return to the website either one or two times over the next 8 to 16 weeks and answer some more simple questions (we will remind you by e-mail, phone, fax or mail if we don't hear from you.) During the course of the trial you will receive one of two types of advice about cholesterol and you will be free to take the advice or ignore it. The type of advice you receive will be decided at random by a computer (as if by the flip of a coin) since this will ensure that the trial results are completely reliable. We will be experimenting with the way we present the advice and by the completion of the trial all participants will receive all advice available. All advice we provide will be in line with standard recommendations from the National Heart Foundation of Australia, the Cardiac Society of Australia and New Zealand and the Australian Pharmaceutical Benefits Scheme.

The trial will take little of your time and although you will not receive any payment for taking part it will, we hope, be an interesting and helpful experience for you. We hope that at least 3,700 people will be involved in this trial.

#### **The trial coordinators**

This trial is being conducted by Associate Professor Bruce Neal of The George Institute, The University of Sydney; Dr David Sullivan of the Department of Clinical Biochemistry, Royal Prince Alfred Hospital and Professor Bruce Armstrong of the School of Public Health, The University of Sydney. Some of the results will be used to meet the examination requirements of a PhD for Dr Stephen Li.

#### **Confidentiality and results circulation**

All information provided by you will be treated in strict confidence. We will retain the contact details you provide to reach you during the trial follow-up period. Once the trial is complete we will erase your contact details from our database and identify your data only by a number. At no time, will any of the information collected in the course of this trial be released or distributed in any form that could identify you to a third party. After we have completed all analyses the results of the trial will be written as research papers and publication will be sought in key medical journals. Results will also be disseminated at appropriate medical conferences and consumer organisations. You will have access to the results via the website and e-mail.

## **Your Rights**

Before you decide if you would like to participate in this trial, it is important for you to understand why the research is being done and what is involved. Please take time to read the information on this sheet carefully and discuss it with friends or relatives if you wish. Your decision to take part in the trial must be based on informed consent meaning you must be told about all the details relevant to your participation before you agree to take part in the trial. Taking part in this trial is totally VOLUNTARY that means you are entirely free to decide whether to take part in this trial or not.

Should you agree to participate in the trial, you are free to discontinue your involvement with the trial at any time and have the option of requesting that any information you have already provided is erased. Withdrawal will not have any affect on treatment given by a health care provider. If there is anything that is not clear, or if you would like more information, please do not hesitate to ask the coordinators using the contact details below. A tick in the "I agree" box on the Consent Form means that you have read and understood the details above, and that you are satisfied with the answers to any queries you have.

## **Funding and Data Storage**

The trial is funded by The George Institute for International Health and a research grant from Pfizer. The data collected in the trial will be in an electronic format and stored in a secure password protected database for at least 15 years.

## **Should you decide to take part**

We would like you to do the following:

- Read carefully this Information Sheet and the Consent Form
- Fill in your details on the Consent Form, click the "I agree" box and submit the form
- If you wish, print out a copy of the Information Sheet and the signed Consent Form for your records
- Fill in the short questionnaire and submit it and then return to the website after 8 weeks to complete a follow-up questionnaire.

## **Contact Details**

IF YOU WOULD LIKE FURTHER INFORMATION ABOUT THE TRIAL OR WOULD LIKE TO SPEAK TO SOMEONE ABOUT YOUR RIGHTS PLEASE CONTACT THE FOLLOWING PERSON:

Dr Stephen Li, Director, Lipid and Cardiovascular Risk Assessment Service, Institute for Clinical Pathology and Medical Research, Westmead Hospital,  
([stephenl@icpmr.wsahs.nsw.gov.au](mailto:stephenl@icpmr.wsahs.nsw.gov.au))

Associate Professor David Sullivan  
Director, Lipid Clinic, Royal Prince Alfred Hospital

I-CAT Tel: (02) 9993 4500

The Human Ethics Committee of The University of Sydney has given approval for the conduct of this trial. Any person with concerns or complaints about the conduct of a research study can contact the Manager for Ethics Administration, University of Sydney on (02) 9351 4811.

***Thankyou.***