PRE-SCREENING PARTICIPANT INFORMATION & CONSENT FORM

Version 2.0 dated 18 February 2014

STUDY TITLE: A 2-year, multi-centre double-blind, randomised, placebo-controlled trial to determine in men with total testosterone ≤ 14nmol/L the efficacy of testosterone treatment together with a lifestyle program in comparison to a lifestyle program alone, to normalise glucose tolerance in those with newly diagnosed type 2 diabetes (T2DM) or prevent progression to T2DM in those with pre-diabetes.

You are invited to participate in a pre-screening evaluation to see if you are a potential candidate for a research study. This study aims to determine whether treatment with testosterone prevents or reverses diabetes in men with newly diagnosed diabetes and men at high risk for the disease.

Whether you are eligible for this study will initially be based on your responses to a set of questions completed on-line or over the telephone. If your responses indicate that you are eligible to enrol in the T4DM study then your details, including your name and other identifying details, will be electronically stored in a secure location by the study co-ordinating centre. These details will be stored so that you can be contacted regarding trial enrolment. If you are found not to be eligible then your identifying details will be deleted but summary information about your questionnaire responses will be stored for research purposes. This summary information will not identify you in any way. If your responses indicate that you may be eligible for this study then we would like your permission for a blood sample to be taken to see if you are eligible for the study.

Please read this form carefully before you agree to the blood tests. This process is called "informed consent." If you want to proceed with the pre-screening and have the blood test you will have to sign this form. To have your blood sample collected, you will need to go to the local blood collection centre shown on your pre-screening instruction sheet and give them a signed copy of this consent form and a copy of the sample collection request. Your decision to take part in this pre-screening is voluntary.

GENERAL INFORMATION

As a first step to determining whether you are eligible for the study we need to know some general health information about you. This involves completing a questionnaire either online or via the study call centre. The questionnaire asks about your current and previous health and medication use and includes a questionnaire about your mental health.

In addition to these questions, a blood test needs to be performed to determine if your blood glucose and testosterone levels meet the criteria required for the main study.

If you consent, you will be requested to make an appointment to visit one of the listed blood collection centres between 7:00 AM -10:00 AM for a blood sample to be collected. You will be required to fast (nothing to eat or drink, except water) from midnight the night before the blood test.

At the pathology centre, blood will be taken from a vein in your forearm and you will then be asked to drink a liquid containing a certain amount of glucose. Further blood samples will be taken at 120 minutes after you drink the liquid. In some cases you may also have a sample taken at 60 minutes. This testing process can 2 - 3 hours to perform. Please ensure that you allow enough time for testing to be completed on the day that you attend the collection centre. In total, about 30mls of blood will be collected.

Your blood will be analysed for glucose. If you glucose result shows that you are pre-diabetic or diabetic then other tests will be done on your blood including: testosterone levels, a blood count, tests to assess your kidney and liver function, thyroid function and a PSA test which is used to screen for prostate cancer. The samples will be destroyed soon after the results are available. You may have some minor discomfort associated with the collection of blood. For example, you may have pain or bruising due to the needle. Fainting and local infection may also occur when blood is taken, although these are rare.

The blood tests will normally be analysed within 2 or 3 days. Once the results are available you will be notified by the study team whether you are eligible to participate in the main study. Whether you are eligible or not, the laboratory will send you these laboratory results to share with your doctor.

If you meet the criteria for the main study you will be asked to attend a study clinic where the entire study process will be explained to you and you will have the opportunity to have your questions about the study answered. If you do decide to participate in the study, you will need to sign a separate 'Participant Information and Consent Form'.

There is no guarantee that by providing this blood sample or completing the questionnaire that you will be eligible for the main study.

There is no cost to you nor will you receive any payment for taking part. By participating in this pre-screening, you are not agreeing to, nor do you have any obligation to participate in the main study. The benefit of participating in the prescreening is that you may find out whether or not you have diabetes and your testosterone level.

By signing this form, you authorize the use and disclosure of your protected information as necessary in order to carry out the research described in this document. Your personal identity will be kept confidential, regardless of whether you are eligible or not for the main study.

PRIVACY AND CONFIDENTIALITY

Your information will remain confidential. The T4DM researchers, representatives of the coordinating centre, regulatory authorities and the ethics committee may have direct access to your information collected. These individuals will do everything possible to protect your identity.

Your name and contact details will be collected so that the coordinating centre (and the study site, if you are eligible) can contact you following your blood tests. These details will be kept confidential and will be destroyed if you are not enrolled in the study.

QUESTIONS/INFORMATION

If you have any questions regarding how your blood samples will be obtained and analyzed or any portion of the study you should contact

This study has been approved by the Sydney Local Health District Human Research Ethics Committee -CRGH. If you have concerns or complaints about the conduct of this study, you should contact the Executive Officer who is the person nominated by the Human Research Ethics Committee to receive complaints from research participants. You should contact them on 02 9767 5622 and quote HREC/12/CRGH/79.

INFORMED CONSENT

I have read the information provided above. I have taken enough time to decide whether or not I would like to give permission to undertake the blood sampling for this pre-screening analysis. I authorize the use and disclosure (sharing) of my personal health information as described in this form. I have retained a signed copy of this form.

_____
Name of Participant (Print)

_____ _____
Signature of Participant Date