MONASH University

Explanatory Statement

August 2015

Explanatory Statement

Title: Health effects of smoke from prescribed burning

Thank you for taking the time to read this information sheet which is for you to keep.

My name is Martine Dennekamp and I am a Senior Research Fellow at the Department of Epidemiology and Preventive Medicine at Monash University. My co-investigators are, Professor Michael Abramson, Professor Malcolm Sim, Dr Anjali Haikerwal from the same department, Dr Fay Johnston from University of Tasmania, Dr Fabienne Reisen and Dr Mick Meyer from CSIRO Marine & Atmospheric Research.

You are invited to take part in a research study funded by the Bushfire Cooperative Research Centre. This research is also part of a doctorate study being undertaken by Anjali Haikerwal who is a candidate at Monash University.

Please read this Explanatory Statement in full before making a decision.

What is the study about?
The aim of the study is to find out how exposure to smoke from planned burning might influence the function of the lungs, heart and blood vessels.

Why have I been invited to take part?
You have been invited to participate in this study because (a) you responded to our advertisement and are willing to take part in our study and (b) you are a resident of an area selected for planned burning.

Possible benefits
There will be no direct benefit to you, but your participation is very important. Exposure to smoke associated with both planned and unplanned fires is a frequent experience in many Australian communities, but there has not been much research about the impacts of smoke exposure on community health. The results will inform the community, land managers and health professionals of any preventive measures required to be undertaken during the planned burning period. The results will allow the potential risks from planned burning to be compared with the risks from severe bushfires.

What does the study involve and what potential risks or inconveniences are there?
The study will involve the following:

1. Measurements of exposure to air pollution
    a. Nanoparticle exposure. This will involve carrying a portable air sampling instrument for a day which will measure and record your exposure to nanoparticles. This is a light monitor which can be worn on your belt or carried in a backpack.
    b. Exposure to fine particles (< 2.5 thousandths of a mm in diameter) indoors and outdoors. A sample of participants will be invited to have air pollution monitors placed inside and outside their homes during the study period. The monitoring will be conducted over a period of 7 days at each participant's house.
2. A questionnaire which will include your age, gender, employment status, education level ,exposure to pollutants from tobacco smoking, home heating and cooking and any pre-existing heart or lung diseases.
3. A daily diary which will be started about a week prior to burning until two weeks after the burning has finished. We would like you to record information on daily symptoms, medications, and use of health services during the planned burning period.
4. Measurement of nitric oxide in exhaled breath. This involves blowing a single breath into a machine which will measure nitric oxide, a marker of inflammation in the lungs. This can result in mild breathlessness similar to that from blowing up a balloon.
5. Lung function testing morning and evening for the duration of study period. This involves filling your lungs and blowing hard into a portable machine (PiKO6) to measure the lung capacity. This can result in mild breathlessness similar to that from blowing up a balloon. You may rest between each blow and the procedures will be strictly monitored and carried out according to internationally approved standards.

6. 24 hour ECG (Holter) monitoring: This involves wearing electrodes for 24 hours connected to a small portable tape recorder which can be secured around your waist belt or hung around the shoulder or neck in a small pouch. Holter monitoring is a very safe test with no risks involved.
7. Blood pressure will be measured by using a digital blood pressure machine. The inflated cuff may cause very brief discomfort in your upper arm which disappears as soon as the blood pressure cuff is deflated.
8. Flow mediated dilation (FMD) will be measured by performing an ultrasound of the arm whilst placing a cuff around your arm. The cuff will be inflated for 5 minutes and then released very quickly. This will cause brief discomfort, tingling or numbness in your arm, which quickly settles down once the cuff is deflated.
9. A blood sample (around 15 mls) will be collected during the study period. The taking of a blood sample from a vein in the arm may cause a brief pricking sensation. Occasionally bruising or tenderness may result, which on rare occasions may persist for a few days. Blood will be taken by experienced researchers and qualified nurses.

How much time will the study take?
The study will take 1 hour for specific health assessment/measurements. The measurements will be repeated 3 times during the study (before, during and after the prescribed burning) per participant.

You can withdraw from the study
Being in this study is voluntary and you are under no obligation to consent to take part. However, if you do consent to participate, you may withdraw from further participation at any stage, but you will only be able to withdraw data prior to the publication of the report of the project.

How will the information you give for the study be kept private?
Your health data will **not** be passed to anyone. The information about you collected for the study will be kept strictly confidential. Only the researchers and their staff will have access to the information. You will not be identifiable in any documents published about the study.

How will this information be stored and protected?
Information collected will be stored in accordance with Monash University regulations and kept on University premises. All records will be kept in locked filing cabinets or in password protected computer files indefinitely. Results of the research will be published as group statistics and reports and will not identify you in any way.

If you would like to contact the researchers about any aspect of this study, please contact the Chief Investigator:	If you have a complaint concerning the manner in which this study **CF12/3097-2012001570** is being conducted, please contact:
Dr Martine Dennekamp Department of Epidemiology & Preventive Medicine, The Alfred Centre, 6th Floor, Commercial Road, Melbourne, VIC 3004 Tel 9903 0166 e-mail martine.dennekamp@monash.edu	Executive Officer Monash University Human Research Ethics Committee (MUHREC) Building 3e Room 111 Research Office Monash University VIC 3800 Tel: +61 3 9905 2052 Fax: +61 3 9905 3831 Email: muhrec@monash.edu

Thank you.

Dr Martine Dennekamp
Chief Investigator