AAA

BREATHE Study - Participant Information Sheet and Consent Form

1. What is the research study about?

You are invited to take part in this research study, which is about reducing the effects of bushfire smoke on your lungs and health. The research study aims to find out if using either of two kinds of masks, a surgical mask, a "P2 or N95 mask", or staying indoors can prevent or reduce exacerbations of asthma, bronchitis, emphysema and other lung conditions during bushfire season. People with these conditions are more vulnerable to effects of bushfire smoke, but there has never been any research to help us with the choice of facemasks, P2/N95 masks or staying indoors for protection.

The findings of this research will help consumers and health authorities identify the best protection against smoke exposure during bushfires or backburning. A surgical mask is an approved product designed to prevent exposure to splash and sprays and may also filter air. It fits loosely around the face. A "P2 or N95 mask" is technically referred to as a respirator, which is also an approved product designed to filter airborne particles and fits tightly around the face. During the study, we will refer to this product as P2 or N95. These are disposable products meant for single use. P2 and N95 respirators meet the same standards

2. Who is conducting this research?

The study is being carried out by the following researchers:

- Professor Raina MacIntyre (Biosecurity Program, The Kirby Institute, UNSW Sydney)
- Doctor Holly Seale (School of Public Health and Community, UNSW Sydney)
- Associate Professor Smita Shah (Western Sydney Local Health District)
- Doctor Abrar Chughtai (School of Public Health and Community, UNSW Sydney)
- Scientia Professor Guy Marks (Professor of Respiratory Medicine - UNSW, South Western Sydney Clinical School)
- A/Prof Samsung Lim (School of Civil and Environmental Engineering, UNSW Sydney)
- Dr Bayzid Rahman (School of Public Health and Community, UNSW Sydney)
- Dr Aye Moa (Biosecurity Program, The Kirby Institute, UNSW Sydney)
- Ms Mallory Trent (Biosecurity Program, The Kirby Institute, UNSW Sydney)

Research Funder: This research is being funded by Medical Research Future Fund (MRFF), through a special call for research on reducing the health impacts of bushfires.

3. Inclusion/Exclusion Criteria

Before you decide to participate in this research study, we need to ensure that you are eligible to take part. The research study will only recruit people who meet the following criteria:

Inclusion criteria: Any adult >18 years with diagnosed asthma, chronic bronchitis, bronchiectasis or emphysema in directly bushfire affected areas or areas affected by bushfire smoke. You have been approached because you live in a postcode which we identified as potentially exposed to bushfire smoke.

You cannot take part in the study if you:

- do not have any of the specified lung conditions (diagnosed asthma, chronic bronchitis, bronchiectasis or emphysema)
- do not live in or near a bushfire-affected area
- are not able or willing to consent
- have a delivery address for masks that does not match the specified postcodes in the study
- have a beard or moustache, due to poor fit of masks on individuals with facial hair
- are not available for daily follow up or not able to fill in the daily diary cards during bushfire season
- age < 18 years.

4. Do I have to take part in this research study? Participation in this research study is voluntary. If you do not want to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the study at any stage.

If you decide you want to take part in the research study, you will be asked to:

- Read the information provided in this form carefully (ask questions if necessary);
- Sign and return the consent form securely online if you decide to participate in the study. You will also be asked to provide your mailing and email address,
- Download a copy of this form with you to keep.

5. What does participation in this research require, and are there any risks involved?

If you agree to participate you will be asked to complete the following research procedures:

We will be randomly allocate you to one of three groups: surgical masks, P2/N95 masks or outdoor air avoidance. If allocated to masks, the masks will be posted to you (to the address that you specify below) each month. Because of the COVID-19 pandemic, and because the study involves people from across NSW and Victoria, your interaction with the research team will be online or by phone. You will receive instructions on how to use your mask or how to practice outdoor air avoidance. For those in mask groups, you will receive a link to a video on how to safely put on and take off your mask. You will complete a survey securely online at the beginning which will take about 15 minutes. Then we will check your health and wellbeing in three periods:

1. From August 1 to October 30 during planned hazard control burning (backburning) for a total of up to 4 weeks around the dates of back burning as advised by your local Fire Service.
2. From December 1 to February 28, every day.
3. April, for a total of 4 weeks.

During those periods we will send you an alert by SMS when the Air Quality Index (AQI, a measure of air pollution) is poor, or if there is a fire alert in your area. You may also use a visual or smell-based assessment of smoke. This will be a trigger for you to use your mask or avoid outdoor air, depending on which group you are in. During the follow up period you will be required to fill in an online diary card every day, which will take about 5 minutes. This will document how you are feeling, whether you were unwell, whether you needed extra medicine, GP visits or a visit to hospital, and what exercise you did that day. This data will allow us to check if the masks or outdoor air avoidance reduced exacerbations of asthma and other lung conditions during prolonged smoke exposure. At the end of the study you will also complete a form about your experience of mask wearing, which will take about 10 minutes.

In addition, you may be asked by the study team to mail in one or more of your used face masks (if applicable) using a preaddressed and prepaid envelope that will be provided to you.

To ensure that each participant has an equal chance of being placed in any group to participate, a computer allocates each study participant into a group randomly, like the flip of a coin. Once randomised, participants will be allocated to one of the following participant groups. An overview of the difference in research procedures that you will be asked to complete is described in the table below.

Interventions
Group (1): Wearing a surgical mask when Air Quality Index (AQI) is poor or there is a fire alert **OR** Group (2): Wearing a P2/N95 when Air Quality Index (AQI) is poor or there is a fire alert **OR** Group (3) Avoiding outdoor exposure when AQI is poor or there is a fire alert

There may also be side effects of wearing masks, such as discomfort and difficulty breathing. The masks you will use (if in a mask group) are approved products in Australia and very safe. There are no serious side effects reported. Any side effects usually go away shortly after taking off the mask. You can record side effects on your daily diary care and also tell the research team immediately about any new or unusual symptoms that you get. If a severe side effect occurs, the research team will discuss the best way of managing any side effects with you.

6. Additional Costs and Reimbursement: There are no costs associated with participating in this research project, nor will you be paid. You will, however, be sent masks by post every month during the observation periods if you are allocated to the mask groups.

7. Psychological Distress: You may feel that some of the questions we ask are stressful or upsetting. If you do not wish to answer a question, you may skip it and go to the next question, or you may stop immediately. If you become upset or distressed as a result of your participation in the research project, the research team will be able to arrange for counselling or other appropriate support. Alternatively, a number of free contactable support services are included at section 9. Any counselling or support will be provided by qualified staff who are not members of the research team. This counselling will be provided free of charge.

8. What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research; however, possible direct benefits may include better control of your lung condition during exposure to bushfire smoke. Your participation will also benefit Australia by informing appropriate use of masks and outdoor air avoidance for Australians affected by increased frequency of exposure to bushfires and hazardous smoke. The findings will be beneficial to people with asthma, chronic bronchitis, bronchiectasis or emphysema in the future.

9. What will happen to information about me?

By signing the consent form, you consent to the research team collecting and using information about you for the research study.

The research team will securely store the data collected from you for this research project for a minimum of 15 years after the publication of research results. The information about you will be stored in a re-identifiable format where any identifiers such as your name, address, date of birth will be replaced with a unique code.

Your information will only be shared in a format that will not identify you.

- Information collected from you in an electronic format stored on a UNSW password protected OneDrive only accessible to the approved research investigators.
- Information collected from you using paper-based measures will be stored in a locked facility at the Kirby Institute, UNSW and only the approved research investigators will have access to this information.

The information you provide is personal information for the purposes of the Privacy and Personal Information Protection Act 1998 (NSW). You have the right of access to personal information held about you by the University, the right to request correction and amendment of it, and the right to make a complaint about a breach of the Information Protection Principles as contained in the PPIP Act. Further information on how the University protects personal information is available in the UNSW Privacy Management Plan.

10. How and when will I find out what the results of the research study are?

The research team intend to publish and/ report the results of the research. All Information will be published in a way that will not identify you. If you would like to receive a copy of the results you can let the research team know by ticking the box below indicating that you would like to receive the results of the study. We will also have a summarised version of the results on the UNSW website after the results are published.

11. What if I want to withdraw from the research study?

If you do consent to participate, you may withdraw at any time. You can do so by completing the 'Withdrawal of Consent Form' which is provided at the end of this document or you can ring the research team and tell them you no longer want to participate. Your decision not to participate or to withdraw from the study will not affect your relationship with UNSW Sydney. If you decide to leave the research study, the researchers will not collect additional information from you. You can request that any identifiable information about you be withdrawn from the research project.

12. What if I have a complaint or any concerns about the research study and will I receive compensation if suffer any injuries or have complications?

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

Complaints Contact

If you have a complaint regarding any aspect of the study or the way it is being conducted, please contact the UNSW Human Ethics Coordinator:

Position	UNSW Human Research Ethics Coordinator
Telephone	+ 61 2 9385 6222
Email	humanethics@unsw.edu.au
HC Reference Number	HC200477

13. What should I do if I have further questions about my involvement in the research study?

The person you may need to contact will depend on the nature of your query. If you require further information regarding this study or if you have any problems which may be related to your involvement in the study, you can contact the following member/s of the research team:

Research Team Contact Details

Name	Professor Raina MacIntyre
Position	Professor and Head of Biosecurity Research Program
Telephone	+61 2 9385 0874
Email	r.macintyre@unsw.edu.au

Chief Investigator

Name	Professor Raina MacIntyre
Position	Professor and Head of Biosecurity Research Program
Telephone	+61 2 9385 0874
Email	r.macintyre@unsw.edu.au

Support Services Contact Details

If at any stage during the study, you become distressed or require additional support from someone not involved in the research please call:

Name/Organisation	UNSW Human Research Ethics

Position	UNSW Human Research Ethics Coordinator
Telephone	+ 61 2 9385 6222

Declaration by the participant

		I agree
1)	**I understand I am being asked to provide consent to participate in this research study;** * must provide value	☐
2)	**I have read the Participant Information Sheet, or someone has read it to me in a language that I understand;** * must provide value	☐
3)	**I understand the purposes, study tasks and risks of the research described in the study;** * must provide value	☐
4)	**I provide my consent for the information collected about me to be used for the purpose of this research study only;** * must provide value	☐
5)	**I have had an opportunity to ask questions and I am satisfied with the answers I have received;** * must provide value	☐
6)	**I consent for the study team to contact me by mail and by email using the contact information I have provided below** * must provide value	☐
7)	**I understand I will need to complete a survey at the beginning and end of the study, and a daily diary form during the observation periods.** * must provide value	☐
8)	**I understand I may be asked to mail in one or more of my masks using a prepaid envelope provided by the study team** * must provide value	☐
9)	**I freely agree to participate in this research study as described and understand that I am free to withdraw at any time during the study and withdrawal will not affect my relationship with any of the named organisations and/or research team members;** * must provide value	☐

10) **I understand that on the next page I will be given a signed copy of this document to download;** ☐
* must provide value

11) **I understand that the results of the research will be made available on the UNSW website;** ☐
* must provide value

12) **First Name**
* must provide value

13) **Surname**
* must provide value

14) **Email Address**
* must provide value

15) **Mailing Address (please include suburb and post code)**
* must provide value

16) **Phone Number (Mobile)**
* must provide value

17) **Signature of research participant**
* must provide value

18) **Today's Date** D-M-Y
* must provide value

Next Page >>