

From: cleanair@cleanairtas.com
Sent: Sunday, 31 December 2023 14:09
To: 's.husakovic@unsw.edu.au'
Subject: URGENT complaint - Human Ethics, Conduct and Integrity
Attachments: BREATHE_study.ab.docx; Loose-fitting-surgical-mask.jpg

Importance: High

Acting Director RECS
UNSW Conduct and Integrity
Research Ethics & Compliance Support
UNSW Sydney
Sydney NSW 2052 Australia
s.husakovic@unsw.edu.au (02 9065 8520)

Dear Samela Husakovic,

Re: [2023/04 BREATHE Study](#) – Kirby Institute

Research Complaint - More than low risk research and Integrity

I wish to lodge an urgent formal complaint in relation to the randomised clinical BREATHE Study using surgical masks to control respiratory outcomes during planned burning or bushfire.

My complaint is in relation to i) immediate and/or, ii) long-term harm caused to study participants already compromised with asthma, emphysema, chronic bronchitis, or bronchiectasis.

Without warning (depending on uncontrollable exposure levels to wood smoke) serious immediate harm can result to surgical mask participants, even death.

Further, it is possible for harm to occur many years after the trial has concluded as a result of deliberately breathing wood smoke.

I have sought to have this matter dealt with urgently by the relevant school – Prof Raina MacIntyre
I am still waiting for a response from Human Research Manager – Leonne Thompson, even though I have stressed the urgency in this matter. This relates to inaction.

I am asking for the Surgical Mask arm of this study to be terminated immediately.

I still maintain; however, it is unethical to lock compromised people inside so that deliberate burning can continue.

Depending on the type of building, little protection may be afforded to this already endangered group.

For your convenience, please find further details attached.

I look forward to hearing from you.

Thank you.

Yours faithfully,

Clive M. Stott

cleanair@cleanairtas.com

BREATHE - WOOD SMOKE STUDY in 2023 - Kirby Institute.

HUMAN ETHICS - Exposing compromised people to wood smoke?

Who can participate in the study?

"Anyone with asthma or COPD (emphysema, chronic bronchitis or bronchiectasis) and who live in an area in Australia affected by bushfires or bushfire smoke, including metropolitan areas, may be eligible to be part of the study."

"The aim of this research is to determine whether the use of surgical masks and P2 masks protects people with asthma, emphysema, chronic bronchitis or bronchiectasis from the effects of smoke exposure during bush fire season in Australia."

"People who consent to be in the study will be randomly allocated to one of three groups: surgical masks, P2 masks or outdoor air avoidance.

If allocated to a mask, they will need to wear a mask when exposed to bush fire smoke.

Their health will be tracked during a maximum of **4 weeks around controlled backburning** between August and November 2023 and through all of December 2023 and January 2024 this summer. A final period of follow up will occur from 1April to 30 April 2024."

BREATHE Study:

[Bushfire smoke, Plannedburn smoke, asthma, lung disease and masks](#)

Correspondence:

[BREATHE STUDY- 02.08.2021.b](#)

[BREATHE STUDY- 23.08.2021.c](#)

[BREATHE STUDY- 08.10.2020.d](#)

[BREATHE STUDY- 01.11.2023.e](#)

[BREATHE STUDY- 14.11.2023.f](#)

[BREATHE STUDY- 14.11.2023.g](#)

[BREATHE STUDY- 24.11.2023.h](#)

[BREATHE STUDY- 24.11.2023.i](#)

[BREATHE STUDY - 08.12.2023.j](#)

[BREATHE STUDY- 08.12.2023.k](#)

31 %

MASK EFFICIENCY