

### INFORMATION LEAFLET AND INFORMED CONSENT

# You must receive, read and understand this document **before** any study-related procedure

**STUDY NUMBER:** 1094837/1037502

STUDY TITLE: Are they breathing?

INSTITUTION: School of Electrical and Information Engineering, University of the

Witwatersrand.

Contact Information: 1094837@students.wits.ac.za && 1037502@students.wits.ac.za

A. Protocol ...... English Informed Consent

B. 2. Version..... (Dated 25.03.2019)

C. Investigator's names:

D. Approved by Wits HREC

E. 5. Date approved: dd.mmm.yyyy

Participant Number:

Participant Initials: \_\_\_\_ \_

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REF: SOP-CTD-002

Version:

Our Version Control No: HREC version March 2019.





### 1. INTRODUCTION:

Good day, our names are Junaid and Matthew, we are 4<sup>th</sup> year undergraduate Electrical Engineering students at the University of the Witwatersrand. would like to invite you to participate in our research study, entitled "Are they breathing?"

- Before agreeing to participate, it is important that you read and understand the following explanation of the purpose of the study, the study procedures, benefits, risks, discomforts, and your right to withdraw from the study at any time.
  - This information leaflet is to help you to decide if you would like to participate. You need to understand what is involved before you agree to take part in this study.
- 2. If you have any questions, do not hesitate to ask us.
- 3. You should not agree to take part unless you are satisfied about all the procedures involved.
- If you decide to take part in this study, you will be asked to sign this document to confirm that you understand the study.

## 2. LENGTH OF THE STUDY AND NUMBER OF PARTICIPANTS:

- The study will be performed on university premises, participants will be mostly limited to university students and staff. However, anyone is able to participate.
- Approximately 15 participants will participate in this study.
- The participants will be between the ages of 18 and 65.
- The total amount of time required for your participation in this study will be a maximum of 10 minutes.

### 3. PROCEDURES:

- If you agree to take part in this study, you will first be asked questions and examined to see if you qualify for this study.
- The testing will initially consist of a mask held near the face of the participant in order to obtain respiratory rate measurements.

- A conventional medical respiratory rate monitor will subsequently be used to measure the participants respiration rate.
- Participants are expected to keep somewhat similar breathing patterns between the two measurements taken.

# 4.WILL ANY OF THESE STUDY PROCEDURES RESULT IN DISCOMFORT OR INCONVENIENCE?

- The only comfort or distress that may occur during the obtaining of measurements relates to the proximity of the measuring device to the face of the participant.
- The measurement device will not inhibit the participant's ability to breathe normally.
- There are no significant risks of harm or injury involved in the participation in this study.

#### 5. RIGHTS AS A PARTICIPANT IN THIS STUDY:

Your participation in this study is entirely voluntary and you can decline to participate, or stop at any time, without stating any reason.

#### 6. ETHICAL APPROVAL:

 This study protocol has been submitted to the University of the Witwatersrand, School of EIE, Human Research Ethics Committee (HREC) and written approval has been granted by that committee.

### 7. CONFIDENTIALITY:

- All information obtained during the course of this study will be kept strictly confidential. Data that may be reported in research reports will not include any information that identifies you as a participant in this study.
- Any information uncovered regarding your test results or state of health as a result of your participation in this study will be held in strict confidence.

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Α.	Protocol English Informed Consent	
В.	2. Version (Dated 25.03.2019)	Participant Initials:
C.	Investigator's names:	
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	Approved by Wits HREC	
E.	<ol><li>Date approved: dd.mmm.yyyy</li></ol>	Participant Number:

REF: SOP-CTD-002 Version:



### **INFORMED CONSENT:**

- I hereby confirm that I have been informed by the students: Junaid and Matthew, about the nature, conduct, benefits and risks of participating in this study.
- I have also received, read and understood the above written information (Participant Information Leaflet and Informed Consent) regarding the study.
- In view of the requirements of research, I agree that the data collected during this study can be processed in a computerised system by the students conducting this research.
- I may, at any stage, without prejudice, withdraw my consent and participation in the study.
- I have had sufficient opportunity to ask questions and (of my own free will) declare myself prepared to participate in the study.

PARTICIPANT:					
Printed Name	Signature / Mark or Thumbprint	Date and Time			
I, Junaid/Matthew, here conduct and risks of the	ewith confirm that the above participant had above study.	as been fully informed about the nature,			
Procedure Conductor:					
Printed Name	Signature	Date and Time			
A. Protocol English II	nformed Consent				
B. 2. Version (Dated 2	5.03.2019)	Participant Initials:			
<ul><li>C. Investigator's names:</li><li>D. Approved by Wits HREC</li><li>E. 5. Date approved: dd.mr</li></ul>	: nm.vvvv	Participant Number:			

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