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[Letter date]

**INVITATION TO PARTICIPATE IN A RESEARCH PROJECT**

**Research Study:** **The feasibility of a smartphone app to follow up survivors of Intensive Care Unit admission – SMART - ICU**

Dear [Title] [Surname],

This letter is to invite you to take part in a study that is currently being performed by the Royal Adelaide Hospital Intensive Care Unit to investigate recovery following intensive care in both participants who own smartphones and those that don’t.

We understand you were discharged from the RAH ICU on [Date of Discharge] and from the hospital on [Hospital Discharge], we would be interested to know if you would be interested to assist us with a research project.All research is voluntary and you are under no pressure to take part, you can also withdraw from the study at any time, we would give you the option to delete all your data if you so wished.

Before agreeing to participate it is important that you read and understand the reasons for the study and what this would involve. This letter details the purpose, procedures, risks and benefits of this study. We encourage you to discuss this with your family and friends. The study investigators, if you wish, are available to answer any questions you may have (their details are below).

**What is this research's purpose?**

Historically, recovery following ICU has been documented using questionnaires, which often miss aspects of recovery and in hospital assessments which can be inconvenient to participants.

Using the pedometer (intrinsic accelerometer) and GPS unit inside smartphones we hope to collect information about post-ICU recovery easily, accurately and continuously.

**What do you need to do?**

If you agree to take part in this study we will ask you to check the contact details on page 4 and add any missing details. We will contact you at 3 and 6 months post hospital discharge to complete a few questionnaires. This should take 30 – 45 minutes. If you don’t own a smartphone this is all that is required.

If you own a smartphone we will request that you install an application called the ‘Patient Outcome Measure’ app this app collects information about the number of steps you take, and records your GPS position every minute. It has minimal impact on your phones battery, and uses your home WiFi network by default, rather than your mobile data, to upload the data it collects, anonymously to a secure cloud database. If your phone doesn’t connect to a Wi-Fi signal within 24 hrs, the app will use your mobile data to connect to the internet, however this will be less that 1MB/day (28MB per month) depending on the data plan you have, this may incur a cost, however these will be small, we can provide you with approximate costs if you let us know your mobile plan. You can disable this by turning off your mobile data, in which case the app will never use mobile data.

Instructions for installing the app onto your phone are included with this letter.

**What will we do with this information?**

We hope to publish this data in a medical journal, however all data will be made anonymous and you won’t be identified, all your results will remain confidential.

**The cost to you**

Ideally there will be no financial cost to you, however, the surveys take around 30 minutes to complete and if you own a smartphone there may be a very small drain on the battery life of your phone while the app runs in the background, your phone should be checked regularly and charged. Data usage for smart phone owners: The App uses a small amount of data in the upload, up to 28MB/ month. Over the 12 month study period a maximum of 0.3 GB of data may be used from your home Wifi network or mobile data, which could cause data associated costs depending on theWifi and mobile data plan you have. When your phone connects to your home Wi-Fi network the Patient Outcome Measure App will upload your GPS and step count data, anonymously to a secure cloud database. However, if your phone doesn’t connect to Wi-Fi within a 24 hour period the Patient Outcome Measure App will utilise mobile data.

**Are there any risks or discomfort of this study?**

This study will not pose any danger to your long term health.

**What to do if something goes wrong?**

Dr Tarr will be available at all times via telephone should anything concern you or your require assistance with the study. If something does go wrong we will discuss if you wish to withdraw from the study.

**Is there anything to gain from participation in this study?**

Although this study will not benefit you personally you will potentially aid future generations of researchers in collecting data about follow up of patients, improving the service for those to come.

**Confidentiality**

As mentioned above your privacy is of the utmost importance during the study. Your participation will not be disclosed to other research or medical personnel unless you agree to, or if necessitated under law. Any published information will be de-identified, and your identity will not be revealed in any way.

**Contacts for further information**

Should you have any questions or concerns before, during or after the study, please contact Dr. Edward de'Lisle-Tarr via switchboard on (08) 7074 0000 or the ICU Research Manager on (08) 7074 1801.

If you would like to talk to someone not directly involved in the study about your rights as a participant, or about the conduct of the study, you may also contact the Chair of the Central Adelaide Local Health Network Human Research Ethics Committee, on (08) 7117 2229

**Compliance with NHMRC National Statement**

This study is conducted according to the principles established in the National Health and Medical Research Council National Statement on Ethical Conduct in Human Research (2007, updated 2018) and has been approved by the Human Research Ethics Committee of the Royal Adelaide Hospital.

**Further Information**

A description of this clinical trial will be available on www.anzctr.org.au. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time

**What you need to do now**

If you are interested in taking part, read and complete the attached consent form and contact details, if you own a smartphone, and want to contribute to this part of the study, complete the second section of the consent form too.

If you do not agree to take part please complete the section below and return it in the pre-paid envelope

If we don’t hear from you by [letter date + 14 days] we will call you enquire about the study.

(Cut here)

-----------------------------------------------------------------------------------------------------------------

[First name] [Surname], Dob:- [DoB], does not wish to participate in this study

 (you do not need to provide any further information, however the information you provide will help us design further studies)

Do you own a smartphone (please circle) Yes / No

Reason for not consenting \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**INTENSIVE CARE UNIT**

**ROYAL ADELAIDE HOSPITAL**

**PARTICIPANT CONSENT FORM AND CONTACT PREFERENCES**

**Protocol Name:** **The feasibility of a smartphone app to follow up survivors of Intensive Care Unit admission**

**Principal Investigator: Dr Edward de'Lisle-Tarr**

 **Intensive Care Unit (ICU), Royal Adelaide Hospital**

The nature, purpose and risks of the research project have been explained to me in this letter. I understand them and agree to take part.

1. I understand that I will not directly benefit, I will not be reimbursed, for taking part in the study.
2. I understand that, while information gained during the study may be published, I will not be identified and my personal results will remain confidential.
3. I understand that I can withdraw from the study at any stage and that this will not affect my medical care, now or in the future.
4. I have had the opportunity to discuss taking part with a family member or friend.

Name of participant: \_\_\_\_\_[First name] [Surname],\_\_\_\_ [UR]\_\_\_\_

Signed: (please sign here) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Do you own a smartphone? (please circle) Yes / No

Do you agree to take part in the smartphone section of the study (please circle) Agree / Don’t agree

If you own a smartphone and agree to take part in the smartphone element of this study:-

1. I agree to install the clinical health tracker app (instructions on the next page)
2. I understand the clinical health tracker app anonymously reports my step counts and location to a secure cloud database

Signed: (please sign here) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Contact preferences**

I would prefer to complete the surveys via (please circle)

Post Emailed (online link) Phone call

Email Address \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Phone number \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_