COMMON RESEARCH PROTOCOL APPLICATION TO RESEARCH ETHICS COMMITTEE

**1. TITLE**

**The Feasibility of a Smartphone App to Follow up Survivors of Critical Illness**

**SMART – ICU**

**2. INVESTIGATOR DETAILS AND QUALIFICATIONS**

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**3.** **PURPOSE OF STUDY** (general) and **AIMS** (specific)

3.1 Objective:

We believe there is a future role to be played by smartphone technology in assessment and monitoring of patients distant to hospital sites. The ability to measure a patient’s functional status and physical reserve more accurately, without the need to bring them into the hospital environment for repeated assessment, will be of great benefit to physicians, patients and the healthcare system. The ability to integrate smartphone data with healthcare utilisation will potentially allow for better allocation of healthcare resources. Specifically, for those who are at greater risk of unplanned hospital re-admissions or deterioration in the community.

We have developed a smartphone application (app) that works on both Android and Apple devices (cross-platform), the ‘POM’ (Patient Outcome Measures) app, that wirelessly reports step-count and Global Position System (GPS) data, obtained by the smartphone, to a cloud database. The app is also able to access only historic steps-per-day and distance walked-per-day data held on the phone. The app stores the data until the participant’s phone connects to Wi-Fi and then securely uploads encrypted data to a cloud database. If no Wi-Fi signal is found after 24 hours then the data will be uploaded using mobile data. We can use these data to derive several novel patient-centered outcomes, assessing physical activity and physical participation for patients distant from hospital care.

We wish to explore the feasibility of using a smartphone app to remotely monitor survivors of ICU, to explore the difference between participants who are smartphone owners and those who are non-owners in terms of subjective ICU outcomes at 3 and 6 months and to assess participant satisfaction using the smartphone app.

3.2 Aims

*Primary:*

To describe the number of successful app activations, data completeness and volume of pre-morbid step data in the smartphone group.

*Secondary:*

1. To describe the outcomes over time of ICU survivors in terms of:-

mean daily step counts;

walking speed;

time spent active;

time spent at home;

distance travelled;

locations visited and

activity spaces.

1. To explore the difference in outcomes at, 3 and 6 months between smartphone owners and non-smartphone owners in terms of;-

Combined activities of daily living;

Hospital Anxiety and Depression Score (HADS);

Impact of Events Scale – Revised (IES-R);

European Quality of Life 5 Dimensions (EQ-5D) and

The World Health Organisations Disability Assessment Schedule (WHO-DAS 2.0)

1. To describe the relationship between WHO DAS 2.0 and smartphone outcomes.
2. To assess participant satisfaction of using a smartphone app to assess their recovery.

Hypothesis:

That eligible patients will successfully activate the app and that when activated the app will provided complete data to describe their recovery.

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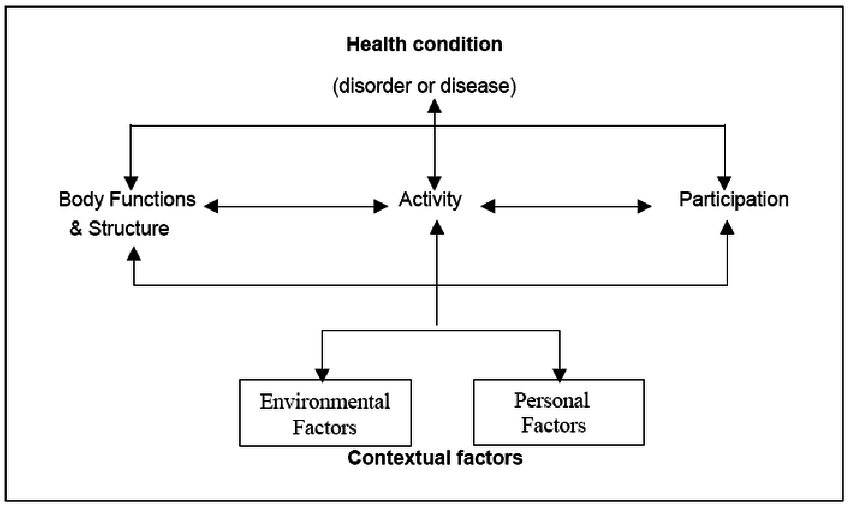
**4.** **BACKGROUND AND PRELIMINARY STUDIES**

*4.1 Post Intensive Care Syndrome*

The physical impact of critical illness is well established, patients who suffered acute respiratory distress syndrome have been shown to walk less than predicted during a 6-minute walk test [1]. ICU survivors have also been shown to have reduced grip strength [2], the physical function scores of quality of life measures have also been shown to be reduced [3, 4], they struggle with activities of daily living for over 12 months [5] and struggle returning to work for over 2 years following ICU [6]. They have an increased incidence of Post-Traumatic Stress Disorder (PTSD) [5, 7], high levels of anxiety and depression [5, 8, 9] and worse cognitive impairment [10-12]. These new or worsening impairments in physical, cognitive or mental health following an ICU admission have been termed Post Intensive Care Syndrome (PICS) [13]. Dale Needham’s group has done a lot of work in determining the best tools to assess PICS in survivors of Adult Respiratory Distress Syndrome (ARDS) [14, 15]. They have described a minimum outcome set derived from the European Quality of Life – Five Dimensions (EQ-5D), Hospital Anxiety and Depression Scale (HADS) [16] and Impact of Events Scale – Revised (IES-R) [13, 15]. While many stake-holder conferences and Delphi-processes have led to these three tools being described, they only describe 3 of the 7 domains, beyond survival, that his group defined affected ARDS survivors. Indeed, Lim and colleagues [17] have shown that the EQ-5D only partially assesses quality of life in survivors of critical illness.

4.2 Assessment of Disability

The World Health Organisation (WHO) describes disability in their International Classification of Function [18], they describe a model (Figure 1) where the disease or health problem causes issues with body functions and structures, activity and participation, and these interact with environmental and personal factors to determine a person’s level of disability. Based on this model the WHO developed the World Health Organisations Disability Assessment Schedule (WHO DAS 2.0) [19]. It may be possible by measuring activity and participation to more accurately define a survivors level of disability.

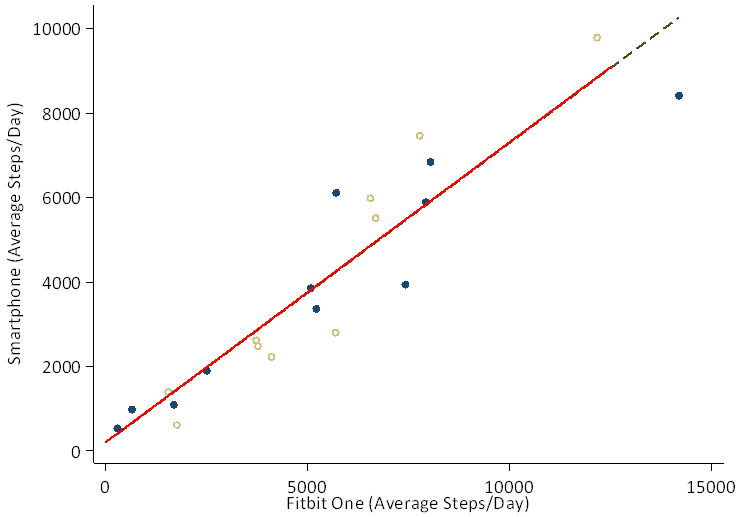


**Figure 1 – The World Health Organisation describes disability in their International Classification of Function**

*4.3 Smartphone assessment*

The many micro-sensors within a smartphone provide a unique and available tool for both patient care and future clinical trials. This will become an increasingly feasible methodology as ownership is anticipated to increase over time [20]. We have developed a cross-platform smartphone app with the capabilities of recording a 6-minute walk test (6MWT) in participants distant from clinical sites, logging responses to health reported quality of life questionnaires and reporting patient step and Global Position System (GPS) data. These data are encrypted and uploaded wirelessly to a secure database. We believe this is an unobtrusive methodology to objectively collect patient data. This will not only allow patient and clinician centred outcomes to be calculated but will allow for distant monitoring of patient activity in real-time.

**Figure 2 - Plot of mean daily step counts at 3 and 6 months following discharge from ICU obtained from a FitBit ONE and a Smartphone. Using a generalised estimating equation model there was shown to be a strong relationship with a smartphone reliably capturing 70% of the Fitbit data (p<0.0001)**



We have shown that half of ICU patients owned a smartphone in 2015 [21], and were able to objectively describe pre-morbid physical activity in terms of step and GPS outcomes for the first time [21]. In 2015 half of the phone we analysed contained premorbid data, however in a survey we recently conducted in 72 conference attendees data were available on 85% of phones, demonstrating the increase in the data availability over the last 3 years. We have demonstrated a strong relationship between mean daily step counts obtained from a smartphone and a pedometer in patients who survived critical illness (Figure 2) [22] and have constructed GPS outcomes that described recovery between 3 and 6 months following ICU discharge (unpublished data).

We are currently conducting a study in patients undergoing cardiothoracic surgery, where the patients are assisted to install a smartphone app pre-operatively, this results in very few unsuccessful app installations and activations. This method of ‘on boarding’ (the process by which an individual installs and activates an app) requires the cost of a staff member, however being able to progress this methodology, by getting the patients and their relatives to install the app would further, drastically reduce the cost of follow up.

*4.4 Step and GPS outcomes*

Step outcomes, such as walking speed [23-25], mean daily step counts [26] and time spent inactive, have been used in a wide range of populations. Our scoping review showed these to be the most commonly used outcomes in ICU survivors [27]. Reduced activity counts have predicted hospital admission in COPD [28] and deterioration in cystic fibrosis [29]. GPS data will allow us to calculate time spent at home, journey frequency, linear distance travelled and activity spaces. An activity space is the geographical area one interacts with in the course of daily life, and is a surrogate for mobility and social interaction [30]. Although these outcomes are relatively novel, they have been used to describe patient activity in several populations [31-36]; however, step and GPS data have never been used to describe patient activity and participation following critical illness.

**5. PARTICIPANTS**

We plan to identify all patients who are discharged alive from hospital following an ICU admission.

**Inclusion Criteria**

* Emergency admission to ICU
* ICU length of stay (LoS) ≥ 48 hrs
* Age ≥ 18 years

**Exclusion criteria**

* Readmitted to ICU
* Non-English speaker

The study will have two arms, a smartphone owning and non-smartphone owning arm.

We aim to recruit 75 smartphone owners, and 75 non-smartphone owners, however due to the study design we will cease further invites being sent out when 75 smartphone owners are recruited.

**6. STUDY PLAN AND DESIGN**

We are proposing a prospective observational cohort feasibility study. Potential participants will be identified from the electronic medical record system (EPAS/ Sunrise). Every 2 weeks a download of the ‘midnight census reports’ containing all ICU discharges during that period will be generated to determine eligibility and obtain contact information for eligible potential participants (see 8.0 Ethical considerations screening waiver request). This data set will be cross referenced with the Births Deaths and Marriages death registry. All past ICU patients who meet the inclusion criteria and no exclusion criteria will be written to 1 month following ICU discharge. An interval delay of one month was chosen pragmatically.

A copy of the participant information and consent form (PICF) and the smartphone app installation instructions will be sent by standard mail. The PICF will include contact details for the study PI, should participants require clarification or assistance with the process.

Potential participants will be asked to complete the consent form, indicating if they are a smartphone owner, and separately consent to the smartphone arm of the study. They will also be asked to confirm their preferred contact method.

Participants will be informed that they are taking part in a follow-up study where they will be contacted at 3 and 6 months to ask some questions about how they are recovering. If the participant owns a smartphone they will be asked, to install our app on their phone.

Those who do not respond to the initial letter within 14 days will be contacted by telephone. Participants who consent and have installed the app but where no data has been uploaded will be contacted by telephone to confirm installation and provided with assistance as needed.

*6.1 No smartphone arm*

At 3 and 6 months participants will be contacted via their preferred method to enquire about their health status. They will be asked to complete, via email or phone call, depending upon their preferred contact method, an assessment of disability (The World Health Organisation’s Disability assessment Schedule (WHO DAS 2.0)), a quality of life assessment (the European Quality of Life Assessment 5 Dimensions (EQ-5D)), an assessment of anxiety and depression (Hospital Anxiety and Depression Scale (HADS)), an assessment of post-traumatic stress disorder (Impact of Events Scale Revised (IES-R)) and an assessment of function (Instrumental Activities of Daily Living (iADL’s) and Activities of Daily Living (ADL’s) combined).

If, after 1 week the survey has not been completed/ returned or contact from the participant made, a follow-up phone call from the ICU Research Unit will be made to facilitate participants in completing the assessments. If participant contact is still not able to be established, paper copies of the questionnaires will be mailed with a cover letter and a pre-paid envelope, explaining that the participant may complete the questionaries or contact ICU research to complete the surveys over the phone. Based on previous experience we estimate that survey completion process takes approximately 30-45 minutes of the participant’s time.

*6.2 Smartphone owning arm*

All participants will be sent instructions on how to install the POM app. Participants who own a smartphone and consent to the process will be directed to these instructions. The instructions will describe how both iPhone and Android phone owners can search for and download the app. Each participant will have prospectively been provided with a unique ID. This unique ID will be included in the initial letter. Participants will return a completed consent and contact preferences page from the PICF. On receipt of the consent form we will check they have activated their app by checking for step and GPS data in our database. If there appears to be a lack of data participants will be contacted to facilitate app installation, this intervention will be recorded in the CRF.

At 3 and 6 months participants in the smartphone arm will also be contacted via their preferred method to enquire about their health status. Participants will be asked to complete, via email or phone call, depending upon their preferred contact method, an assessment of disability (The World Health Organisation’s Disability assessment Schedule (WHO DAS 2.0)), a quality of life assessment (the European Quality of Life Assessment 5 Dimensions (EQ-5D)), an assessment of anxiety and depression (Hospital Anxiety and Depression Scale (HADS)), an assessment of post-traumatic stress disorder (Impact of Events Scale Revised (IES-R)) and an assessment of function (Instrumental Activities of Daily Living (iADL’s) and Activities of Daily Living (ADL’s) combined). If, after 1 week the survey has not been completed/ returned or contact from the participant made, a follow-up phone call from the ICU Research Unit will be made to facilitate participants in completing the assessments. If contact is still not able to be established, paper copies of the questionnaires will be mailed with a cover letter and a pre-paid envelope, explaining that the participant may complete the attached questionaries or contact ICU research to complete the surveys over the phone. Based on previous experience we estimate that survey completion process takes approximately 30-45 minutes of the participant’s time.

Participants will keep the smartphone app on their phone for 12 months following ICU admission. After this period they will receive a SMS from ICU research to delete the app from their phone.

6.3 Confidentiality, data storage and security

6.3.1 Paper records

All returned signed consent forms, contact details and CRF’s will be stored securely in locked tambours in ICU research ‘blue space’. Data will be re-identifiable; all participants will be allocated a study code and all smartphone owners and additional unique ID for anonymised storage of electronic data. There will be a paper copy of the linking data kept separately in ICU research. The contact and CRF details will also be transferred to an electronic database, this will be stored in accordance with digital records below.

6.3.2 App data and database storage

The data collected by the smartphone app are associated with a unique ID, these data will uploaded to a secure database held on Google Firestore which has server side encryption. No participant details will be held on this server, maintaining the data separation principle. The database has undergone extensive vulnerability testing and can only be viewed from a University of Adelaide IP address. At the conclusion of the study, participant data will be removed from the online database and stored off line, in accordance with digital records below.

6.3.3 Digital Records

Details held in the CRF will be transferred to an excel spreadsheet, these will be associated with a unique ID, but will contain participant details for mail merging of survey reminders.

3 and 6-month survey responses will be collected and entered using REDCap. This is held on the South Australian intensive care association servers. Once data collection is complete, 3 and 6-month survey responses will be exported to an excel spreadsheet in combination with a summary step and GPS outputs. These data will be kept on a secure SA Health Server accessible only to ICU research staff.

6.3.4 Data Deletion

All data will be stored for 7 years following publication and will then be deleted by the ICU Clinical Research Manager.

6.3.5 Confidentiality

All participants will be assigned a study code and three-word code, the linking data will be held securely (as above) by the ICU research department at the Royal Adelaide Hospital. Data will be anonymised for analysis. Individuals can be re-identified by using the code and linking data sets. However, data separation will be maintained, as the REDCap and paper responses will be stored separately to the linking dataset.

**7. OUTCOMES**

*7.1 Demographics*

Demographic participant information will be collected. The demographic and outcome data is collected as part of routine clinical practice for submission to the Australian and New Zealand Intensive Care Society Centre for Outcome and Resource Evaluation (ANZICS CORE) Adult Patient Database (APD) Registry using the CORE Outcome Measurement and Evaluation Tool (COMET) database. Data for this study will be collected from the existing ANZICS COMET APD Database as per the CRF.

*7.2 Surveys*

Survey fatigue is a consideration and for this reason the aforementioned outcomes are listed in order of their priority with the most desired data listed first, should participants be unable to complete all surveys.

*7.2.1 World health Organisation Disability Assessment Schedule (WHODAS 2.0)*

The WHO DAS 2.0 [19] is an assessment of health and disability, its framework is set out in the WHO’s International Classification of Function [18]. It assesses function across 6 domains, cognition, mobility, self-care, getting along, life activities and participation.

*7.2.2 The European Quality of Life Assessment 5 Domains (EQ-5D)*   
The EQ-5D is a standardised instrument to measure health related quality of life over 5 domains:- mobility, self-care, usual activities, pain and discomfort, and anxiety and depression. It also includes a visual analogue score (VAS) self-rating an individual’s health.

*7.2.3 Hospital Anxiety and Depression Score (HADS)*

The HADS [37] consist of 14 statements relating to anxiety and depression, with each statement score 0-3 it gives a maximum total score of 21. A score of >8 in either domain or a total score >16 identifies individuals with anxiety and depression.

*7.2.4 PTSD symptoms; Impact of Events Scale Revised (IES-R)*

PTSD symptoms will be recorded using the Impact of Events Scale Revised (IES-R). This is a 22 item self-report questionnaire with 3 sub-scales of intrusion, avoidance and hyperarousal. Each item has 5 response levels (0-4) which are summed to produce the total score [38].

*7..2.5 Activities of Daily living; Combined activities of Daily living Scale*  
We will record a combination of Katz Activities of Daily Living [39] and Lawton’s Instrumental activities of daily living [40] (see combined Activities of Daily Living and Instrumental activities of daily living).

*7.3 Smartphone App Outcomes*

7.3.1 Step outcomes

7.3.1.1 – Daily step count – The sum of number of steps taken per day.

7.3.1.2 – Distance walked – The sum of the daily distance walked.

7.3.1.3 – Average walking speed – The average daily walking speed.

7.3.1.4 – Time spent inactive – The sum of the time spent not walking per day

7.3.2 GPS outcomes

7.3.2.1 – Time spent at home – Calculated by finding the location where the 7 longest period of inactivity took place over the last 7 days. This data is run through a clustering algorithm, the modal cluster (cluster with most points) is used to define the home nodal point, by averaging the latitude and longitude of the points in the modal cluster. The amount of time spent within 100m of this nodal point is calculated per 24 hr period and expressed as a percentage of total time in 24 hrs.

7.3.2.2 – Number of locations visited – The Spatial-Temporal Density-Based Spatial Clustering of Applications with Noise (ST-DBSCAN) [41], allows for clusters to be defined as the number of sequential GPS positions, within a pre-specified distance from the last point. We defined this a 3-points (15 minutes) with 100 m of the last point. The number of clusters or locations visited per 24 hours was recorded.

7.3.2.3 – Linear distance travelled – The distance between each GPS point was measured and summed over a 24-hour period. In addition, to overcome the coastline paradox, where by the distance travelled increases with shortening GPS epoch, the distance between locations visited will also be calculated.

7.3.2.4 – Minimum Convex Polygon Activity Space – A minimum convex polygon activity space is the area of a polygon that bounds the GPS locations, such that no internal angle of the polygon is greater than 180o.

7.3.2.5 – Standard Deviation Ellipse Activity Space – A standard deviation ellipse is the area of an ellipse plotted from the mean longitude and latitude where the short access is formed by minimum standard deviation in longitude and latitude and the long axis is calculated by the maximum standard deviation in longitude and latitude.

*7.4Data completeness*

7.8.1 – The number of individuals who successfully download and activate the app will be taken as the number of unique study IDs with successful data upload.

– We will also report the total number of days of step and GPS data provided over a 12-month period. A day will be counted as complete if there is greater than 8 hours of data.

*7.5 Participant satisfaction*

Participant satisfaction with smartphone follow-up will be assessed using the satisfaction survey.

8. ETHICAL CONSIDERATIONS

The study will be performed according to National Health and Medical Research Council (NHMRC) Guidelines for research published in the National Statement on Ethical Conduct in Human Research (2007, updated 2018).

*Screening:*

We are requesting a waiver of consent to access electronic medical records (EPAS/ Sunrise) to determine eligibility and obtain contact information for eligible potential participants (cross referenced with the Births, Deaths and Marriages death registry). The Investigators are proposing that a waiver of consent for screening is the most applicable process for screening and eligibility assessment.

It is not always feasible or appropriate to discuss screening with potential participants or their families/ person responsible to obtain consent to access registry data. Due to the potential distress that consent processes may cause to a patient and/ or their family/ person responsible it is imperative to establish eligibility and suitability prior to burdening families with complex information. The screening process is a low risk/ negligible risk process part of research. The NHMRC National Statement section 2.3.10 (a-f & i) addresses the issues pertaining to a waiver of consent process. The ICU Consultants and the Study Investigators believe that screening for research studies and audits complies with these issues and are requesting approval for a waiver of consent for this study.

2.3.10a Involvement in the research carries no more than low risk to participants: Screening only involves accessing EPAS/ Sunrise ICU “midnight census reports” to determine eligibility for inclusion in approved research studies and with appropriate measures in place to preserve privacy and confidentiality, is a negligible risk procedure. As such, care of participants medical condition is unaffected by this.

2.3.10b The benefits from the research justify any risks of harm associated with not seeking consent: There is no anticipated harm from completing screening/ eligibility assessment. Although there may not be a direct benefit to the participant research has the potential to benefit health care by providing additional information regarding an existing or new treatment.

2.3.10c It is impracticable to obtain consent: Due to the significant number of admissions to the ICUs it is not feasible for the clinical team to obtain consent for screening/ eligibility assessment from all critically ill patients or their relatives for clinical research studies. The ICU Consultants believe it would be both inappropriate and impracticable to obtain consent for the purposes of screening. Further, many ICU patients have impaired ability to consent (due to medical condition, or consciousness), and a decision maker may not be available.

2.3.10d There is no known or likely reason for thinking that participants would not have consented if they had been asked: The ICU Consultants have no reason to believe that ICU patients would not have consented to research screening activities if asked. Accessing electronic medical records (EPAS/ Sunrise) cross referenced with the Births, Deaths and Marriages death registry to determine eligibility prior to approaching patients to participate will ensure that patients are not unnecessarily approached for studies for which they are ineligible.

2.3.10 e & f Privacy and Confidentiality: At all times ICU Patients’ privacy and confidentiality will be respected an upheld. ICU Research staff are employed by CALHN and as such comply with the organisational requirements; SA Health job and person specifications acknowledge:

“SA Health employees will not access or attempt to access official information, including confidential patient information other than in connection with the performance by them of their duties and/or as authorised. SA Health employees will not misuse information gained in their official capacity. SA Health employees will maintain the integrity and security of official or confidential information for which they are responsible. Employees will also ensure that the privacy of individuals is maintained and will only release or disclose information in accordance with relevant legislation, industrial instruments, policy, or lawful and reasonable direction.” Screening information is important to later analyse generalisability of findings and describe the population; CALHN screening logs will not contain any patient identifiers and will be housed along with the study document files for the required duration for the study.

2.3.10i The waiver is not prohibited by State, federal, or international law: A waiver of consent is not prohibited in South Australia.

*Enrolment:*

All potential participants will be provided with an information sheet, and will have provided informed consent to take part. There are no known risks or discomforts involved in participating in the study. However, participating in this study may make the participant more aware of their emotional state and the difficulties that they are currently facing. If they need any support to cope with this, we would strongly encourage them to discuss this with their GP as soon as possible. Their GP may be able to provide them with some support and may also be able to discuss with them the alternatives for helping to improve their mood. If the participants are unable to talk with their GP then the following services will be advised:

* Assessment and Crisis Intervention Services (ACIS) is a free 24-hour mental health crisis intervention service. ACIS staff members will be able to assist them over the phone and may even be able to send a staff member to their home to talk with them personally. ACIS can be reached on 13 14 65 (metropolitan area) or 1800 182 232 (country callers) and is available for emergency situations only.
* Lifeline is a free 24-hour counseling service that provides telephone support to people in need. Lifeline counselors may also be able to provide them with contact information for community resources in their area. Lifeline can be reached on 13 11 14.
* Community Health Centers offer a free counseling service to residents in their local area. The waiting list for this service depends upon the demand in each area. They can find contact details for their local center under “SA Health” in the business listings of the White Pages.

If the participants are currently receiving psychological support, they would be strongly advised to discuss any concerns with their treating practitioner.

We appreciate there will be a time commitment with taking part in the study, however this is clearly explained in the PICF, and as such no honorarium will be offered. The smartphone app uploads data primarily using Wi-Fi (it will resort to using mobile data if no Wi-Fi signal has been found for 24 hours).. The data upload packages are very small (approximately one megatbyte per day) and will not impact on data usage from a Wi-Fi package. In the event that there is no identifiable Wi-Fi, and mobile data is utilised, the small data packets are unlikely to impact on most data plans, although, potential costs will depend on the individual data plans, patients will have provided informed consent to this.

**9. SPECIFIC SAFETY CONSIDERATIONS** (e.g. Radiation, toxicity)

N/A

**10. DRUGS/ DEVICES**

N/A

**11. ANALYSIS AND REPORTING OF RESULTS**

These data will be collected by the study investigators, the data will be digitalised into a secure database. The data will be kept on a secure SA health network drive and used to drive future quality improvement projects. Only the investigators and staff of the RAH ICU research will have access to the records. These data will be owned by the director of RAH ICU Research. Summative data will be presented a n (%), mean (SD) or median [IQR] depending on normality. Between group comparisons will be calculated with student t-tests or fisher exact test as appropriate.

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**13. OTHER RELEVANT INFORMATION**

N/A

**14. OTHER ETHICS COMMITTEES TO WHICH THE PROTOCOL HAS BEEN**

**SUBMITTED**

N/A

**15. DATE OF PROPOSED COMMENCEMENT.**

1st July 2019

**16. DATE OF EXPECTED COMPLETION**

30th June 2020

**17. FINANCIAL AND INSURANCE ISSUES**

The investigators do not have any financial interest in the outcome of this project. At this time there is no funding attached to this project. The study will be conducted ‘in-kind’ by the Investigators.