COMMON RESEARCH PROTOCOL APPLICATION TO RESEARCH ETHICS COMMITTEE

### 1. TITLE

**The ICU Feedback Study**

### 2. INVESTIGATOR DETAILS AND QUALIFICATIONS

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

3.1 Objective:

Our primary objective is to test the feasibility of using a multimodal platform (online and paper based) compared to a sole paper based platform that allows patients to provide feedback about their care and to elicit their outcomes.

In this randomised cohort study, we plan to contact groups of patients at three different time points (3, 6 and 12 months) following ICU discharge. We will randomise patients into two groups, one group will be asked to complete a 30 minute online questionnaire with non-responders being provided with a paper questionnaire while the other group will be provided with the same questionnaire but only in paper form.

We hope to assess the overall response rate, the response rate in relation to the time period following ICU discharge and the effect of questionnaire modality on response rate.

3.2.1 Aims:

*Primary:*

To report the difference in response rates of the addition of an online component in a multimodal platform against a paper only platform.

*Secondary:*

1. To assess the difference on response rate caused by the time period following ICU discharge
2. To perform an approximate cost analysis for each group.

**4. BACKGROUND AND PRELIMINARY STUDIES**

4.1 Post Intensive Care Syndrome

Post intensive care syndrome (PICS) is increasingly recognised in survivors of intensive care [[1](#_ENREF_1)]. It is used to describe the new or worsening impairments in physical, cognitive or mental health following an ICU admission. Dale Needham’s group has done a lot of work in determining the best tools to assess outcomes in survivors of Adult Respiratory Distress Syndrome (ARDS) [[2](#_ENREF_2), [3](#_ENREF_3)]. They have determined that the minimum question set would involve 42 questions and take 12 minutes to complete while the maximum question set would involve 91 questions and take 26 minutes to complete [[3](#_ENREF_3)].

4.2 Response rate to online questionnaires

The use of­­ online questionnaires has been assessed in several populations. In patients following knee surgery the response rate was higher for an online versus a paper questionnaire at 1, 2, and 5 years post-surgery [[4](#_ENREF_4)]. Follow up for hip replacement patients from the Swedish hip arthroplasty register showed that paper questionnaires had higher response rates than online alone and that the online response rate correlated with a younger patient age. Despite this finding it was still concluded that an online platform was likely to be beneficial by virtue of providing more complete data collection and a reduction in manual handling of paperwork [[5](#_ENREF_5)].

In patients undergoing investigation and treatment for breast cancer [[6](#_ENREF_6)], there was no difference in response rates between those given a multimodal questionnaire (online questionnaire followed by a paper questionnaire) compared to a paper only questionnaire. It was more cost effective to use an online approach, however online responders were again found to be younger and also had more years of education. A follow up of colorectal cancer patients found that a multimodal versus paper only platform had the same response rates although the overall chosen response modality was 60% paper and 40% online [[7](#_ENREF_7)].

The implementation of the option of an online questionnaire increased response rates for EQ5D from 67% to 78.8% in patients with chronic rhinosinusitis [[8](#_ENREF_8)]. Although the use of an online platform is considerably cheaper there is potential for bias in the results as non-responders have been shown to be from non-traditional, immigrant and less educated families when investigating response rates of children with a mental health diagnosis [[9](#_ENREF_9)].

Although 45% of medical practitioners responded to an online questionnaire, and this response rate was lower than a paper based questionnaire [[10](#_ENREF_10)]­­­­, a systematic review demonstrated that General Practitioners’ response to paper questionnaires were higher than online or multimodal questionnaires [[11](#_ENREF_11)].

A 2015 Swiss Spinal Cord Injury Cohort Study showed that having an online platform improved response rates for patients with tetraplegia as they often would have aids for using an electronic device as well as negate the need for external mobility to return post a paper questionnaire [[12](#_ENREF_12)]. In a study of college students in USA it was found that a sequential multimodal platform worked best for increasing response rates (online first followed by option of paper questionnaire) as opposed to being allocated to either modality alone or the choice of either modality being provided initially to the respondent [[13](#_ENREF_13)].

4.3 Cost effectiveness

A Danish children health and welfare survey demonstrated very similar response rates across paper, online or multimodal platforms with a cost effectiveness benefit in the online implementation [[14](#_ENREF_14)]. A 2010 survey of recent post-partum patients showed that despite a lower response rate with multimodal platform vs paper only platform the cost was significantly less in the multimodal platform making it the better choice for large scale surveys [[15](#_ENREF_15)].

A 2012 study from a multidisciplinary primary care clinic in Sydney found that overall response rates to online only or paper only questionnaires were no different but the online platform had economic advantage by costing approximately only 5% of the paper platform [[16](#_ENREF_16)]. On the contrary results from a community based survey regarding greywater usage on an unselected population in Melbourne found that a paper only platform was more cost effective [[17](#_ENREF_17)].

4.4 Application

The current methodology is to call all patients to provide responses requiring a time that is convenient to both the patient and the researcher as well as the necessary researcher manpower. Researcher time is costly and due to the constraints of work hours finding a mutually convenient time may limit the number of patients who can be successfully followed-up.

With the ability to contact a bigger patient cohort by online or by multimodal platform, even with relatively lower response rates it may still increase the total number of respondents. If the online questionnaire either in isolation or in a multimodal platform is shown to be feasible then an automated process would reduce the costs associated with this intervention. In addition, being able to engage with patients about outcomes and experiences is an important facet of healthcare to be able to drive quality improvement.

### 5. PARTICIPANTS

We aim to enrol approximately 300 patients, 100 each at 3, 6 and 12 months following ICU discharge. Anticipating a 50% non-response/non-consent rate we will retrospectively approach 200 patients at each time period who were in ICU for >48 hours, were discharged home and are still alive. The sample is a convenience sample based on existing data.

Individuals will be eligible if;

* Aged > 18 years
* Were discharged home from hospital.
* ICU length of stay > 48 hours.

Exclusion criteria will be:

* Refusal of consent
* Readmitted to ICU
* Remain in hospital
* Death during ICU or following ICU discharge

### 6. STUDY PLAN AND DESIGN

6.1.1 Protocol

Using the existing Australia and New Zealand Intensive Care Societies AORTIC/COMET (ANZICS APD) and Birth Death Marriages (BDM) databases we plan to retrospectively identify patients who survived ICU and meet inclusion and exclusion criteria over the prior 12 months. All patients will be written to introducing ICU research and informing them of the study (see letter of introduction and PICF) 6-weeks prior to their required involvement, asking for consent to contact them further. Patients will be told that they are being asked to provide responses to questionnaires about their outcomes and experience of surviving ICU.

They will be asked to provide contact details (email and phone). They will not be told they are being randomised to receive a paper or multimodal questionnaire, so as to improve blinding. They will be told that the maximal time commitment is 30 minutes and that this will be at a time convenient to them.

Participants will be provided with a pre-paid envelope to allow the return of their consent form and contact details. Patients who don’t respond to the consent letter will be called after 11 days to explain the study and if needed a consent form re-mailed or emailed (Appendix A).

Patients who consent will be randomised using a random number generator in excel to either the multimodal group or the paper only group.

Once randomised, patients will be written to at least 14-days before their 3, 6 or 12-month ICU discharge time point. No patient will provide responses at two different time points.

Patients in the multimodal group will be sent an email (if an email address was provided at consent) or letter that contains a web address ([www.icufeedback.com](http://www.SAICA.com/feedback)) (Appendix B) 14 days prior to their 3, 6 or 12-month time point.

The initial email/letter will provide a unique three-word code made from a combination of the 1000 most used words in the English language. They will input the three-word code into the web page to act as a unique identifier. They will then proceed to answer the questionnaire.

For patients who have provided an email address and if no response has been received, a further email will be sent after 3 days, up to a total of 3 repeat requests (Appendix A). If no response has been obtained after a further 5 days (14 days post initial email) a letter with a paper questionnaire (Appendices C - H) will be sent with a pre-paid envelope for its return.

Patients who don’t provide an email address will be mailed a letter with a web address in order to complete the survey. If no response is obtained after 14 days they will be sent a letter with a paper based questionnaire. We will call all non-responders after a further 7 days. A final open disclosure and thank you letter will be sent 7 days after that (appendix I).

Open Disclosure letter

Consent

letter

No consent

Phone call

Initial Email OR letter with web address

Reminder emails x 3

Letter with questionnaire

T-21 days

T -10 days

T 0

T +3 to +9 days

T +14 days

T + 28 days

T +21 days

Phone call reminder

Figure 1 - Protocol for multimodal group

Patients randomised to the paper only group will be sent a letter (Appendix B) with the questionnaire (Appendices C – H). This will be followed by a repeat questionnaire at 14 days if no response is received. If still no response is received, a phone call will be made to enquire if they have received either letter (Appendix A). A final open disclosure and thank you letter will be send 7 days after that (Appendix I).

Open Disclosure letter

Consent

letter

No consent

Phone call

Initial Letter with questionnaire

Repeat letter with questionnaire

T-21 days

T -10 days

T 0

T +14 days

T + 28 days

T +21 days

Phone call reminder

Figure 2 - Protocol for control group

Phone calls will only be attempted once during office hours and once out of office hours. If a reason for non-compliance is identified during any phone call all measures, short of completing the questionnaire on behalf of the respondent, will be taken.

6.2 Confidentiality, data storage and security

6.2.1 Paper records

All returned consent forms, contact details, and preferences will be stored securely in a locked filing cabinet in ICU research. The contact details and preferences will also be transferred to an electronic database; this will be stored in accordance with digital records below.

6.2.2 Digital Records

We will use existing databases to identify patients. This data will be copied into a screening database to enable the creation of letters to contact participants. A field will be created to identify patients who consent, refuse consent or don’t respond. Patients who consent, and are randomised to the multimodal arm will have their contact details and contact preferences entered into a separate database. Consented patients will then be associated with a unique study code and unique three-word code for online questionnaire identification.

The responses provided to the questionnaire will be held in a secure cloud database (Redcap) during the study and exported to an excel file on study completion at which point in time the cloud database (Redcap) will be deleted. All offline electronic data will be stored on a secure SA health network drive only accessible by members of ICU research for 7 years before being destroyed by the nursing director of ICU research.

6.2.3 Confidentiality

All patients 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 de-identified 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 Response rate

The response rate will be counted as the number of patients who enter their three-word code online, or complete and return their allotted questionnaires.

7.2 Contact preferences and demographic details

Patients will be asked about their contact preferences and demographic details as per the questionnaire in Appendix C.

7.3 Outcome questionnaires

7.3.1 EQ-5D

The EQ-5D it is a multi-attribute instrument which has been frequently used in ICU follow-up studies [[20](#_ENREF_20)]. It is a descriptive system of five domains: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression along with a visual analogue score (VAS) of overall health on the given day (Appendix D).

7.3.2 Hospital Anxiety and Depression Score (HADS)

The HADS is a validated scale to detect features of depression and anxiety in the out-patient setting [[21](#_ENREF_21)]. It has been used extensively in the study of the critically ill (Appendix E).

7.2.3Impact of Events Scale Revised (IES-R)

The IES-R is a brief and easy-to-administer self-rating scale that measures traumatic stress responses related to PTSD after a variety of traumatic events [[22](#_ENREF_22)] (Appendix F).

7.2.4 Patient experience

Patient experience will be assessed using just the open questions at the end of the ICE questionnaire [[23](#_ENREF_23)] (Appendix G).

7.5 Patient satisfaction

Patient satisfaction will be assessed by the final questions by asking the patient to score their satisfaction with completion of the questionnaire they completed (Appendix H).

### 8. ETHICAL CONSIDERATIONS

The study will be performed according to NHMRC guidelines. While all the techniques are harmless and non-invasive, we appreciate potential concerns about accessing health related information. Data uploaded to the cloud database will be associated with a unique ID, and re-identifiable using a dataset held separately.

All patients will be provided with an information sheet and will provide written consent prior to the commencement of the study (PICF). There are negligible risks 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 will 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.
* A searchable National Health Services Directory is available on the SA Health website. Mental Health services can be found in any specific location using the search function: [https://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/health+services/national+health+services+directory](https://www.sahealth.sa.gov.au/wps/wcm/connect/public%2Bcontent/sa%2Bhealth%2Binternet/health%2Bservices/national%2Bhealth%2Bservices%2Bdirectory)

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

We have a well-established process for the vital status follow-ups. The staff will make every effort possible to establish the vital status of the patient prior to any patient or family contact. For example, the Royal Adelaide Hospital Intensive Care Research Units current practice is prior to attempting to contact patients the state-wide health database “OACIS” for admission and mortality status; the ANZIO hospital database; and the “Death List information from the SA Health” (information provided by Births, Deaths and Marriages), “Applications Management web site” are checked for mortality status.

There will be limited disclosure to participants; they will not be told that the main aim of the study is to assess response rates to different modalities of feedback. In reference to the National Statement on Ethical Conduct in Human Research (Updated 2018) Section 2.3.1:

* Fuller disclosure would not be possible as this may bias patients’ response rates and their choice of response modality.
* The limited disclosure poses no risk or harm to the participating patients.
* The benefit of this study is to elicit if online feedback is a feasible and cost effective method for following up ICU patients hence allowing us to capture a larger patient cohort in further follow up studies.
* If the patients had full disclosure on onset, it would not change their consent to participation as we are only looking at the method of providing feedback.
* There will be a follow up letter or email at the end of the study to inform the patients of the limited disclosure and the reason for the pre-existing need for it during the study. Participants will also be offered the choice of withdrawing from the study in this final communication.

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, coded, and then stored in the secure area of the RAH ICU Research Department. Only the investigators and staff of the RAH ICU Research Department will have access to the records. These data will be owned by Prof Chapman and the Royal Adelaide Hospital Intensive Care Research Unit. All authors will collaborate to publish these data in a peer-reviewed international journal.

### 12. REFERENCES

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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 October 2018

### 16. DATE OF EXPECTED COMPLETION

1st February 2019

### 17. RESOURCE CONSIDERATIONS

All costs will be covered through existing cost centres held by Dr Chapman. Patients will not be reimbursed as we do not feel they will suffer any ill consequence or financial hardship due to recruitment. We feel a maximal time commitment of 30 minutes is not onerous, and patients will have given written informed consent to this.

### 18. FINANCIAL AND INSURANCE ISSUES

The investigators do not have any financial interest in the outcome of this research project. Study indemnity will be sought from SA Health through insurance services, corporate governance and policy office following HREC approval.

### 19. SIGNATURES OF INVESTIGATORS

See LNR application form

**Appendix A – Follow-up email and phone call scripts**

**Phone call script for failure to return consent form.**

Hi this is [researcher name]. I am calling from the Royal Adelaide Hospital ICU research. Am I speaking to [first\_name] [Surname]? We wrote to you recently about a study we are conducting that investigates patients’ outcomes following intensive care. Have you had a chance to read the patient information sheet?

Yes (go to 1)

No (go to 3)

1. Have you got any questions? Have you thought about if you would be happy to take part?

No – Thank you for your time. We wish you the best with your recovery.

 Yes – (go to 2)

1. Thank you. Do you still have the consent form?

 Yes - Can we please ask that you complete the consent form and send it back.

No - Can we email or mail you another form, and can we ask that you fill it in as soon as possible.

1. Do you have 5 minutes for me to explain the study to you?

 Yes – (Go to 4)

 No – Is there a more convenient time for me to call?

1. Thank you. We are investigating how patients recover following intensive care and we would like to ask you to complete a questionnaire to assess this. We will send you this questionnaire over the next few weeks. The questionnaire will take less than 30 minutes to complete. While we appreciate that this study won’t help you we hope that it will benefit others. You are free to take part voluntarily, and you can change your mind about taking part at any time. Your answers will remain confidential, and while we hope to publish the results of our study you won’t be identified. Do you have any questions? Are you happy to take part?

 Yes – (go to 2)

 No – Thank you for your time. We wish you the best with your recovery.

**Follow-up email to patients in multimodal arm for failure to return survey.**

Dear [first\_name] [surname],

We recently emailed you asking you to respond to a survey, unfortunately we are yet to receive a response.

We would ask that you complete the questionnaire by going to [www.icufeedback.com](file:///%5C%5Cdhgsf05%5Cusers%24%5Chwong08%5CDownloads%5Cwww.icufeedback.com). The website will ask you to put in a three-word code, it is important that you enter these words in order.

Word 1 – [word 1]

Word 2 – [word 2]

Word 3 – [word 3]

Many thanks,



Dr Hao Wong

**Phone call script for failure to return survey.**

Hi this is [researcher name]. I am calling from the Royal Adelaide Hospital ICU research. Am I speaking to [first\_name] [Surname]? We wrote to you 1 and 3 weeks ago asking you to complete a questionnaire as part of the study you consented to take part in did you receive these surveys? Was there a reason you have not been able to complete them?

Many thanks for taking part in the study.

**Appendix B – Letter to consenting participants**

1. **Letter to patient randomised to multimodal**

**INTENSIVE CARE UNIT**

 **ROYAL ADELAIDE HOSPITAL**

Dr Hao Wong

Intensive Care Unit Research Department

4G 751

Royal Adelaide Hospital

Port Rd

SA 5000

[Letter date]

**R.e. – ICU Feedback Study**

Dear [First\_Name] [Surname],

Firstly, thank you for agreeing to take part in our study, we are incredibly grateful.

We would ask that you complete a questionnaire by going to [www.icufeedback.com](http://www.icufeedback.com). The website will ask you to put in a three-word code, it is important that you enter these words in order.

Word 1 – [word 1]

Word 2 – [word 2]

Word 3 – [word 3]

Once you have entered the three-word code you will able to proceed with the questionnaire.

If we have not received your response by [letter date plus 21 days] we will call you to remind you.

Thank you again for helping us with this study, the information you provide will be incredibly useful.

Yours Sincerely,



Dr Hao Wong

1. **Email to consenting patients randomised to the multimodal arm**

Dear [First\_Name] [Surname],

Firstly, thank you for agreeing to take part in our study, we are incredibly grateful.

We would ask that you complete a questionnaire by going to [www.icufeedback.com](file:///%5C%5Cdhgsf05%5Cusers%24%5Chwong08%5CDownloads%5Cwww.icufeedback.com). The website will ask you to put in a three-word code, it is important that you enter these words in order.

Word 1 – [word 1]

Word 2 – [word 2]

Word 3 – [word 3]

Once you have entered the three-word code you will able to proceed with the questionnaire.

If we have not received your response by [letter date plus 21 days] we will call you to remind you.

Thank you again for helping us with this study, the information you provide will be incredibly useful.

Yours Sincerely,



Dr Hao Wong

1. **Letter to consenting patients randomised to the paper only arm**

**INTENSIVE CARE UNIT**

 **ROYAL ADELAIDE HOSPITAL**

Dr Hao Wong

Intensive Care Unit Research Department

4G 751

Royal Adelaide Hospital

Port Rd

SA 5000

[Letter date]

**R.E. – ICU Feedback Study**

Dear [First\_Name] [Surname],

Firstly, thank you for agreeing to take part in our study, we are incredibly grateful.

We would ask that you complete a questionnaire that is attached to this letter and return it in the pre-paid envelope provide.

If we have not received your response by [letter date plus 21 days] we will call you to remind you.

Thank you again for helping us with this study, the information you provide will be incredibly useful.

Yours Sincerely,

 

Dr Hao Wong

**Appendix C – Contact preferences and demographic details**

Do you own a smartphone? Yes  No 

Are you able to install an app on your phone? Yes  No 

Contact preferences, please indicate on the 5-point scale how capable you are with completing questionnaires in the following manner; 1 – Not able & 5 - Fully able

I would be happy to complete questionnaires on paper sent by the postal service

 1 2 3 4 5

 Not able Fully able

I would be happy to complete questionnaires online

 1 2 3 4 5

 Not able Fully able

I would be happy to complete questionnaires on a smartphone app

 1 2 3 4 5

 Not able Fully able

How many years did you spend in full time employment?

\_\_\_\_\_\_\_\_\_ Years

What is your ethnic origin

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Prefer not to say 

**Appendix D - EQ-5D**

Under each heading, please tick ONE box that best describes your health TODAY

**MOBILITY**

I have no problems in walking about 

I have slight problems in walking about 

I have moderate problems in walking about 

I have severe problems in walking about 

I am unable to walk about 

**SELF-CARE**

I have no problems washing or dressing myself 

I have slight problems washing or dressing myself 

I have moderate problems washing or dressing myself 

I have severe problems washing or dressing myself 

I am unable to wash or dress myself 

**USUAL ACTIVITIES** *(e.g. work, study, housework, family or leisure activities)*

I have no problems doing my usual activities 

I have slight problems doing my usual activities 

I have moderate problems doing my usual activities 

I have severe problems doing my usual activities 

I am unable to do my usual activities 

**PAIN / DISCOMFORT**

I have no pain or discomfort 

I have slight pain or discomfort 

I have moderate pain or discomfort 

I have severe pain or discomfort 

I have extreme pain or discomfort 

**ANXIETY / DEPRESSION**

I am not anxious or depressed 

I am slightly anxious or depressed 

I am moderately anxious or depressed 

I am severely anxious or depressed 

I am extremely anxious or depressed **



We would like to know how good or bad your health is TODAY.

This scale is numbered from 0 to 100.

100 means the best health you can imagine.

0 means the worst health you can imagine.

Mark an X on the scale to indicate how your health is TODAY.

Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY =

**Appendix E – Hospital Anxiety and Depression Scale (HADS)**

Tick the box beside the reply that is closest to how you have been feeling in the past week. Don’t take too long over you replies: your immediate is best.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **I feel tense or ‘wound up’:**  |  |  | **I feel as if I am slowed down:**  |  |
| Most of the time  | 3  |  | Nearly all of the time  | 3  |
| A lot of the time  | 2  |  | Very often  | 2  |
| Time to time, occasionally  | 1  |  | Sometimes  | 1  |
| Not at all  | 0  |  | Not at all  | 0  |
|  |  |  |  |  |
| **I still enjoy the things I used to enjoy:**  |  |   | **I get a sort of frightened feeling like ‘butterflies in the stomach’:**  |  |
| Definitely as much  | 0  |   | Not at all  | 0  |
| Not quite so much  | 1  |   | Occasionally  | 1  |
| Only a little  | 2  |   | Quite often  | 2  |
| Not at all  | 3  |   | Very often  | 3  |
|  |  |  |  |  |
| **I get a sort of frightened feeling like something awful is about to happen:**  |  |  | **I have lost interest in my appearance:**  |  |
| Very definitely and quite badly  | 3  |  | Definitely  | 3  |
| Yes, but not too badly  | 2  |  | I don’t take as much care as I should  | 2  |
| A little, but it doesn’t worry me  | 1  |  | I may not take quite as much care  | 1  |
| Not at all  | 0  |  | I take just as much care as ever  | 0  |
|  |  |  |  |  |
| **I can laugh and see the funny side of things:**  |  |   | **I feel restless as if I have to be on the move:**  |  |
| As much as I always could  | 0  |   | Very much indeed  | 3  |
| Not quite so much now  | 1  |   | Quite a lot  | 2  |
| Definitely not so much now  | 2  |   | Not very much  | 1  |
| Not at all  | 3  |   | Not at all  | 0  |
|  |  |  |  |  |
| **Worrying thoughts go through my mind:**  |  |  | **I look forward with enjoyment to things:**  |  |
| A great deal of the time  | 3  |  | A much as I ever did  | 0  |
| A lot of the time  | 2  |  | Rather less than I used to  | 1  |
| From time to time but not too often  | 1  |  | Definitely less than I used to  | 3  |
| Only occasionally  | 0  |  | Hardly at all  | 2  |
|  |  |  |  |  |
| **I feel cheerful:**  |  |   | **I get sudden feelings of panic:**  |  |
| Not at all  | 3  |   | Very often indeed  | 3  |
| Not often  | 2  |   | Quite often  | 2  |
| Sometimes  | 1  |   | Not very often  | 1  |
| Most of the time  | 0  |   | Not at all  | 0  |
|  |  |  |  |  |
| **I can sit at ease and feel relaxed:**  |  |  | **I can enjoy a good book or radio or TV programme:**  |  |
| Definitely  | 0  |  | Often  | 0  |
| Usually  | 1  |  | Sometimes  | 1  |
| Not often  | 2  |  | Not often  | 2  |
| Not at all  | 3  |  | Very seldom  | 3  |

**Appendix F - Impact of Events Scale Revised (IES-R)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Not at all** | **A little bit** | **Moderately** | **Quite a bit** | **Extremely** |
| Any reminder brought back feelings about it | 0 | 1 | 2 | 3 | 4 |
| I had trouble staying asleep | 0 | 1 | 2 | 3 | 4 |
| Other things kept making me think about it | 0 | 1 | 2 | 3 | 4 |
| I felt irritable and angry | 0 | 1 | 2 | 3 | 4 |
| I avoided letting myself get upset when I thought about it or was reminded of it | 0 | 1 | 2 | 3 | 4 |
| I thought about it when I didn’t mean to | 0 | 1 | 2 | 3 | 4 |
| I felt as if it hadn’t happened or wasn’t real | 0 | 1 | 2 | 3 | 4 |
| I stayed away from reminders about it | 0 | 1 | 2 | 3 | 4 |
| Pictures about it popped into my mind | 0 | 1 | 2 | 3 | 4 |
| I was jumpy and easily startled | 0 | 1 | 2 | 3 | 4 |
| I tried not to think about it | 0 | 1 | 2 | 3 | 4 |
| I was aware that I still had a lot of feelings about it, but I didn’t deal with them | 0 | 1 | 2 | 3 | 4 |
| My feelings about it were kind of numb | 0 | 1 | 2 | 3 | 4 |
| I found myself acting or feeling as though I was back at that time | 0 | 1 | 2 | 3 | 4 |
| I had trouble falling asleep | 0 | 1 | 2 | 3 | 4 |
| I had waves of strong feelings about it | 0 | 1 | 2 | 3 | 4 |
| I tried to remove it from my memory | 0 | 1 | 2 | 3 | 4 |
| I had trouble concentrating | 0 | 1 | 2 | 3 | 4 |
| Reminders of it caused me to have physical reactions, such as sweating, trouble breathing, nausea, or a pounding heart | 0 | 1 | 2 | 3 | 4 |
| I had dreams about it | 0 | 1 | 2 | 3 | 4 |
| I felt watchful or on-guard | 0 | 1 | 2 | 3 | 4 |
| I tried not to talk about it | 0 | 1 | 2 | 3 | 4 |

**Appendix G – ICU Patient experience open questions**

**What was best about your stay in intensive care?**

**What was worst about your stay in intensive care?**

**What could we improve about your time in ICU?**

**Appendix H – Patient satisfaction questionnaire**

**Rate your satisfaction with the contact method used during follow-up process (circle appropriate number)**

1 2 3 4 5 6 7 8 9 10

Not at all satisfied Ambivalent Totally satisfied

**Rate your satisfaction with the questions asked during the follow-up process (circle appropriate number)**

1 2 3 4 5 6 7 8 9 10

Not at all satisfied Ambivalent Totally satisfied

**Rate your overall satisfaction with the follow-up process (circle appropriate number)**

1 2 3 4 5 6 7 8 9 10

Not at all satisfied Ambivalent Totally satisfied

**Comments**

**Appendix I - End follow up letter for open disclosure**

 **INTENSIVE CARE UNIT**

 **ROYAL ADELAIDE HOSPITAL**

Dr Hao Wong

Intensive Care Unit Research Department

4G 751

Royal Adelaide Hospital

Port Rd

SA 5000

[Letter date]

**R.E. - Response rates and cost benefit of online first multimodal vs paper only feedback platform for ICU patients**

****Dear [First\_Name] [Surname],

Thank you for participating in our study. Your time and effort in contributing to this study is greatly appreciated and we look forward to learning a great deal from the responses that we have received from patients such as yourself.

I would also like to take this opportunity to explain that the study was primarily looking at the rate of response from patients depending on whether or not they were provided with a online or paper questionnaire. This was not made clear to yourself at the beginning as this may have changed your choice of which method you would have used to respond to us.

Depending on your study group, you would have been given the option of an online questionnaire or of a paper questionnaire only. We were trying to find out which method works best for patients to provide their feedback to us.

Once again, thank you for your consent and participation. This will be the last direct contact from us in regards to this study.

If you have any concerns, I will be happy to answer any questions by phone (0412 383 825) or email (hao.wong@sa.gov.au).

Kind regards,



Dr Hao Wong

**Introduction letter from Clinical Director**

 **INTENSIVE CARE UNIT**

 **ROYAL ADELAIDE HOSPITAL**

Dr Michael Anderson

Intensive Care Unit

Royal Adelaide Hospital

Port Rd

SA 5000

[Letter date]

****Dear [First\_Name] [Surname],

I am writing to you on behalf of the Royal Adelaide Hospital Intensive Care Unit consultant group. We occasionally contact patients such as yourself that have been discharge from our ICU to gather information on their wellbeing and to gather feedback on our service.

Dr Hao Wong is a Senior Registrar in our unit and is undertaking a study to gather outcomes post discharge from intensive care. I hope you can find the time to participate in this study so that we can learn from our past performance.

Sincerely,

Dr Michael Anderson

Clinical Director

Intensive Care Unit

Royal Adelaide Hospital

**Initial contact letter for consent of participation**

 **INTENSIVE CARE UNIT**

 **ROYAL ADELAIDE HOSPITAL**

Dr Hao Wong

Intensive Care Unit Research Department

4G 751

Royal Adelaide Hospital

Port Rd

SA 5000

[Letter date]

****Dear [First\_Name] [Surname],

We understand you were discharged from the Royal Adelaide Intensive Care Unit on [discharge date]. We are hoping you might be interested in helping us by taking part in a study.

We are hoping you would answer some questions relating to how you are recovering from critical illness and about your experience of being in ICU. This kind of information helps us to carry out studies and improve the services we offer.

If you were to take part in this study we would require a maximum of 30 minutes of your time (it may be less than this), completing questionnaires.

I have included an information sheet giving more details. Please read this and discuss it with a relative if you wish. We ask that you indicate if you are happy to take part or would prefer not to take part by completing the attached consent form. If you are happy to take part please provide the information requested and return it in the pre-paid envelope in the next few days. If we do not hear from you, we will call you after [date of letter plus 11].

I will be happy to answer any questions by phone (0412 383 825) or email (hao.wong@sa.gov.au).

I look forward to hearing from you.

Kind regards,



Dr Hao Wong

****

**INTENSIVE CARE UNIT**

 **ROYAL ADELAIDE HOSPITAL**

**PARTICIPANT INFORMATION SHEET**

**Project Title:** **The ICU Feedback Study**

**Principal Investigator: Dr Hao Wong**

**Intensive Care Unit, Royal Adelaide Hospital**

**Your participation is voluntary**

You are invited to take part in a clinical research study. Before agreeing to participate, it is important that you read and understand this information sheet. It describes the purpose, procedures, benefits and risks of the study. Please ask the investigators to explain any part of this form that you do not understand. It is a good idea to discuss your decision to participate in this study with a family member or friend.

You can stop participating at any point during the study period. You can also ask for all your data to be withdrawn from the study at any point.

**Introduction**

This information sheet is to inform you about a study that we are currently performing in patients who have survived critical illness. We are assessing how patients have recovered following critical illness at different time points.

**What is the purpose of this research?**

Many research studies currently utilise the questionnaires we are asking, however it is often difficult to contact patients or clarify the responses they give. If we can ask the questionnaires through different methods, or at different times after discharge it may affect the responses given. Allowing patients the opportunity to respond is important in research but is also important for us to gather data to improve our service. This has the potential to reduce the costs of research and quality improvement and allow more patients to express their views.

**What will you have to do?**

If you consent to participate in this study, we will ask some questions about your contact details and some demographics. You will then be contacted to complete a questionnaire. The maximal time commitment required will be 30 minutes.

**What will be done with the information?**

We intend to publish the study findings in a medical journal – you will not be identified.

**What problems might occur during or after the study?**

Nothing we are proposing will pose any danger to your long-term health. However, answering these questions may make you more aware of your emotional and physical situation. We would ask that you discuss these issues with your General Practitioner or you can call ICU research on 0412 383 825

**What happens if something goes wrong?**

In the event that something does go wrong please contact ICU Research (0412 383 825). They will be able to assess and assist in any care that you require. If this does occur, we will consult with you regarding your ongoing participation in the study. Any treatment required to manage such an event would be provided through the public healthcare system.

**Is there anything to gain from participating?**

This study will not benefit you. We hope that these results will be able to be used to inform future research and quality improvement activities. We would be ever so grateful for your participation in the study.

**Confidentiality**

Your participation in this study is strictly confidential and will not be disclosed to other medical or research staff unless you agree to it, or if disclosure is required by law.

The data from the questionnaire is collected anonymously and is held on a secure, encrypted server.

Any information that is published will not reveal your identity.

**Who should I contact for further information?**

Should you have any questions or concerns before, during or after the study, please contact Dr. Hao Wong on or hao.wong@sa.gov.au or 0412 383 825.

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 Chairperson of the Central Adelaide Local Health Network Human Research Ethics Committee, Royal Adelaide Hospital on 08 7117 2229 during office hours.

**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) and has been approved by the Central Adelaide Local Health Network Human Research Ethics Committee of the Royal Adelaide Hospital.

**INTENSIVE CARE UNIT**

**ROYAL ADELAIDE HOSPITAL**

**PARTICIPANT CONSENT FORM**

**PROTOCOL NAME**: **ICU Feedback Study**

**Principal Investigator: Dr Hao Wong**

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

1. The nature and purpose of the study has been explained to me. I understand it and agree to take part.
2. I understand that I will not directly benefit from taking part in the project.
3. I understand that, while information gained during the study may be published, I will not be identified and my personal results will remain confidential.
4. 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.
5. I have had the opportunity to discuss taking part in this study with a family member or friend.

Please tick the appropriate box

 I am happy to take part (complete the signature panel and initial questionnaire)

 I am NOT happy to take part. Reason\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**(by providing a reason you consent to us using this information to try to improve consent rates in future studies - please return in pre-paid envelope)**

Name of participant: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signed: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Dated: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Please complete the questions on the next page

**PROTOCOL NAME:** **ICU Feedback Study**

[study ID]

**Contact details**

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

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

Access to email Yes  No  Email address\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_