Appendix 1

PATIENT INFORMATION SHEET

Psychological stRess in Intensive CarE survivors (PRICE study)

Invitation

You are invited to participate in a research study being conducted by the _____ Intensive Care Unit (ICU) looking at the incidence of psychological symptoms in patients who have been admitted to the ICU. We will also study the incidence of psychological symptoms in families of intensive care patients.

Critically ill patients requiring support in ICU may take a minimum of 6-12 months to physically get back to what is normal for them. In addition, recent literature suggests that some patients who survive intensive care unit are likely to have some psychological symptoms. Although this may relate to the critical nature of the illness itself, but also to some of the treatment necessitating recovery, e.g. sedation, breathing machines (ventilators), etc.

1. What is the purpose of this study?

To screen ICU patients for psychological symptoms after their discharge from ICU. This study will follow up intensive care patients up to 12 months post discharge from ICU. This knowledge will assist in deepening understanding of the long term impact of ICU thus facilitating strategies, prevention and treatment of these psychological symptoms.

2. Who is conducting this study?

The research team at the Intensive Care Unit of the _____Hospital is conducting the study.

3. Why have I been invited to participate in this study?

As a critically ill patient who was admitted to the intensive care unit for organ support, you are eligible to participate in the study.

4. What if I don't want to take part in this study or if I want to withdraw later?

Participation in this study is voluntary and your decision will not affect the medical management. If you wish to withdraw from the study you can do so at any time without justifying your decision. If you do withdraw from the study, all of the data already collected about you as part of the study will be destroyed and no data or information collected will be used in anyway by the researchers or sent outside this

institution. No additional information will be collected for the purposes of this study and you will not be contacted again.

5. What does this study involve?

Participation in this study involves allowing the study investigators to access your medical records and to be involved in 3 short surveys after your discharge from ICU. An initial survey will be done in hospital after ICU discharge. One of the research investigators will meet you while you are still in hospital. A follow up survey will be done at 3 and 12 months after discharge. This will be in the form of either a postal or a telephonic interview answering a short series of questions. This will assist us to determine if there have been any changes during that time.

We will be using a set of screening tools (questionnaire) called Post Traumatic Stress Scale (PTSS-14); Impact of Events Scale-Revised (IES-R); Depression Anxiety Stress Scales (DASS 21). These tools measure some of the symptoms you may be experiencing as a result of being through a traumatic event of being admitted to intensive care. In addition, we would be assessing the impact of hospitalisation on your quality of life using a validated tool called EQ-5D

6. Will my taking part in this study be kept confidential?

You have the right to privacy and all information that is collected during this study is confidential to the extent permitted by the applicable laws and regulations. Your study data will be made anonymous by the assignment of a unique number to you alone. All data collected from you will then be identified by this number. No data which could be used to identify you will be transferred from your medical notes.

The medical information collected during this study will then be transferred into study database(s) and processed to allow the results of this study to be analysed and reported or published for scientific purposes. Paper records including contact information will be stored in locked rooms accessible only to authorized study personnel. Electronic information will be kept on password-protected computers accessible only to authorized study personnel.

Your identity will be kept confidential at all times. Your personal information will only be disclosed with your permission, except as required by law.

7. Are there risks to me in taking part in this study?

No questions will be asked of you about any specific instances or memories of your time in the ICU. However, it is possible that you may experience some discomfort or distress as you may recollect some unpleasant memories from your stay in intensive care. Participation in the study will ensure that distress can be potentially diagnosed and appropriate referral made. In the unlikely event that you do feel distressed by any of the questions, we would encourage you to discuss any concerns with the study coordinator or your General Practitioner.

8. Will I benefit from the study?

This study aims to look at the psychological impact of ICU stay and gain further medical knowledge. This study may help to improve treatment for others with similar conditions, and the results of the study will be published in a major international medical journal. You may not receive any direct benefits from this research.

9. Will taking part in this study cost me anything, and will I be paid?

Participation in this research study will not cost you anything. You will not be paid or receive any financial benefits from taking part in this research study.

10. What happens with the results?

The results obtained will be collated and published in medical journals, conference presentations and other professional forums. In any publication, information will be provided in such a way that you cannot be identified. Results of the study will be provided to you, if you wish.

11. What should I do if I want to discuss this study further before I decide?

When you have read this information, the study investigator will discuss it with you and clarify any queries you may have. If you would like to know more at any stage, please do not hesitate to contact _____ on _____, or study coordinator _____ on _____.

12. Who can I contact if I have any questions or problems?

For questions about the study you can contact the principal investigator, Dr _____ on _____or email _____. You may also contact the site research coordinator, _____ on _____ or email at _____

If you find that any of the research questions are distressing to you, please do not continue with the study. There are services to help you. Please talk to your GP, or contact one of the services below:

- Lifeline (24 Hours): 13 11 14 - www.lifeline.org.au
- ACT Health (Crisis Team): 1800 629 354 or (02) 6205 1065
- NSW Mental Health Line: 1800 011 511
- Beyond blue (24 Hours): 1300 224 636 - www.beyondblue.org.au
- SANE (9:00am - 5:00pm): 1800 187 263 - www.sane.org
- Suicide Callback Service (24 Hours): 1300 659 467 - www.suicidecallbackservice.org.au

13. Who should I contact if I have concerns about the conduct of this study?

This study has been approved by _____ Health Human Research and Ethics Committee. Any concerns or complaints about the conduct of this study can be directed to the _____ Health Directorate Human Research Ethics Committee Secretariat, on _____ or via email _____

Thank you for taking the time to consider this study.
If you wish to continue to take part in it, please sign the attached consent form.
This information sheet is for you to keep.

Appendix 2

FAMILY MEMBER/NEXT OF KIN INFORMATION SHEET

Psychological StRess in Intensive CarE Survivors (PRICE study)

Invitation

You are invited to participate in a research study being conducted by the _____ Hospital Intensive Care Unit (ICU) looking at the incidence of psychological symptoms in close family members of patients who have been admitted to the ICU. We will also study the incidence of psychological symptoms in intensive care patients.
Critically ill patients requiring support in ICU may take a minimum of 6-12 months to physically get back to what is normal for them. It has become apparent that ICU relatives are also traumatised by their ICU experience and can sometimes show high levels of psychological symptoms. This study is being conducted to look for the incidence of such symptoms.

1. What is the purpose of this study?
To screen families/next of kin of ICU patients for psychological symptoms after their stay in ICU. Participants in the study will be followed up to 12 months post discharge from ICU. This knowledge will assist in deepening understanding of the long term impact of ICU thus facilitating strategies, prevention and treatment of psychological symptoms.

2. Who is conducting this study?
The research team at the Intensive Care Unit of the _____ Hospital is conducting the study.

3. Why have I been invited to participate in this study?
You are the family member/next of kin (NOK) of a critically ill patient who is admitted to intensive care needing organ support This makes you eligible to participate in the study.

4. What if I don't want to take part in this study or if I want to withdraw later?
Participation in this study is voluntary and your decision will not affect the medical management of your loved one. If you wish to withdraw from the study, you can do so at any time without justifying your decision. If you do withdraw from the study, all of the data already collected about you as part of the study will be destroyed and no data or information collected will be used in anyway by the researchers or sent

outside this institution. No additional information will be collected for the purposes of this study and you will not be contacted again.

5. What does this study involve?

Participation in this study involves 3 short surveys after the discharge of your loved one from ICU. An initial survey will be done in hospital after ICU discharge. One of the research investigators will meet you while you are still in hospital. Follow up surveys will be done at 3 and 12 months after discharge. This will be in the form of either a postal or a telephonic interview answering a short series of questions. This will assist us to determine if there have been any changes during that time.
Families/next of kin will be responding to a Revised Impact of Event Scale (IES-R) & Depression Anxiety Score Scale-21 (DASS-21). These tools measure the level of distress you may be experiencing as a result of your loved one being admitted to intensive care. In addition, we would be assessing the impact of your family members' hospitalisation on your quality of life using a validated tool called EQ-5D

6. Will my taking part in this study be kept confidential?

You have the right to privacy and all information that is collected during this study is confidential to the extent permitted by the applicable laws and regulations. Your study data will be made anonymous by the assignment of a unique number to you alone. All data collected from you will then be identified by this number.
Paper records including contact information will be stored in locked rooms accessible only to authorized study personnel. Electronic information will be kept on password-protected computers accessible only to authorized study personnel.
Your identity will be kept confidential at all times. Your personal information will only be disclosed with your permission, except as required by law.

7. Are there risks to me in taking part in this study?

No questions will be asked of you about any specific instances or memories of the time your loved one was admitted in the ICU. However, it is possible that you may experience some discomfort or distress as you may recollect some unpleasant memories from that time. Participation in the study will ensure that distress can be potentially diagnosed and appropriate referral made. In the unlikely event that you do feel distressed by any of the questions, we would encourage you to discuss any concerns with the study coordinator or your General Practitioner.

8. Will I benefit from the study?

This study aims to look at the psychological impact of ICU stay and gain further medical knowledge. This study may help to improve support for others with similar experiences, and the results of the study will be published in a major international medical journal. You may not receive any direct benefits from this research.

9. Will taking part in this study cost me anything, and will I be paid?

Participation in this research study will not cost you anything. You will not be paid or receive any financial benefits from taking part in this research study.

10. What happens with the results?

The results obtained from de-identified data will be collated and published in medical journals, conference presentations and other professional forums. In any publication, information will be provided in such a way that you cannot be identified. Results of the study will be provided to you, if you wish.

11. What should I do if I want to discuss this study further before I decide?

When you have read this information, the study investigator will discuss it with you and clarify any queries you may have. If you would like to know more at any stage, please do not hesitate to contact _____ on _____, or study coordinator _____ on _____.

12. Who can I contact if I have any questions or problems?

For questions about the study you can contact the principal investigator, Dr _____ on _____ or email _____. You may also contact the site research coordinator, _____ on _____ or email at _____

If you find that any of the research questions are distressing to you, please do not continue with the study. There are services to help you. Please talk to your GP, or contact one of the services below:

- Lifeline (24 Hours): 13 11 14 - www.lifeline.org.au
- ACT Health (Crisis Team): 1800 629 354 or (02) 6205 1065
- NSW Mental Health Line: 1800 011 511
- Beyond blue (24 Hours): 1300 224 636 - www.beyondblue.org.au
- SANE (9:00am - 5:00pm): 1800 187 263 - www.sane.org
- Suicide Callback Service (24 Hours): 1300 659 467 - www.suicidecallbackservice.org.au

13. Who should I contact if I have concerns about the conduct of this study?

This study has been approved by _____ Health Human Research and Ethics Committee. Any concerns or complaints about the conduct of this study can be directed to the _____Health Directorate Human Research Ethics Committee Secretariat, on _____ or via email _____.

Thank you for taking the time to consider this study.
If you wish to continue to take part in it, please sign the attached consent form.
This information sheet is for you to keep.

Appendix 3

Psychological stRess in Intensive CarE survivors (PRICE Study)

Patient Consent Form

I, _____(Full name of patient) of _____(address), have been explained about the study and have been asked to consent to participate in a research project entitled: PRICE: Psychological stRess in Intensive CarE survivors

In relation to this study I have read the Patient Information Sheet and have been informed of the following points:

1. Approval has been given by the _____ Health Directorate Human Research Ethics Committee. The aim of the study is to investigate cognitive and psychosocial function of patients who are critically ill and mechanically ventilated in Intensive Care Unit (ICU).
2. The results obtained from the study will not be of direct benefit to my medical management.
3. The study procedure will involve an initial assessment immediately after ICU discharge and 2 follow up surveys up to 12 months after ICU discharge.
4. I consent to being surveyed via post/telephone/both (strike out which is not applicable), as explained in the Study Information Sheet.
5. Possible adverse effects or risks related to this study may include potentially experiencing discomfort as a result of reflecting on the experience in ICU. I am aware that in this case I will be offered psychological assistance.
6. I understand that I have the ability to withdraw consent and therefore participation in the study at any stage. I am also aware that this will not in any way jeopardise my present or future care, or my relationship with the hospital.
7. Should I develop a problem which I suspect may have resulted from my involvement in this project, I am aware that I may contact the study principal investigator, Dr _____ on _____ or email at _____.
8. Should I have any problems or queries about the way in which the study was conducted, and I do not feel comfortable contacting the study staff, I am aware that I may contact the _____ Health Directorate Human Research Ethics Committee Secretariat, on _____ or via email _____
9. Participation in this project will not result in any extra medical or hospital costs to either my partner/friend/relative or I.
10. I understand that while the results of the research will be made accessible, my involvement and the identity will not be revealed.

11. In giving my consent, I acknowledge that the relevant Health Department Officials and the staff directly involved in the study may examine my medical records only as they relate to this project.
12. There is no foreseeable injury as a result of participating in this study; therefore any compensation will not be applicable.

After considering all these points, I accept the invitation to participate in this study.

Name: _____Date: _____
Signature _____
Investigator (Name): _____Date: _____
Signature (Investigator) _____

REVOCATION OF CONSENT

PRICE: Psychological stRess in Intensive CarE survivors

I hereby wish to WITHDRAW my consent to participate in the study described above and understand that such withdrawal WILL NOT jeopardise any treatment or my relationship with my health care providers.

Signature Date

Please PRINT Name _____

Appendix 4

Psychological stRess in Intensive CarE survivors (PRICE Study)

Family members' consent form

I, _____(Full name) of _____(address), have been explained about the study and have been asked to consent to participate in a research project entitled: PRICE: Psychological stress in intensive care survivors

In relation to this study I have read the Information Sheet and have been informed of the following points:

1. Approval has been given by the _____ Health Directorate Human Research Ethics Committee. The aim of the study is to investigate the psychological effect of a stay in the ICU.
2. The results obtained from the study will not be of direct benefit to my loved one's medical management.
3. The study procedure will involve an initial assessment immediately after ICU discharge and 2 follow up surveys till 12 months.
4. I consent to being surveyed via post/telephone/both (strike out which is not applicable), as explained in the Study Information Sheet.
5. Possible adverse effects or risks related to this study may include potentially experiencing discomfort as a result of reflecting on the experience in ICU. I am aware that in this case I will be offered psychological assistance.
6. I understand that I have the ability to withdraw consent and therefore participation in the study at any stage. I am also aware that this will not in any way jeopardise the present or future care of my loved one, or my relationship with the hospital.
7. Should I develop a problem which I suspect may have resulted from my involvement in this project, I am aware that I may contact the study principal investigator, Dr _____ on _____ or email at _____.
8. Should I have any problems or queries about the way in which the study was conducted, and I do not feel comfortable contacting the study staff, I am aware that I may contact the _____Health Directorate Human Research Ethics Committee Secretariat, on _____ or via email _____.
9. Participation in this project will not result in any extra medical or hospital costs to either my partner/friend/relative or I.
10. I understand that while the results of the research will be made accessible, my involvement and the identity will not be revealed.

11. In giving my consent, I acknowledge that the relevant Health Department Officials and the staff directly involved in the study may examine my loved one's medical records only as they relate to this project.
12. There is no foreseeable injury as a result of participating in this study; therefore any compensation will not be applicable.

After considering all these points, I accept the invitation to participate in this study.

Name: _____Date: _____
Signature _____
Investigator (Name): _____Date: _____
Signature (Investigator) _____

REVOCATION OF CONSENT

PRICE: Psychological stress in intensive care survivors

I hereby wish to WITHDRAW my consent to participate in the study described above and understand that such withdrawal WILL NOT jeopardise any treatment of my loved one, or my relationship with my health care providers.

Signature Date

Please PRINT Name _____

Appendix 5

PTSS-14 Intensive Care Screen

This form should not take longer than about 5 minutes to complete. The form has two sections, Part A and Part B.

PART A

This consists of four statements about your memory of the time you spent on the Intensive Care Unit. Read each statement. If a statement is FALSE, tick the NO box. If the statement is TRUE, tick the YES box. Please answer ALL four questions. Tick only ONE box for each statement. If you make a mistake, simply cross out the wrong answer and tick the correct box.

PART B

This consists of 10 statements about how you have been feeling in the past few days. You need to decide HOW OFTEN you have been feeling this way in the past few days.

If you have NOT EVER felt or experienced what the statement says in the past few days, circle 1 (never).

If you have been feeling or experiencing it ALL THE TIME, circle 7 (always).

Otherwise, circle one of the numbers in between that best describes how much you have been feeling or experiencing what the statement says in the past few days.
Please circle only one number for each statement. If you make a mistake, simply cross it out and circle the correct number. PLEASE be sure to choose a number for ALL 14 statements.

A. When I think back to the time of my severe illness and the time I spent in the Intensive Care Unit (ICU), I remember:

Nightmares	No	☐	Yes	☐
Severe Anxiety or Panic	No	☐	Yes	☐
Severe Pain	No	☐	Yes	☐
Troubles to breath, feelings of suffocation	No	☐	Yes	☐

B. Presently (this means in the past few days) I suffer from:

1. sleep problems

never						always
1	2	3	4	5	6	7

2. nightmares

never						always
1	2	3	4	5	6	7

3. depression, I feel dejected/downtrodden

never always

1 2 3 4 5 6 7

4. jumpiness, I am easily frightened by sudden sounds or sudden movements

never always

1 2 3 4 5 6 7

5. the need to withdraw from others

never always

1 2 3 4 5 6 7

6. irritability, that is, I am easily agitated/annoyed and angry

never always

1 2 3 4 5 6 7

7. frequent mood swings

never always

1 2 3 4 5 6 7

8. a bad conscience, blame myself, have guilt feelings

never always

1 2 3 4 5 6 7

9. fear of places and situations, which remind me of the ICU

never always

1 2 3 4 5 6 7

10. muscular tension

never always

1 2 3 4 5 6 7

11. *upsetting, unwanted thoughts or images of my time on the ICU*

never always

1 2 3 4 5 6 7

12. *feeling numb (e.g. cannot cry, unable to have loving feelings)*

never always

1 2 3 4 5 6 7

13. *avoid places, people or situations that remind me of the ICU*

never always

1 2 3 4 5 6 7

14. feeling as if my plans or dreams for the future will not come true

never always

1 2 3 4 5 6 7

Citation: Twigg E, Humphris G, Jones C, Bramwell R, Griffiths RD. Use of a screening questionnaire for post-traumatic stress disorder (PTSD) on a sample of UK ICU patients. Acta Anaesthesiologica Scandinavica. 2008 Feb;52(2):202–8.

Appendix 6
IMPACT OF EVENT SCALE- REVISED

INSTRUCTIONS: Below is a list of difficulties people sometimes have after stressful life events. Please read each item, and then indicate how distressing each difficulty has been for you **DURING THE PAST SEVEN DAYS** with respect to _____, which occurred on _____. How much were you distressed or bothered by these difficulties?

Not at all = 0	A little bit = 1	Moderately = 2	Quite a bit = 3	Extremely = 4

1. Any reminder brought back feelings about it.
2. I had trouble staying asleep.
3. Other things kept making me think about it.
4. I felt irritable and angry.
5. I avoided letting myself get upset when I thought about it or was reminded of it.
6. I thought about it when I didn't mean to.
7. I felt as if it hadn't happened or wasn't real.
8. I stayed away from reminders of it.
9. Pictures about it popped into my mind.
10. I was jumpy and easily startled.
11. I tried not to think about it.
12. I was aware that I still had a lot of feelings about it, but I didn't deal with them.
13. My feelings about it were kind of numb.
14. I found myself acting or feeling like I was back at that time.
15. I had trouble falling asleep.
16. I had waves of strong feelings about it.
17. I tried to remove it from my memory.
18. I had trouble concentrating.
19. Reminders of it caused me to have physical reactions, such as sweating, trouble breathing, nausea, or a pounding heart.
20. I had dreams about it.
21. I felt watchful and on-guard.
22. I tried not to talk about it.

Citations: Weiss, D.S. & Marmar, C.R. (1997). The Impact of Event Scale-Revised. In J.P. Wilson, & T. M. Keane (Eds.), *Assessing Psychological Trauma and PTSD: A Practitioner's Handbook*. (pp. 399-411). New York: Guilford.
Weiss, D. S. (2004). The Impact of Event Scale-Revised. In J. P. Wilson, & T. M. Keane (Eds.), *Assessing psychological trauma and PTSD: A practitioner's handbook* (2nd ed., pp. 168-189). New York: Guilford Press.

Appendix 7

DASS21	*Name:*	*Date:*

Please read each statement and circle a number 0, 1, 2 or 3 which indicates how much the statement applied to you *over the past week*. There are no right or wrong answers. Do not spend too much time on any statement.

The rating scale is as follows:
0 Did not apply to me at all
1 Applied to me to some degree, or some of the time
2 Applied to me to a considerable degree, or a good part of time
3 Applied to me very much, or most of the time

1	I found it hard to wind down	0	1	2	3
2	I was aware of dryness of my mouth	0	1	2	3
3	I couldn't seem to experience any positive feeling at all	0	1	2	3
4	I experienced breathing difficulty (eg, excessively rapid breathing, breathlessness in the absence of physical exertion)	0	1	2	3
5	I found it difficult to work up the initiative to do things	0	1	2	3
6	I tended to over-react to situations	0	1	2	3
7	I experienced trembling (eg, in the hands)	0	1	2	3
8	I felt that I was using a lot of nervous energy	0	1	2	3
9	I was worried about situations in which I might panic and make a fool of myself	0	1	2	3
10	I felt that I had nothing to look forward to	0	1	2	3
11	I found myself getting agitated	0	1	2	3
12	I found it difficult to relax	0	1	2	3
13	I felt down-hearted and blue	0	1	2	3
14	I was intolerant of anything that kept me from getting on with what I was doing	0	1	2	3
15	I felt I was close to panic	0	1	2	3
16	I was unable to become enthusiastic about anything	0	1	2	3
17	I felt I wasn't worth much as a person	0	1	2	3
18	I felt that I was rather touchy	0	1	2	3
19	I was aware of the action of my heart in the absence of physical exertion (eg, sense of heart rate increase, heart missing a beat)	0	1	2	3
20	I felt scared without any good reason	0	1	2	3
21	I felt that life was meaningless	0	1	2	3