### PLEASE INSERT NAME & ADDRESS OF DEPARTMENT

# RESEARCH STUDY INFORMATION & ASSENT FORM

STUDY TITLE:

# PRINCIPAL INVESTIGATOR:

It is hoped to include your relative in a research study. As your relative is not able to discuss this at the moment, thank you for taking time to read this.

# WHAT IS THE PURPOSE OF THIS STUDY?

(Background info if applicable) The aim of the study is…

# WHY HAS MY RELATIVE BEEN CHOSEN?

Your relative has been chosen because…

# WHY HAVE I BEEN APPROACHED?

Normally patients are included in medical research studies only if they agree to be included in the study and understand what is involved **(“*Informed Consent*”**). In medical research into conditions where the patient is critically ill, the patient is often unable to discuss what is involved at that time. Your relative is unable to have a discussion at the moment.

As next-of-kin we will keep you informed of what is happening with your relative. If you know of any wishes of your relative that might be relevant, you have should let us know.

# YOUR RELATIVE WILL BE INCLUDED IN THIS RESEARCH STUDY ONLY:

* If there is no known objection by your relative to being included

**and**

* If ***you*** have no objection to your relative being included (your ***“Assent”***).

If your relative is not included in this research study it will not affect his or her treatment in any way. If your relative’s doctors think it is in your relative’s best interest to withdraw him or her from this study they will do so. (Insert/delete as appropriate) If you later change your mind your relative can be removed from the study without you having to give a reason.

Once your relative is well enough, it will be discussed with him or her what (is/was) involved in being included in the research study: if he or she decides not to be involved, his or her participation in the research study will end; any results to do with him or her will be deleted and any samples will be destroyed. (Insert/delete as appropriate)

# WHAT WILL HAPPEN IF MY RELATIVE IS INCLUDED IN THIS RESEARCH STUDY?

If your relative is included in this study, he or she will have (Insert/delete as appropriate), samples taken eg: donate a blood, tissue, urine sample, etc. Specify, sample volume which should be quantified.

# ARE THERE ANY BENEFITS FROM BEING INCLUDED IN THE RESEARCH STUDY?

Delete as appropriateYou relative (will/will not) benefit directly from taking part in this study but the information we will obtain will provide further knowledge of this condition.

# ARE THERE ANY RISKS INVOLVED IN BEING INCLUDED IN THE STUDY?

The risks involved in this study are... Please enumerate and quantify all risks (eg: blood sample risks: bruising at site, swelling etc)

# WHAT HAPPENS IF MY RELATIVE IS NOT INCLUDED IN THE STUDY?

If your relative is not included in this study his or her treatment will not be affected in any way.

# CONFIDENTIALITY

Include/Delete as necessary:

Your relative’s identity will remain confidential. A study number will identify him or her. Your relative’s name will not be published or disclosed to anyone.

# COMPENSATION

Your relative’s doctors are adequately insured by virtue of their participation in the clinical indemnity scheme.

# WHO IS ORGANISING AND FUNDING THIS RESEARCH?

Include/Delete as necessary:

This study is organised and funded by …

Will my relative be paid for taking part in this study? …

Will expenses for taking part in this study be covered? …

# HAS THIS STUDY BEEN REVIEWED BY AN ETHICS COMMITTEE?

The Ethics and Medical Research Committee of St. Vincent’s Healthcare Group has reviewed and approved this study. As this study involves patients unable to participate in a discussion at the time of the study, this committee is satisfied that: Include/Delete as necessary:

- any risks involved are minimal or any risks are low relative to the potential for benefit

- of the two treatments being compared it is not known which is better

- that the study is being carried out in a scientific manner with potential to benefit future patients

- that the rights and dignity of patients will be respected.

# CONTACT DETAILS

If you need further information…Name & tel. number of investigator for further information. Suggest not personal mobile.

# PLEASE TICK YOUR ANSWER IN THE APPROPRIATE BOX

Has your relative been made a “ward of court”? YES NO

Has your relative gone through a legal process to give “enduring

power of attorney” to somebody (to make medical decisions on

his or her behalf)? YES NO

Has your relative written down his or her views in a “living will”? YES NO

Are you aware of any objections he or she had to being included

in a medical research study? YES NO

I have read and understood this Information & Assent Form : YES NO

I have had the opportunity to ask questions and discuss the study: YES NO

I have received satisfactory answers to all my questions: YES NO

I have received enough information about this study : YES NO

I understand that I am free to withdraw my relative from the study

at any time without giving a reason and without this affecting

my relative’s medical care: YES NO

I know that as soon as my relative is well enough, he or she will

be asked whether he or she consents to be included in the study: YES NO

Do you have any objection to your relative taking part in the study? YES NO

Next-of-kin signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Next-of-kin name in print: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Investigator’s Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Investigator’s Name in print: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_