###  PLEASE INSERT NAME & ADDRESS OF DEPARTMENT

St. Vincent’s University Hospital

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# PARTICIPANT INFORMATION AND CONSENT FORM

STUDY TITLE:

# NAME OF PRINCIPAL INVESTIGATOR:

You are being invited to participate in a research study. Thank you for taking time to read this.

# WHAT IS THE PURPOSE OF THIS STUDY?

The aim of the study is to

# WHY HAVE I BEEN CHOSEN?

# WHAT WILL HAPPEN IF I VOLUNTEER?

Your participation is entirely voluntary. If you initially decide to take part you can subsequently change your mind without difficulty. This will not affect your future treatment in any way. Furthermore your doctor may decide to withdraw you from this study if (Insert/delete as appropriate), he/she feels it is in your best interest.

If you agree to participate, you will be requested to ( Insert/delete as appropriate), eg: donate a blood, tissue, urine sample, complete a questionnaire or interview etc.

**Specify, sample volume** which should be quantified in terms of tsps/tablsps

(Insert/delete as appropriate) If additional time and/or visits are required this should be clearly stated and include **how long** and **how many** and **where they will take place.**

# ARE THERE ANY BENEFITS FROM MY PARTICIPATION?

Delete as appropriate You will/will not benefit directly from taking part in this study but the information we will obtain may provide further knowledge of this condition.

# ARE THERE ANY RISKS INVOLVED IN PARTICIPATING?

There are risks associated with this study.

Please enumerate and quantify **all** possible risks (eg: blood sample risks: bruising at site, swelling, dizziness, fainting, infection at site etc)

# WHAT HAPPENS IF I DO NOT AGREE TO PARTICIPATE?

If you decide not to participate in this study your treatment will not be affected in any way.

# CONFIDENTIALITY & DATA PROTECTION

You must provide the data subjects (research subjects) with the following information. It is a legal requirement under data protection law:

1. The purpose or reason for processing their personal data. e.g. we will be using your personal information in our research to help us study medication compliance.
2. The legal basis under which you are processing their data. e.g. legitimate interests interest and for scientific research purposes – see Article 6 and 9 of the General Data Protection Regulation 2016. If uncertain contact the Data Protection Officer.
3. Who are the recipients of the data e.g. who will have access to the research participants’ information?
4. How long will the data be stored for and, if it is not possible to say, please give the criteria which will be used to determine that period.
5. That the data subjects have a right to withdraw consent.
6. That the data subjects have a right to lodge a complaint with the Data Protection Commissioner.
7. That the data subjects have a right to request access to their data and a copy of it, unless their request would make it impossible or make it very difficult to conduct the research.
8. That data subjects have a right to restrict or object to processing, unless their request would make it impossible or make it very difficult to conduct the research. e.g. the data subject doesn’t want their data shared but doesn’t mind having it collected and stored.
9. That the data subjects have a right to have any inaccurate information about them corrected or deleted, unless their request would make it impossible or make it very difficult to conduct the research.
10. That the data subjects have a right to have their personal data deleted, unless their request would make it impossible or make it very difficult to conduct the research. e.g. they wanted to delete their data at the end of a research project just before it is due to be published.
11. That the data subjects have a right to data portability, meaning they have a right to move their data from one controller to another in a readable format.
12. Will there be automated decision making, including profiling? Profiling is any form of automated processing of personal data consisting of the use of personal data to evaluate certain personal aspects relating to the person, in particular to analyse or predict aspects of their performance at work, health or behaviour.
13. That the data subjects have a right to object to automated processing including profiling if they wish.

1. You must inform the data subject if you intend to further process their personal data and provide the data subject with information on that other purpose.
2. You must inform the data subject if you wish to transfer their data to a country outside of the EU or an international organisation and advise them of the safeguards you have in place to protect their data.

Include/Delete as necessary:

Your identity will remain confidential. A study number will identify you. Your name will not be published or disclosed to anyone.

# COMPENSATION

Your 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 I be paid for taking part in this study?

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

# HAS THIS STUDY BEEN REVIEWED BY AN ETHICS COMMITTEE?

The St. Vincent’s Healthcare Group, Ethics and Medical Research Committee have reviewed and approved this study.

# CONTACT DETAILS

Include: contact details for further information**.**

**Please note:**  Telephone number should be study specific.

**RESEARCH PARTICIPANT’S RIGHTS**

If you have any questions about your rights as a research participant, then you may contact the Hospital’s Quality & Patient Safety Department 01 2214013

# PLEASE TICK YOUR RESPONSE IN THE APPROPRIATE BOX

* I have read and understood the Participant Information 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 from the study at any time without

giving a reason and without this affecting my future medical care YES NO

* I am aware of the potential risks, benefits and alternatives of this research

study. YES NO

* I consent to take part in this research study having been fully informed of

the risks, benefits and alternatives. YES NO

* I give informed consent to have my data processed as part of this research

study. YES NO

**STORAGE & FUTURE USE OF INFORMATION:**

* I give permission for material/data to be stored for possible future research

related to the current study only if consent is obtained at the time of the

future research but only if the research is approved by a Research Ethics

Committee. YES NO

* I give permission for material/data to be stored for possible future research

related to the current study without further consent being required but only

if the research is approved by a Research Ethics Committee. YES NO

* I give permission for material/data to be stored for possible future research

unrelated to the current study only if consent is obtained at the time of the

future research but only if the research is approved by a Research Ethics

Committee. YES NO

* I give permission for material/data to be stored for possible future research

unrelated to the current study without further consent being required but

only if the research is approved by a Research Ethics Committee. YES NO

* I agree that some future research projects may be carried out by researchers

working for commercial/pharmaceutical companies. YES NO

* I understand I will not be entitled to a share of any profits that may arise

from the future use of my material/data or products derived from it. YES NO

Participant’s Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_

Participant’s Name (block capitals): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

Investigator’s Name (block capitals): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Translator’s Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_

Translator’s Name (block capitals): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Legal Rep./Guardian’s Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_

Legal Rep./Guardian’s Name (block capitals): \_\_\_\_\_\_\_\_\_\_