

# PARTICIPANT INFORMATION SHEET

***I would like to invite you to take part in a research study. Before you decide, you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Ask questions if anything you read is not clear or would like more information.***

**Project Title**

A comparison of anxiety levels between device shock and non-shock groups in implantable cardioverter defibrillator (ICD) recipients.

**What is the purpose of the study?**

An implantable cardioverter defibrillator (ICD) is a small device that is used to treat people with dangerously abnormal heart rhythms. An ICD can give the heart electric pulses or shocks to get the heart rhythm back to normal. The aim of the research is to assess the level of shock anxiety in a sample of ICD recipients, and to compare the differences between anxiety with patients who have experienced shocks from their ICD’s compared with patients who haven’t received shocks. The completion of the online Florida Shock Anxiety Scale (FSAS) survey questionnaire will allow us to determine if ICD recipients who receive shocks from their ICD’s have higher anxiety levels compared to recipients who have not received shocks from their ICD’s.

**Who am I?**

I am currently a third year Cardiac Physiology student at the University of Sunderland. I am carrying out this research to fulfil the requirements for the 30-credit Dissertation module (HCS325).

**What will you have to do?**

You will have to complete an online survey questionnaire posted on the website ‘Survey Planet’, the link will be shared with you through your ICD Support Group leaders. There are no other commitments associated with participating in the research.

**Do I have to take part?**

Participation is entirely voluntary. If you change your mind about taking part in the study, you **can withdraw at** **any point during the session** **without giving a reason and without penalty** by simply not submitting the online questionnaire to the researcher, or if you have submitted your online questionnaire and decide to withdraw later on, you canemail the researcher your ‘two random/secret words’, which you will have provided as this will be the second question asked on the online survey(*contact details down below*). Please note, withdrawal is possible anytime within the next **3 months** after completion**,** until the **31st of May.** Your data will therefore be destroyed and withdrawn from being used in the study. After the withdrawal deadline, your data will then be destroyed after the exam board, held in June 2019.

**What if something goes wrong?**

If you change your mind about participation, please contact me via email to cancel your participation. If you feel unhappy about the conduct of the Study, please contact me immediately or the Chairperson of the University of Sunderland Research Ethics Group, whose contact details are given below.

**How long will the questionnaires take to complete?**

It will take approximately 5-10 minutes to complete the online survey questionnaire on ‘Survey Planet’.

**Who can take part?**

Participants aged 18 or over who have been implanted with an Implantable Cardioverter Defibrillator (ICD).

**Who cannot take part?**

* People whose competence to exercise informed consent is in doubt such as infants & children under the years of 18.
* People who suffer from psychiatric or personality disorders (e.g. schizophrenia), including those conditions in which capacity to consent may fluctuate.
* People with disabilities & people who are frail or in poor health.
* Inability to communicate in the English language.
* Documented cognitive impairment that would deem a person unable to consent or who lack mental capacity (e.g. dementia).
* People diagnosed with neurological disorders such as: Alzheimer’s, dementia, cerebrovascular diseases including stroke & Parkinson’s disease.

**What about my Privacy & Confidentiality?**

All questionnaires will be completed anonymously, and the research will only be seen by the researcher and the project supervisor. In order to maintain confidentiality, we will not ask for your name or other personal information, in accordance with the NHS Confidentiality Code of Practice. The responses you provide will be used in the researcher’s final year dissertation. All information will remain completely anonymous throughout the study. All the information collected from you will be **destroyed after 10 months** of theresearch taking place, with the exception of the facts printed.

**Data Storage**

Data collected will be stored in a secure locker with the key in the possession of the researcher. Data will also be kept securely on a password-protected computer with the password in the sole possession of the researcher.

**What advantages are there of taking part? Are there any risks?**

We cannot promise that the study will directly benefit you, however the information we obtain from the study will expand our insight into the levels of anxiety patients experience before and after receiving shock therapy from their ICD’s. It will explore the effects of receiving shocks on patient’s overall quality of life, helping us to establish better outcomes and approaches in order to improve patient experiences and satisfaction whilst living with their ICD’s.

The intent of the research is to purely investigate the differences between anxiety levels in participants who have experienced shock with participants who have not. Therefore, if any worries or concerns arise following the questionnaire you can contact the University of Sunderland for advice or contact your local Cardiac Rhythm Management Department *(contact details provided below*).

**Who has approved of the study?**

This project has been approved by the University of Sunderland Research Ethics Group.

**Contact for further information:**

1. You can contact the researcher **Amina Ellahi** via email: Bh03uf@student.sunderland.ac.uk
2. The dissertation supervisor **Christopher Cox** via email: Chris.cox@sunderland.ac.uk
3. The Chair of the UoS Research Ethics Group **John Fulton** via email: John.fulton@sunderland.ac.uk