**Parent Information Sheet (Case)**

Title of Project:- Is Antenatal Exposure to Selective Serotonin Reuptake Inhibitors (SSRIs) Associated with Prolongation of the QT Interval in Term Neonates (37 Complete Weeks Gestation or Greater)?

Researcher: Marie Lindsay-Sutherland Ethics number: 8442

**Please read this information carefully before deciding to take part in this study. If you are happy to participate you will be asked to sign a consent form.**

**Why am I receiving this leaflet?**

We would like to invite you and your baby to take part in a research study. Before you decide you need to understand why the research is being done and what it will involve for you both. This leaflet will explain this. Please ask if there is anything that you do not understand or would like more information about.

**Part 1**

**Why is this study being done?**

SSRIs such as Sertraline, Citalopram, and Fluoxetine, are a group of antidepressants used in the treatment of mental health problems. Their use in pregnancy may increase the risk of your baby being born early, having heart problems or having withdrawal symptoms. There is very limited information available, but it is also thought that use of these antidepressants in pregnancy may affect a baby’s heart beat, in a way which can cause adults to collapse.

This study is looking at whether these antidepressants, when taken in pregnancy, affect the way a baby’s heart beats by doing an Electrocardiogram (ECG) at 48- 72 hours of age. We also want to compare this to babies whose mothers haven’t taken these antidepressants in pregnancy. We hope to perform ECGs on about 120 babies in each group.

**Why have I been invited?**

Your maternity notes show that you have taken a SSRI antidepressant at some point in your pregnancy. We are asking all mothers who have done this to take part in the study.

**Do I have to take part?**

You do not have to take part. It is up to you to decide if you want to. This leaflet describes the study so you can make that decision. If you do decide to take part, you can withdraw at any time, without giving a reason. This will not affect the care you receive.

**What will I have to do?**

Taking part in this study will involve your baby having an ECG at 48 -72 hours of age. This test will be done when your baby is comfortable and settled. It involves placing sticky pads on your baby’s chest, arms and legs which are then connected to the ECG machine. A print out of your baby’s heart beat will be taken. This will take about 15 minutes. The sticky pads will then be removed. You will be told immediately if the ECG result looks normal at that time by the Advanced Neonatal Nurse Practitioner or the person who has done the ECG. You can go home as planned if the result looks normal. A confirmed result will be sent to you in the post once the ECG has been checked by a senior member of the neonatal team. The result of your baby’s ECG will be noted on your discharge letter and their hospital electronic record so your GP is aware. If there are concerns, you will be asked to remain in hospital for any further investigations or monitoring that may be needed.

**What should I expect if I decide to take part?**

You will have about 36 hours to read this leaflet before we ask if you would like to take part in the study. If you are happy to do so, we will arrange a suitable time and place to do your baby’s ECG. We will give you a chance to ask any questions before we do the ECG. We will then ask you to sign a consent form which states you are happy for yourself and your baby to take part. Also that you allow us to use your baby’s ECG result and your details, both which will be unidentifiable, in the study report. The consent form will also give us permission to look at your baby’s records at 6 months of age to check their health. We will finally ask you some questions about yourself, your pregnancy, and your medication.

**Expenses and payments**

No expenses or payments are offered.

**What are the possible disadvantages and risks of taking part?**

We do not believe there will be any harm to you or your baby from taking part in this study. However, we understand that discussing your mental health and the effects of your medication on your baby may be upsetting. We aim to support you with any worries you may have at this time. Extra support will be provided if the ECG result is not normal and further monitoring is needed.

The sticky ECG pads are used on the delicate skins of premature babies without any problems.

A normal ECG result at this time will not exclude future unrelated problems.

**What are the possible benefits of taking part?**

An ECG is not offered to everyone. It may find an unexpected problem, or confirm a normal heart pattern. The information from the study that you and your baby give, may help improve the services provided for other babies born to mothers who have taken these antidepressants in their pregnancy.

**What happens when the research study stops?**

We hope to be able to use the information provided by you and your baby to decide whether all babies of mothers who took these antidepressants in their pregnancies, should have an ECG after birth.

**What if there is a problem?**

Any concerns about the way you have been taken care off during the study or any possible harm to you or you baby will be addressed (see part 2).

**Will my taking part in the study be kept confidential?**

All information about you and your baby will be handled confidentially (see part 2). This will only change if the safety of your baby and yourself are at risk. You will be told if this is necessary.

**This completes Part 1. If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before you make any decisions.**

**Part 2**

**What will happen if I don’t want to carry on with this study?**

You can withdraw from the study at any time without giving a reason.

**What if there is a problem or I have a complaint?**

If you have a question about any part of this study, you can speak to the researcher, Marie Lindsay-Sutherland, who will do her best to answer it.

If you continue to have a concern or a complaint about this study you can contact the Research Governance Manager, at the Research Governance Office (Address: University of Southampton, Building 37, Highfield, Southampton, SO17 1BJ ; Tel: +44 (0)23 8059 5058; Email: rgoinfo@soton.ac.uk .  If you remain unhappy and want to take it further, this office can provide you with details of the University of Southampton Complaints Procedure.

If you have a concern or a complaint about the care you received from Xxxxx NHS Foundation Trust Hospital, you should contact Matron XX on XXXXX 448217 (Neonatal Unit) or Head of Midwifery, XX on XXXXX 442190. If you wish to make an official complaint, you can do this through the NHS Complaints Procedure. The hospital can provide you with details on how to do this.

**Will my taking part in the study be kept confidential?**

All the information which is collected about you and your baby during the course of the study will be kept strictly confidential unless it affects either your own or your baby’s safety. It will be coded so that neither of you can be identified. All documents will be kept in a locked filing cabinet in a secure office. Identifying data such as your name and hospital number, will be kept with matching codes in a separate locked cabinet. All original data will be kept for 21 years as required by NHS policy. All anonymous data will be stored in a password protected computer.

**What will happen to the information I give?**

The results of the heart beat pattern and the questionnaire will be used for analysis.

**What will happen to the results of the research study?**

* A thesis
* Presentations
* Papers for publication (links will be available through the hospital’s newsletter, Grapevine).

**Who is organizing and funding this research?**

This work is self-funded and will be used as part of the researcher’s Doctorate.

**Who has reviewed the study?**

This study has been reviewed by Xxxxx NHS Foundation Trust Hospital Research and Development Office and the Xxxxx Xxxx – Xxxxxx Research Ethics Committee to make sure that you and your baby’s safety, rights and dignity are protected.

**Further information and contact details of the researcher**

Marie Lindsay-Sutherland (Doctoral Research Student)

Neonatal Unit, Xxxxx Hospital NHS Foundation Trust

Xxxxx, Xxxxxx

Telephone:- XXXXX 442330 (Neonatal Unit)

Email:- Marie.l.Sutherland@xxxxx.nhs.uk

**Supervisors**

Dr Elizabett Cluett

Director of Programs for Family, Child and Psychosocial Health, University of Southampton

(023) 8059 7850

E.Cluett@soton.ac.uk

Dr Helen Rushforth

MSc Advanced Clinical Practice Programme Leader, Centre for Innovation and Leadership in Health Sciences, University of Southampton

(023) 8059 7919

her@soton.ac.uk

Dr Michael Hall

Consultant Neonatologist / Clinical Lead, University Hospital Southampton NHS Foundation Trust

(023) 8079 6001 (NICU)

mike.hall@uhs.nhs.uk

If you have any concerns or need independent advice, you can contact the Patient Advise and Liaison Service (PALS) by calling XXXXX 448499 or by visiting the PALS Health Information Centre on XXXX Rd near the hospital’s main car park. Alternatively you can email them at PALS@xxxxx.nhs.uk

If you decide to participate you will be asked to sign a consent form and given a copy of the consent form to keep for your records.

**Thank you for taking the time to read this leaflet**