PATIENT INFORMATION SHEET

A REGISTER IN THE UK TO DETERMINE THE SAFETY OF THE ANTI-EPILEPTIC DRUGS IN PREGNANCY

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your GP if you wish. Ask us if there is anything that is not clear if you would like more information. Take time to decide whether or not you wish to take part.

Purpose of Study

We are conducting a study to determine which of the drugs used to treat seizures (or epilepsy) are the safest in pregnancy. The reason for doing this is that whilst there is some evidence that the older anti-epileptic drugs (AEDs) can rarely affect foetal development, there is very little information on the safety of the more recently introduced AEDs. We have therefore set up a register in the United Kingdom for comparing the safety of all available AEDs. To do this we propose to collect information on the outcome of all pregnancies occurring in women with seizures (or epilepsy), whether or not AEDs are being taken. As a woman with seizures (or epilepsy) you have therefore been chosen to take part in the study.

It is however, up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason. This will not affect the standard of care you receive.

If you do decided to take part the information we initially need to be forwarded to the Register includes demographic details (including name and date of birth), details on your seizures (or epilepsy), past and present AED intake, and expected date of delivery. We need to know your name and date of birth as at intervals after the expected date of delivery we need to gather information on the course and outcome of this, and any other previous pregnancies, if appropriate. This information will be collected from your GP and any other doctors who may have been involved in your care during this pregnancy (for example paediatricians, clinical geneticists). All information will be sent to us at the Register, which is based at the Department of Neurology, Royal Victoria Hospital, Belfast.

All information is strictly confidential and will not be made available by us to anyone other than those who are directly involved with your care. In addition, any results from the study will be presented only in a way that does not allow you, or anyone else who takes part in the study, to be identified.

If you decide to take part, you will not be required to make any additional visits to any clinics or to have any additional tests or procedures. If you decided to take part we, at the Register, will also not be in direct contact with you. However, if you wish to contact us for any further information, contact details are as given at the bottom of this page.

Thank-you for taking the time to read this, and for considering taking part in the study.

Contact Details: Dr James Morrow, Consultant Neurologist, Department of Neurology, Ward 4E, Royal Victoria Hospital, Grosvenor Road, Belfast, BT12 6BA. Tel. No: 01232 240503 Ext. 4325. Fax No: 01232 235258.

FREEPHONE TELEPHONE NUMBER: 0800 389 1248

IN CONFIDENCE REPORT OF ANTI-EPILEPTIC DRUGS (AED'S) IN PREGNANCY – EPILEPSY FOLLOW UP

PLEASE PRINT

Maternal Data (or affix Label)

Patient CHI/UNIT Number: _____

Surname:_____ DOB:_____

Forename_____ EDD: _____

Address: _____ or Date of Delivery:_____

_____ Gestational Age

_____ at time of Registration:_____

Seizure History

Date or age of onset of epilepsy:_____ Aetiology if known:_____

Seizure Types

Major (tonic-clonic) Yes/No Seizures During Pregnancy: Yes/No

Other (please specify): 1._____ Seizures During Pregnancy: Yes/No

2 _____ Seizures During Pregnancy: Yes/No

AED Treatment

AED Treatment During Pregnancy:

(please include daily doses, dates and indications _____

if any changes made) _____

_____

Was Folic Acid Prescribed?: Yes/No _____

Preconceptually?: Yes/No/Don't Know _____

Dose: 400Mcgs 5Mgs Other _____

Other treatment during pregnancy: _____

AED Treatment 3/12 prior to conception

(please include daily doses, dates and indications _____

if any changes made) _____

Other Treatment 3/12 prior to conception _____

_____

_____

Current AED Treatment *(dose and frequency)* _____

_____

Does this patient currently attend a specialist clinic for her epilepsy? Yes/No

If Yes, who does she see and where _____

_____

General Practitioner Details:

Name:_____ Phone No: _____

Address:_____ Fax No: _____

_____ Form Completed by: _____

_____ Date Form Completed: _____

Where did you/your patient hear about this register? _____

Please send completed form to:-

Dr J I Morrow, Consultant Neurologist, Department of Neurology (Ward4E), Royal Victoria Hospital, Belfast, BT12 6BA. Telephone No: 028 90240503 ext. 3525 Fax: 028 90235258

Thank you for your time.

CONSENT FORM

A REGISTER IN THE UK TO DETERMINE THE SAFETY OF THE ANTI-EPILEPTIC DRUGS IN PREGNANCY

Dr James Morrow, Consultant Neurologist, Department of Neurology,

Ward 4E, Royal Victoria Hospital, Grosvenor Road, Belfast, BT12 6BA.

		Please Initial Box
1	I confirm that I have read and understand the information sheet dated …….. for the above study and had the opportunity to ask questions.	☐
2	I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	☐
3	I understand that sections of any medical notes may be looked at by regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to access my records and those of my child.	☐
4	I agree to take part in the above study.	☐

_____	_____	_____
Name of Patient	Date	Signature
_____	_____	_____
Name of Person taking consent (if different from researcher)	Date	Signature
_____	_____	_____
Researcher	Date	Signature

1 for patient; 1 for researcher; 1 to be kept with hospital notes.