PARTICIPANT INFORMATION SHEET AND CONSENT FORM
PATIENT /PATIENT RECOVERED CAPACITY

Scottish Autoimmune Encephalitis register

You are being invited to consider taking part/continuing 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 others if you wish. Please ask me if there is anything that is not clear or if you would like more information. Thank you for reading this.

Why may I already be in this study?
During your recent admission to hospital you may have been unable to give consent for entry into a study. We therefore asked your nearest relative or welfare attorney or guardian who gave consent on your behalf to enter this study. This is permissible under the Adults with Incapacity Act (Scotland) 2000.

What is the purpose of the study?
In the last few years a group of patients with neurological symptoms due to autoimmune encephalitis have been recognised. These illnesses have been found to be associated with antibodies, which can be detected in the blood or spinal fluid. As these conditions are rare and only recognised in recent years it is important that doctors become aware of the range and frequency of the symptoms patients present with. It is also important to review the key investigation results including the MRI brain scans, body scans, EEGs and lab results. This is to better guide doctors as to which investigations to undertake in the future.

Why were you chosen?
You were admitted to hospital for treatment and suspected of having an autoimmune encephalitis, your nearest relative, welfare attorney or guardian agreed that you could join the study. However, you are now capable of making an informed decision about whether you wish to continue in the study or not.

Do you have to continue to take part?
No. It is up to you to decide whether to take part in the research or not. If you decide to take part you will be free to change your mind at any time and without giving a reason and this will not in any way alter your care, now or at any stage in the future. If you decide to not continue you can allow all the information and samples collected so far to remain in the study, or if you prefer we can destroy all samples and information so that you will be completely removed from the study.

What will happen to you if you take part in the research?
Some background information including your age, sex and postcode will have been recorded. Details of your presenting symptoms and examination findings will have been submitted by electronic questionnaire to the study database. We also asked your local clinicians to submit information about your progress with follow up. However, your entry into the study should not alter your ongoing care.

What are the possible benefits of taking part?
There are no direct benefits to you taking part in this study, but information gained from this research might inform on the future healthcare of other patients.

What are the possible disadvantages and risks of taking part?
Your doctors should follow you up as they see fit. We ask them to record some information about how you do with follow up. This may lead to a few extra questions being asked, which should take about 5 minutes to complete.

What if there is a problem?
If you have a concern about any aspect of this study please contact *Dr Graham Mackay, grahammackay@nhs.net* who will do their best to answer your questions.
The normal National Health Service complaints mechanisms will still be available to you.

What happens when the study is finished?
Your data will be held in a national database in an anonymised basis. We aim to potentially link this data with relevant NHS digital follow up data from the subsequent 5 years. With permission we would aim to retain the CSF/blood samples sent to the Glasgow Neuroimmunology lab in their established biobank. This is to allow for potential research into currently unrecognised antibodies and potentially into other factors, which might explain why people go on to develop these illnesses. We aim to collect similar data from other patients over the next 20 years.

Will my taking part in the study be kept confidential?
All the information we collect during the course of the research will be kept confidential and there are strict laws, which safeguard the privacy of the patient at every stage. Study researchers will need access to your medical records and digitally stored NHS results data to carry out this research. The data will be received, stored and managed in NHS Greater Glasgow and Clyde's Safehaven data system. The doctors undertaking the study will therefore not directly hold any of the information collected. This means potentially identifying information can be removed before researchers are given any data to analyse protecting confidentiality.

To ensure that the study is being run correctly, we will ask your consent for responsible representatives from NHS Greater Glasgow and Clyde and the Safehaven team to access your medical records and data collected during the study, where it is relevant to them taking part in this research. NHS Greater Glasgow and Clyde Research and Development is responsible for overall management of the study and providing insurance and indemnity.

What will happen to the results of the study?
Researchers out with the study group may request some of the data being collected for their own projects. In a rare condition such sharing of information may prove important. Data will only be shared when a group of the doctors undertaking this study and the representatives of the Safehaven project agree the request is appropriate. Only the minimal required data will be shared and on an anonymised basis.

The study will be written up for both medical publications and conference presentations. However, you will not be identifiable in any published results. We also plan to give updates to "the Encephalitis Society" the UK national charity for patients with these conditions to allow appropriate results to be publicly disseminated.

Who is organising the research and why?

This study has been organised by a group of interested Neurologists across Scotland and funded by Tenovus a charitable organisation.

Who has reviewed the study?
NHS Research and Development has reviewed the study proposal. All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee. A favourable ethical opinion has been obtained from Scotland A REC. NHS management approval has also been obtained

If you have any further questions about the study please email: grahammackay@nhs.net or telephone 0141 2012831 or contact the Glasgow Neuro-immunolgy lab on 0141 3549010/9023

If you would like to discuss this study with someone independent of the study please contact: james.overell@ggc.scot.nhs.uk, telephone 0141 2012831

If you wish to make a complaint about the study please contact:

NHS Glasgow Complaints Team
Tel: 0141 201 4500
Email: complaints@ggc.scot.nhs.uk

Thank you for taking the time to read this information sheet

CONSENT FORM

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Participant ID:

Please initial box

1. I confirm that I have read and understand the information sheet (version 4. 21/02/15) for the above study and have had the opportunity to consider the information and 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 relevant sections of my medical notes and data collected during the study may be looked at by individuals from the from the study team and NHS Greater Glasgow and Clyde Safehaven team. Where it is relevant to my taking part in this research I give permission for these individuals to have access to my records. I also agree to relevant aspects of my electronic records being linked to this data for the next five years. ☐

4 I agree to the Glasgow neuroimmunology lab retaining blood or spinal fluid samples sent to them for autoimmune encephalitis antibody testing for research purposes ☐

5. I agree to my anonymised data/tissue being used in future ethically approved studies ☐

6. I agree to take part in the above study ☐

Name of Participant	Date	Signature
Name of Person taking consent	Date	Signature

1x original – into Site File; 1x copy – to Participant; 1x copy – into medical records