PARTICIPANT INFORMATION SHEET AND CONSENT FORM
Nearest Relative/Guardian or Welfare Attorney

Scottish Autoimmune Encephalitis register

You are being invited to consider giving permission for your relative 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.

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 has the patient been chosen?
You are being asked to agree to your relative's information being entered into a national register of patients potentially felt to have an autoimmune encephalitic illness. This does not mean your relative has one of these illnesses. This will only be confirmed by the results of their antibody testing. However, your doctor has been asked to collect information on patients who might potentially have the diagnosis. This is to allow for a comparison between patients confirmed to have the illness and those who may eventually receive other diagnoses. This is to help guide doctors as to how to recognise the potential differences between this and other similar illnesses.

However, they currently lack the capacity to make an informed decision about whether they can take place in a research study. We are asking you as their nearest relative, welfare attorney or guardian if you will give consent on their behalf to join this study. If possible we would like you to make your decision based on what you think your relative would want to do in this situation, if they were in a position to decide. This is permissible under the Adults with Incapacity (Scotland) Act 2000. We would ask that you base this decision on what you believe your relative would wish if they retained capacity.

Do they have to take part?
No. It is up to you to decide whether they take part in the research or not. If you decide that should take part you are free to change your mind at any time and without giving a reason and this will not alter their care in any way, now or at any stage in the future.

What will happen to your relative if they take part in the research?
Taking part in the study will not change your relative's care. A doctor with an interest in these conditions may assess your relative prior to completing an electronic questionnaire detailing their symptoms and tests. As your doctor is considering the possibility of an autoimmune encephalitic illness they will be sending samples for autoimmune encephalitis antibody testing anyway (either as blood or CSF samples). However, we would like your permission to retain these samples in the Glasgow

Neuroimmunology lab 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.

If your relative regains capacity they will be asked to give their consent to continue in the study. We will collect some background information including their age, sex and postcode along with details of their illness and tests. We have asked the local doctors to give us information on your relatives progress with follow up, which will allow re-assessment as to their ability to give consent.

What are the possible benefits of taking part?
There are no direct benefits to your relative 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?
Other than the assessment of the local clinician with an interest to allow them to complete the questionnaire, your relative's care will be unchanged.

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 his 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 relative's 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 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 relative's medical records and digitally stored NHS results data to carry out this research. The data will be received, stored and managed within the 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, thereby 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 the patient's 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.

Eventually aspects of the study will be written up for both medical publications and conference presentations. However, your relative 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

Nearest Relative/Guardian or Welfare Attorney 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 relative's participation is voluntary and that I am free to withdraw my relative at any time, without giving any reason and without my relative's medical care or legal rights being affected. ☐

3. I understand that relevant sections of my relative's 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 relatives records. I also agree to relevant aspects of my relatives 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 ☐

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

6. I agree to my relative taking part in the above study ☐

I confirm that I am the nearest relative for _____ and that no other nearest relative or welfare attorney or guardian exists.

Relationship to patient _____

I confirm that I am the Welfare Attorney or Guardian for _____

_____	_____	_____
Name of person giving consent	Date	Signature

_____	_____	_____
Name of person taking consent (if different from Researcher)	Date	Signature

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