



THE UNIVERSITY *of* EDINBURGH



Rowling CARE

Participate and shape future research at the Anne Rowling Clinic

1. Introduction

You are being invited to consider giving your permission 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 if there is anything that is not clear or if you would like more information. Thank you for reading this.

2. What is the purpose of Rowling CARE?

Rowling CARE is an electronic record of healthcare data (for example, this information includes how your condition affects you, when you were diagnosed, what investigations were carried out and current management) that allows us to conduct research, identify research projects that are relevant to individuals, and to identify people who can help shape future research. Such a collection of data is called a registry.

Rowling CARE has been developed in response to requests by our attendees to increase the opportunities for their active involvement in research. It offers participants the ability to choose from any combination of the following options.

- **The opportunity to contribute to research using data collected in your routine care**
Every year at the Anne Rowling Clinic we make thousands of clinical contacts. We strive to deliver the best care possible, and in the delivery of that routine care we generate a wealth of data about the people we see and the conditions they have. Currently we don't use any of that data for research. **Rowling CARE allows you to give permission for anonymised healthcare data to be used in research about the people and the conditions we see.**
- **The opportunity to hear directly about research opportunities**
Participating in research requires awareness about the projects that are relevant to you, together with access to the information needed to make an informed choice. At present, this may only be available through contact with a healthcare professional who is both aware of the current research opportunities and able to provide information. **Rowling CARE allows you to tell us whether you would like to hear directly from us about research projects that you may be eligible to participate in.**
- **The opportunity to shape future research**
Our researchers design and lead world-class clinical research. However, the people best placed to tell us how to do even better research are our patients and their carers/relatives. **Rowling CARE allows you to tell us whether you would like to help shape the design and implementation of our next generation of research projects.**



3. Why have I been invited to take part in Rowling CARE?

Rowling CARE is available to people living in Scotland who are at least 16 years old.

In addition, participants must be one of the following:

- A person with suspected or confirmed motor neurone disease
- A person who attends or has a booked appointment to attend at The Anne Rowling Regenerative Neurology Clinic
- A carer or relative of someone who meets either of the two options above

4. Do I have to take part?

No, and if you choose not to join Rowling CARE this will not have any influence on your clinical care. You are also free to withdraw from the register at any time without providing a reason.

5. What will happen if I take part in Rowling CARE?

Participants are asked to provide permission for the use of their anonymised healthcare data in the following ways:

Using and sharing of data for research

- Use of non-identifiable data for research (by the Rowling CARE research team)
- Sharing of non-identifiable data with third parties for research

Direct contact about participation in research activities

- Contact about research studies that may be of interest
- Contact to assist in the design and implementation of future research projects
- Contact to invite membership of focus or consultation groups

Participants can select any combination of these options, depending on personal preference.

Participation **will not** influence your routine clinical care. Your level of involvement (responses to the options above) is entirely voluntary and is at your discretion. You can change your mind at any time – if you would like to be more or less involved, or removed from Rowling CARE – all you need to do is to contact us at the address below.

6. What are the possible benefits of taking part?

Rowling CARE offers the opportunity to contribute to research, learn about research projects that you may wish to participate in, and/or to get involved with the design and management of research projects.

7. What are the possible risks or disadvantages of taking part?

We take every possible measure to ensure data security, including compliance with all standards that apply to data held in NHS Scotland. However, there is a very small risk that the additional data management steps for Rowling CARE participants (holding a copy of details from your medical records within the University of Edinburgh systems) increase the risk of a data breach by third parties.

8. What if there is a problem?

If you have a concern about any aspect of this study please contact Mrs. Shuna Colville (contact details below) who will do her best to answer your questions. In the unlikely event that something goes wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal



action for compensation against NHS Lothian but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

9. What happens when the study is finished?

Rowling CARE is an ongoing project that will continue for the foreseeable future.

10. Will my taking part in Rowling CARE, and my healthcare data be kept confidential?

Healthcare data includes information about your condition including details of your journey to diagnosis – such as symptoms, timeliness of referral to see a specialist doctor, family history, and current treatment plan and interventions. Study researchers will access your medical records to extract this healthcare data. Your data will be held on a secure NHS approved server within the University of Edinburgh with appropriate data processing agreements in place. 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. Details that could identify you will only ever be seen by our core clinical research team; no identifiable information will ever be shared with a third party. To ensure that the study is being run correctly, we may be audited and so we will also ask your consent for responsible representatives from the Sponsor (University of Edinburgh) and NHS Lothian to access your medical records and the data collected in Rowling CARE, where it is relevant to your taking part in this research. The Sponsor is responsible for overall management of the study and providing insurance and indemnity. Anonymised data will not be shared with commercial entities under this ethical permission.

11. What will happen to the results of the study?

Results from Rowling CARE research will be written up as scientific papers and published at specialist conferences and meetings. **You will not be identifiable in any published results.** We will also provide updates on Rowling CARE through the Anne Rowling Clinic website and newsletter.

11. Who is organizing Rowling CARE and why?

Rowling CARE has been organised by the Anne Rowling Regenerative Neurology Clinic and is sustainably funded internally.

12. Who has reviewed this study?

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 Rowling CARE, please contact:

Shuna Colville (Rowling CARE), The Anne Rowling Regenerative Neurology Clinic, 49 Little France Crescent, Edinburgh, EH16 4SB. Tel: 0131-465-9517. Email: anne.rowling.clinic@ed.ac.uk

If you would like to discuss Rowling CARE with someone independent of the study please contact:

Dr David Hunt (Consultant Neurologist), 0131-465-9500.

If you wish to make a complaint about Rowling CARE please contact NHS Lothian:

NHS Lothian Complaints Team: 2nd Floor, Waverley Gate, 2-4 Waterloo Place, Edinburgh, EH1 3EG, Tel: 0131 465 5708, Email: craft@nhslothian.scot.nhs.uk