



THE UNIVERSITY of EDINBURGH



Rowling CARE

Participate and shape future research in Neurological conditions in Scotland

1. Introduction

You are being invited to consider giving your permission to contribute data to a research database called Rowling CARE (Clinical, Audit, Research, Evaluation). Before you decide if you would like to take part it is important for you to understand why we have this database and what consenting to be part of it will involve.

Please read the following information carefully and discuss it with others if you wish. Please ask a member of staff if there is anything that is not clear or if you would like more information. Thank you for reading this and considering being part of Rowling CARE.

2. What is the purpose of Rowling CARE?

Our primary aim at the Anne Rowling Clinic is to improve the quality of life of people living with progressive neurological conditions in Scotland, and to identify new treatments for these disorders. The best way for us to do this is to learn directly from people living with these neurological conditions.

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

Rowling CARE has been developed in response to requests by our attendees at the Rowling Clinic, people with neurological conditions throughout Scotland and clinicians to increase the opportunities for active involvement in research. It offers participants the option to contribute in the following ways:

- **The opportunity to contribute to research using data collected in your routine care**
Every year at the Anne Rowling Clinic, and elsewhere in Scotland, doctors and nurses make thousands of clinical contacts, assessments, out-patient appointments, telephone reviews and more. 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. This existing information can be used to advance our understanding of neurodegenerative conditions and how they affect those living with them. Currently we don't use any of this data for research. **By consenting to Rowling CARE you give permission for your anonymised healthcare data to be used in research and audit about the people and the conditions we see at the Anne Rowling Clinic.**



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- **The opportunity to hear directly about research opportunities**

Participating in research (e.g. clinical trials) 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 living in Scotland with, or under investigation for, a neurodegenerative condition such as Motor Neurone Disease, Multiple Sclerosis, Parkinson's Disease, Young onset Dementia (or any other neurodegenerative condition not listed).

OR

- A person who attends or has a booked appointment to attend at The Anne Rowling Regenerative Neurology Clinic

OR

- 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 from medical records for research

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

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 whether they wish to receive direct contact about participation in research activities.

Participation **will not** influence your routine clinical care. Your level of involvement (whether you are interested in direct contact about research activities) 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. Some people who have previously been involved in Rowling-CARE have felt positive benefit from an increase in contact with research nurses and doctors to discuss potential participation in research projects and focus group.

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. We comply with all audits to ensure data governance is adhered to. No identifiable data (e.g. your name, contact details or date of birth) is released to researchers out with the small core team.

8. What if there is a problem?

If you have a concern about any aspect of this study please contact Dawn Lyle (contact details below) who will do her best to answer your questions. In the unlikely event that you wish to take the complaint further 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. We will contact you annually to remind you that you are part of the database.

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 **in line with current General Data Protection Regulation (GDPR)** 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 other researchers out with the core team. 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.



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 provide updates on research facilitated by Rowling CARE through the Anne Rowling Clinic website and newsletter.

11. Who is organising 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:

Dawn Lyle (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:

Please contact: Dr Peter Foley, Consultant Neurologist, The Anne Rowling Clinic, 49 Little France Crescent, Edinburgh, EH16 4SB; Tel: 0131 465 9517.

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

