



THE UNIVERSITY of EDINBURGH



Rowling CARE

Participate and shape future research in Neurological conditions in Scotland

Information for those providing consent on behalf of another individual

Note – throughout this information leaflet the term “relative” is used to represent the person for whom you are considering consent. Consent can only be provided if you are the nearest relative, guardian, or welfare attorney.

1. Introduction

You are being invited to consider giving consent for your relative to contribute data to a research database called Rowling CARE (Clinical, Audit, Research, Evaluation). Before you decide it is important for you to understand why we have the database and what consenting to be part of it will involve for your relative. We would then ask that you consider what the wishes of your relative would be, had they been able to consent for themselves. 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 relative condition affects them, when they were diagnosed, what investigations were carried out and current management. This allows us to conduct research, and identify research projects that are relevant to individuals. Such a 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 relative’s routine care**
Every year at the Anne Rowling Clinic and elsewhere in Scotland 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. 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. **Rowling CARE allows you to give consent for your relative’s anonymised healthcare data to be used in research about the people and the conditions we see.**
- **The opportunity to hear directly about research opportunities**



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Participating in research (e.g. clinical trials) requires awareness about the projects that are relevant to each individual, 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 your relative may be eligible to participate in.**

3. Why has my relative 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 they have to take part?

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

5. What will happen to my relative if they take part in Rowling CARE?

You will be asked to provide consent 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

You can select whether you wish to receive direct contact about participation in research activities, depending on what you feel would best represent the personal preferences of your relative.

Participation **will not** influence your relative's routine clinical care. Their 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 your relative 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 for your relative to contribute to research, and to learn about research projects that they may wish to participate in.

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 Mrs. 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.

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

Where we have consent, the University of Edinburgh/NHS will collect information about your relative for research and audit purposes from medical records. We will not provide any identifying information about them to other researchers. We will use this information in line with current General Data Protection Regulation (GDPR).

Healthcare data includes information about your relative's condition including details of the 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 relative's medical records to extract this healthcare data. Your relative's data will then 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**. Details that could identify your relative will only ever be seen by our core clinical research team; no identifiable information will ever be shared with other researchers.

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 relative's medical records and the data collected in Rowling CARE, where it is relevant to their 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. **Your relative will not be identifiable in any published results.** We will also provide updates on research facilitated by Rowling CARE through the Anne Rowling Clinic website and newsletter.



12. Who is organising Rowling CARE and why?

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

13. 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

