PATIENT INFORMATION SHEET

Study Title

Partnership for **A**ssessment and **I**nvestigation of **N**europathic Pain: **S**tudies **T**racking **O**utcomes, **R**isks and **M**echanisms (PAINSTORM).

PAINSTORM Dundee epidemiology study – investigating risk factors and possible causes of neuropathic pain.

Chief Investigator (Person with responsibility for the research)

Blair Smith, Professor of Population Health Science, University of Dundee.

We are inviting you to take part in a research study

Before you choose whether or not to take part, we want you to understand why we're doing the study. We also want to tell you what you will need to do if you do decide to take part. Please take time to read this information carefully - we'll do our best to answer your questions and provide more information if needed.

Contact details are given at the end of this information sheet.

Why are we doing this study?

Many people who have diabetes, or who get chemotherapy treatment for cancer, may also get long-term, or chronic, pain in their feet and/or hands. This might be because their diabetes or the chemotherapy treatment damages the nerves that cause pain, known as neuropathic pain. Neuropathic pain is one of the most severe types of pain and its often difficult to treat, and there are no effective treatments to prevent it. Although there are now some treatments available and newer treatments are being developed, we don't fully understand why some people with diabetes, and some people who have had chemotherapy, get neuropathic pain but others do not.

We've already completed a study in people with neuropathic pain called DOLORisk. This study showed that sometimes a person's lifestyle, other health conditions or even past experiences and family history (genetics) can lead to a person having neuropathic pain.

We're doing the PAINSTORM study to find out if these factors are relevant in people with diabetes and people who have had chemotherapy. We also want to find out if

there are factors which will help us to predict what will happen with the neuropathic pain in the long term. We hope that this information will help us to improve the care and treatment for people living with neuropathic pain.

Why have I been contacted?

We're contacting you because you are on the GoDARTS/SHARE register and you may have diabetes or you may be receiving chemotherapy to treat cancer. You may also have previously taken part in DOLORisk. We are therefore inviting you to complete a questionnaire as part of the PAINSTORM research.

Do I have to take part?

No - it's entirely up to you. If you choose to take part, you can stop at any time, without giving a reason. You can return a blank questionnaire using the pre-paid envelope provided or send to the postal address at the end of this information sheet. Alternatively, you can opt-out of the study on the questionnaire website. We'll then know you don't want to take part and we won't contact you again regarding this study. If you decide not to take part the medical care you get and your relationship with the medical or nursing staff looking after you won't be affected. This will not affect your future involvement with SHARE/GoDARTS.

However, if you decide to stop taking part after beginning the study, and if you agree, we would like to keep the information you have already given us. It is important for the research that we use all information collected. However, if you do not wish for any of your information to be used, just let us know.

What do I have to do if I take part?

The study is collecting information about your current health and about any pain that you might have. We plan to collect this information at two different time points, in 2022 (baseline) and approximately 18 months later in 2023/24 (follow-up), but the exact timings could change if necessary (e.g. COVID-19 restrictions).

In 2022

Please:

- Complete the questionnaire.
- Return the questionnaire.

The return of a completed questionnaire will be taken as confirmation that you agree to take part in the study. The questionnaire can be completed either in paper form or online. For website details see your invitation letter or email or you can contact the study team using the details at the end of this information sheet.
The questionnaire will take approximately 15 minutes to complete and contains questions about your current health and any current pain. **Even if you aren't in pain just now, your answers to the questions are important to us, so please complete the questionnaire anyway.**

In 2023/24 (approximately 18 months after baseline)
We may contact you again in 2023/24. If so, please complete and return the questionnaire we send you.
By comparing the information you give us 18 months later with your first response we will be able to find out how different factors affect whether you develop pain and whether it gets better or worse over time.

What are the possible benefits of taking part?

Our study might not bring any direct benefit to you personally, but we hope that the information from this large research project will improve the treatment of people receiving chemotherapy for cancer and people with diabetes and help to develop new ways to prevent or treat neuropathic pain.

What are the possible disadvantages and risks of taking part?

We do not think there will be any risks in taking part as you will only need to complete two questionnaires. There is a small possibility that you could find some of the questions distressing. If this happens, please contact the research team, using the contact details at the end of this Information Sheet.

Who is organising and funding this research?

This study is being sponsored by NHS Tayside and the University of Dundee. It is being delivered through the Advanced Pain Discovery Platform (APDP). The APDP is a new, unique partnership that has developed from a shared vision, funded by Government, charities and the private sector. It is a multi-million-pound, long-term initiative established with joint and equal investment from UK Research & Innovation and Versus Arthritis, with additional support from Eli Lilly. This study, is part of the

Partnership for Assessment and Investigation of Neuropathic Pain: Studies Tracking Outcomes, Risks and Mechanisms (PAINSTORM) which is one of the consortia/ groups of the APDP (see https://www.ukri.org/news/new-data-hub-and-research-into-chronic-pain/). The PAINSTORM Dundee epidemiology study is being led by Professor Blair Smith with Professor Lesley Colvin and Professor Douglas Steele. Harry Hebert is the postdoctoral research assistant and study co-ordinator.

How have patients and the public been involved in the study?

People with lived experience of neuropathic pain have been closely involved throughout the project (and will continue to be for the duration of this study and beyond) in a number of ways, including:

- Understanding what is important to people living with neuropathic pain and helping to design and shape the study to address these priorities.
- Applying for funding to carry out the study, with 4 patient partners as equal co-applicants on the funding application.
- Working with the team to develop the details of the study protocol.
- Co-producing the study documents, including this Participant Information Sheet, which we give to participants.
- Involved as equal members of the research team to help with how to best run the study.

What will happen with the information I give you?

Your contact details are held securely and confidentially by the SHARE/GoDARTS team and the Health Informatics Centre (University of Dundee), who have sent out this information to you. Your personal details (name, address, email and telephone number) have not been given to the PAINSTORM study team.

The questionnaire will be returned to the Health Informatics Centre at the University of Dundee. All your information in the questionnaire will be completely confidential and anonymous. The information you provide will be stored in an approved secure and protected database maintained by the Health Informatics Centre. The information will only be available to the study research team. The research team will not have access to your name or contact details and will not be able to identify you by your responses. Any personal information which could identify you individually will

be encoded by the Health Informatics Centre so that your details will be anonymous. This means that your name or anything linked to your name will not be used.

Your information will be kept securely for at least 5 years after the end of the study. After 5 years any information which identifies you will be destroyed, but your anonymised data will be kept by the research team. Information which identifies you personally will not be published or shared.

We would like to link up the information you provide in the PAINSTORM Dundee questionnaires to data that is held and we know about you in your NHS records. We link your data using standard, secure methods and procedures. Your data will remain anonymous at all times and we will not be able to identify you. The Health Informatics Centre (HIC) at the University of Dundee will do this. HIC routinely perform such linkage for research purposes. As part of the questionnaire, we will ask you for permission to do this electronic data linkage. We will not do the data linkage without your consent (this will not affect your involvement in the rest of the PAINSTORM Dundee study).

We may share your study information with other researchers but any information which identifies you will be removed before we share it. Other researchers may be from commercial companies and may be from outside of the UK and EU.

The Data Protection Privacy Notice section gives more information about this and how we handle your data.

What if I am concerned about taking part in the study?

If you are concerned about taking part in the study you have the right to discuss your concern with a researcher involved in carrying out the study. Information on how to contact the research team can be found at the end of this information sheet.

If you have a complaint about your participation in the study, first you should talk to a researcher involved in the study. You can also make a formal complaint. You can make a complaint to a senior member of the research team or to the Complaints Officer for NHS

Tayside:

Complaints and Feedback Team

NHS Tayside

Ninewells Hospital

Dundee DD1 9SY

Freephone: 0800 027 5507

Email: feedback.tayside@nhs.net

Who has reviewed the study?

This study has been reviewed and approved by London - Brighton & Sussex Research Ethics Committee (ref: 22/PR/0803) who are responsible for reviewing research which involves humans. The Research Ethics Committee doesn't have any objections to this study going ahead.

Data Protection Privacy Notice

How will you use my information?

We'll need to use information from you for this research study.

This information will include your initials, NHS number, name and contact details. Staff will use this information to do the research or to check your records to make sure that the research is being done properly.

People who don't need to know who you are won't be able to see your name or contact details. Your data will have a code number instead.

We'll keep all information about you safe and secure.

Once we've finished the study, we'll keep some of the data so we can check the results. We'll write our reports in a way that no-one can work out that you took part in the study.

What are my choices about how my information is used?

- You can stop being part of the study at any time, without giving a reason, but we'll keep information about you that we have already collected. If you do not want us to do this, then we will remove the information collected when you were taking part in the study.

- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

You can find out more about how we use your information at:

- www.hra.nhs.uk/information-about-patients/
- http://www.ahspartnership.org.uk/tasc/for-the-public/how-we-use-your-information
- https://www.dundee.ac.uk/information-governance/dataprotection/
- http://www.nhstayside.scot.nhs.uk/YourRights/PROD_298457/index.htm
- or by contacting Research Governance, Tayside Medical Science Centre (TASC)
  Telephone: 01382 383900
  Email: tascgovernance@dundee.ac.uk

Where can I get more information or help with the study?

Thank you for taking time to read this information and for considering taking part in this study. If you'd like more information or want to ask questions about the study, please contact the study team using the contact details below. You can also contact us if you are having problems answering any of the questions or would like to request a paper version of the questionnaire.

Email: painstorm-study@dundee.ac.uk

Email contact is preferred as we could be working off-site and emails would reach us more quickly than telephone messages. We will aim to respond as soon as we can.

Study Coordinator: Harry Hébert, PhD

Telephone: 01382 383191

Email: h.hebert@dundee.ac.uk

Chief Investigator: Professor Blair Smith

Telephone: 01382 383795

Email: b.h.smith@dundee.ac.uk

You can contact us Monday – Friday between 10am and 6pm.

Paper questionnaires can be returned to the following address:

Health Informatics Centre (HIC)

Second Floor, Level 7

Mail Box 15

Ninewells Hospital and Medical School

Dundee

DD1 9SY