







PARTICIPANT RECORD, DO NOT RETURN

Interreg Diabetes CPM: Unscheduled Care in Diabetes Study 2, Part C: Evaluative Interview Study

PATIENT PARTICIPANT INFORMATION SHEET

This participant information sheet describes the above study and explains what we are asking you to do. Please ask us if there is anything that is not clear or if you would like more information. Thank you for reading this leaflet and considering whether to take part in the study.

Evaluative interview study: As part of a larger study to reduce unscheduled care for people with diabetes, we are seeking to test an intervention to improve glucose (sugar) monitoring for people with diabetes who have been admitted to hospital. The larger diabetes study makes up one research cluster within a five-cluster project conducted by the Centre for Personalised Medicine, Clinical Decision Making and Patient Safety (CPM). The wider project is a cross-border collaboration between research institutes in Northern Ireland, the Republic of Ireland, and Scotland.

Why are you asking me to take part? You are being contacted because you took part in the inpatient pilot study (Part B) and agreed to being contacted to take part in the evaluative interview study (Part C). We would like to find out what people think about the intervention and/or their experience of inpatient diabetes care. We would like to know what you think went well, and what you think could have been done differently and/or what could be improved.

What are you asking me to do? If you would like to take part, you will have the choice to do the interview face-to-face or over the phone, and this will last around half an hour to an hour at the most. Interviews will take place in your home unless you specify another suitable location or prefer to travel to the research centre. The interviews will be audio-recorded and transcribed anonymously. If you volunteer, we will need to keep your contact details to get in touch with you, but after we have done the interview these details will be destroyed.

What are the possible disadvantages and risks of taking part? We do not consider there to be any serious risks in taking part. This evaluation will have no bearing on your individual health or medical treatment.

Do I have to take part? No, it is voluntary, and entirely up to you to decide. Even if you volunteer, you can change your mind at any time without having to give a reason. Your present or future care will not be affected by a decision not to take part in the study.

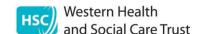
What are the possible benefits of taking part? There are no direct benefits from taking part in this interview study beyond having the opportunity to share your thoughts and experiences confidentially and anonymously.

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What will happen if I decide I don't want to continue with the study? You are free to withdraw from the interview study at any time, you do not need to give a reason and it will not have any impact on your present or future care. If you withdraw from the study you can choose to either a) to withdraw from further participation but allow the team to retain any data already collected or b) withdraw completely in which case we will destroy all data collected and/or any contact details given. If you have given informed consent and lose capacity to consent during the study you will be withdrawn. Identifiable data already collected with consent will be retained and used in the study. No further data will be collected, or any other research procedures carried out on, or in relation to, your participation.

What if something goes wrong? In this study we will just be interviewing people, so it is highly unlikely that it will cause harm to anyone. If you become distressed or indicate distress as a result of any of the questions asked in the evaluation then we will offer to end the interview immediately and to contact the nearest health care professional to provide support. If you wish to complain or have any concerns about the way you have been approached or treated in connection with the study, you can contact Professor MacRuryor go to the normal National Health Service complaints mechanisms.

What will happen to the results of the evaluation? A report will be generated from the evaluation which may result in a publication. There will be no information in any report or publication that will identify you. If you would like a copy of the results these can be made available to you.

Who will be told about my condition? Any information collected will be entirely confidential and only available to members of staff directly involved in running the evaluation.

What will happen to my data? The University of Highlands and Islands is the data controller of this study and is responsible for looking after your information and using it properly. Data protection regulation requires that we state the legal basis for processing information about you. The legal basis of this study, is 'a task in the public interest.' We will be using information from your medical records, and anonymised transcripts from the interview order to undertake this pilot study and will use the minimum personally-identifiable information possible. Transcription of interviews will be undertaken by [insert name of supplier - TBC] and the audio recordings of interviews destroyed up to 12 months following the end of the study. We will keep research data for 10 years after the study has finished. This excludes any research documents with personal information, such as consent forms which will be held for up to 12 months following the end of the study. All your data will be held on a secure database for the purpose of this study and only members of the study team and approved regulatory personnel will have access to your records. It's important for you to be aware that if you decide to take part your rights to access, change or move information about you are limited. This is because researchers need to manage your information in order for the research to be reliable and accurate. Direct quotes from interviews will potentially be published. This is a multi-site study, with a study team based across the Scottish Highlands, Northern Ireland and the Republic of Ireland, as such, data will be shared between the study sites but this will only happen with your

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explicit consent. As this study is part of a larger multi-study project, your anonymous data may be stored and used for further analysis at a later date as a part of the wider project. This is optional and would only happen with your explicit consent. It will not affect whether or not you can participate in this study, nor will it have any bearing on your current or future care. All non-identifiable outcome data collected in this study will be stored for 10 years from the end of study funding.

I think I may be interested in taking part, what do I need to do? If you have decided to volunteer to take part in the study, please discuss this with the researcher when they contact you via the telephone number you previously provided. If you would prefer to contact her beforehand, or if you would like to discuss the study further, please find her contact details below.

Who is organising and funding the study? The study is being carried out by researchers at Ulster University (UU). The study has Research Ethics Committee approval. The study is part of a larger multi-study project as part of the CPM and is funded by the Interreg European Regional Development Fund.

I have some questions about the study Professor Vivien Coates or Ms Michelle Friel will be pleased to answer any questions, she can be contacted by email (friel-k5@ulster.ac.uk) or telephone (028 7167 5817)

For more independent advice about taking part in studies please contact:

Dr Maurice O'Kane Altnagelvin Hospital

Glenshane Road

Derry

Telephone: 02866382000

Alternatively visit the website: www.invo.org.uk

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