PARTICIPANT RECORD, DO NOT RETURN

Interreg Diabetes CPM: Unscheduled Care in Diabetes
Study 2, Part B: Inpatient Pilot 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.

Pilot 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 have been chosen because we know that you have diabetes and have been admitted to Altnagelvin hospital. You have been identified as an eligible participant by hospital staff who are bound by patient confidentiality guidelines. Your patient records have not, nor will ever be, accessed by any other non-clinical research staff unless you provide explicit consent to do so.

What are you asking me to do? If you decide to take part, you will be placed into either the intervention or non-intervention group. This will be done using a process called randomisation and the researcher will have no control or knowledge of which group you will be placed in to. If you are placed into the intervention group, you will wear a Flash Glucose Monitoring device for the duration of your stay in hospital. Flash Glucose Monitoring devices include small sensors that you wear just under your skin. It measures your glucose levels continuously throughout the day and night and can be checked by simply scanning a monitor over the sensor. Flash Glucose Monitoring provides additional information such as trends and trajectories beyond the stand alone reading. Your treatment will not be affected or changed but we will ask you to check your glucose levels using the monitor to scan the sensor every two hours as well as having the usual finger prick testing carried out in the ward. If you are not well enough or feel unable to carry this out we will ask the ward staff to help. When you are discharged you will be given the choice to take home the Flash Glucose Monitoring device for the remaining time left on the sensor (up to a maximum of 2 weeks). If you are placed in to the non-intervention group you will receive routine care for your diabetes while you are in hospital and/or be discharged home as normal when you leave the hospital. Whichever group you are placed into, you will fill out a short questionnaire and the researcher will collect information about your glucose monitoring and diabetes treatment from your notes.

What are the possible disadvantages and risks of taking part? We do not consider there to be any serious risks in taking part. You may feel slight discomfort when the sensor is first applied and/or mild skin irritation from the adhesive. Taking part 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? If you are placed into the intervention group, taking part will give you the opportunity to experience the use of innovative technology to monitor your diabetes whilst you are in hospital, and if you are placed into the take-home intervention group you could experience the use of this at home following your discharge also. All participants will be given the opportunity to confidentially and anonymously share your experiences and opinions on inpatient diabetes management at Altnagelvin hospital.

What will happen if I decide I don't want to continue with the study? You are free to withdraw from the 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? Since Flash Glucose Monitoring devices are worn just under the skin, it is highly unlikely that it will cause harm to anyone. However, 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 Coates or go to the normal National Health Service complaints mechanisms.

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

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 the glucose data from the Flash Monitor order to undertake this pilot study and will use the minimum personally-identifiable information possible. 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 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? Please let the researcher know that you are interested and they will go through the consent procedure with you. If you would prefer to take some more time to think about this or to read the information, you can contact the researcher via the details given or next time they are on the ward.

Who is organising and funding the study? The study is being carried out 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 Mairice O'Kane
Altnagelvin Hospital
Glenshane Road,
Derry
Telephone: 02866382000

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