We would like to invite you to take part in a research study. Before you decide to take part you need to understand why this research is being undertaken and what it would involve for you.

Please take time to read the following information carefully and, if you wish, talk to friends or family about the study as this may help in your decision-making.

If anything is unclear or you require further information feel free to contact us, our details can be found at the end of this leaflet. Thank you for taking the time to read this information leaflet.

What is the purpose of the study?

This study forms part of a wider programme of work that aims to understand how mobile phones and other digital devices can be used to provide information and advice about medicines and their best use for people with type 2 diabetes. In the future, new communication and computing technologies will play a key part in health care. The research team, working with people with diabetes, is developing a system that may play an important part in future health care. The work so far has included looking at the sort of information and advice that people might find helpful, finding ways to make the information personally relevant, and looking at the design of the system so it is easy to use. We want to test this system with a large number of patients in a research study.

For this study we want to find out how someone with type 2 diabetes experiences using a mobile phone based system to receive messages and to find out views about using the system to be sure that it is user-friendly and meets the needs of people with diabetes.
Why have I been invited?

You have been invited to take part in this study as we are currently approaching people living with type 2 diabetes in the Thames Valley and Greater Manchester areas.

We are looking to include up to 50 participants living with type 2 diabetes for this part of the research.

Do I have to take part?

No. It is up to you to decide as any participation is entirely voluntary. If you do decide to take part, we would ask you to sign a consent form to show that you have agreed to take part. You would be free to withdraw at any time without giving a reason.

If you decide not to take part or to withdraw from the study, the clinical care you receive now and in the future will not be affected.

What will happen to me if I decide to take part?

If you decide to take part we will ask you to take part in a six-month study, where you will receive short messages (for example SMS text-messages) on your mobile phone. Messages will include information about type 2 diabetes and its treatment. You may receive up to three messages per week.

We will seek your permission to access a limited range of personal electronic health record data to personalise the messages. The content of these messages may be adapted and changed during the study.

We would also ask you to record some of your thoughts on this messaging system using different recording mechanisms (audio diaries, short survey and electronic ratings) and take part in a series of short telephone interviews (no more than once a week) throughout this six-month period. At the end of the six months, we would invite you to take part in a focus group discussion of 6-8 people that will be at a local clinic or other community centre, or a telephone interview to talk about your experiences of using this system, what you liked, and what we could improve in the future.

What sort of information would you store about me and why?

We will store information about you in two ways. We will store some information about you temporarily on an NHS hospital-based computer and use this to
personalise the messages that might be sent to you. This set of information is a copy of other information held about you, and will be erased from the hospital computer. The data will be transferred in a coded form on computer networks that are approved for transfer of NHS data. We will also store a set of information from which all information that might identify you as an individual has been removed. We will use this as a research data set to help understand and improve the technology being developed.

The information that we would store temporarily includes:

- Personal identifiers, for example your NHS number.
- Mobile phone number. We will use this to send you messages, and/or contact you if you have given consent.

The research information that we would store includes:

- Prescriptions issued, blood pressure measurements, weight and height, blood test results related to diabetes, record of clinic attendance and with whom.

What should I consider?

This research is intended to develop a system that will be of help to most people with type 2 diabetes. Type 2 diabetes (sometimes also called maturity onset diabetes) can occur at any age, although usually after the age of 30 years, and is treated with tablets to lower blood sugar levels, although sometimes injections are also needed alongside tablets. You may be able to take part in this study even if you have other medical conditions or are taking part in other research studies.

What are the possible benefits of taking part?

We hope that everyone taking part will improve their knowledge and understanding about type 2 diabetes and taking medicines to treat it. However, we cannot guarantee this. The information we gain from this study may help us to treat patients with type 2 diabetes better in the future.

Are there any possible disadvantages or risks from taking part?

You would be asked to take part in a series of short telephone interviews and record your thoughts about the system, which may take up some of your time. You would also receive short messages on a daily basis and would be asked to make time to meet at the end of the six month study.
Will my General Practitioner/family doctor (GP) be informed of my participation?

We will tell your general practitioner that you are taking part in this study. Please let us know if you would not want us to do this. Whether you choose to take part in this research or not will not affect the care you receive from your GP.

Will my taking part in the study be kept confidential?

All information that you might give during the study would be kept strictly confidential. Information that would help with your health care will be stored on NHS computer systems (including GP systems and NHS Hospitals computer systems). Information collected for research purposes will not include identifiable personal data and will be securely stored on University or NHS computer systems accessed only by members of the research team, or in a safe, lockable place at University premises, and only the researchers on this research project will have access to it.

We would ask for permission to look at your medical records in written or computerised form to help us look at ways to make the information provided more relevant to you.

We would ask for permission to contact central NHS bodies and NHS Digital (formerly the Health and Social Care Information Centre) to obtain stored information about you that would help us with this research.

Responsible members of the University of Oxford and the relevant NHS Trust(s) may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

Audio recordings will be transcribed and the transcripts anonymised. Audio recordings will be deleted three years after the study is complete and we will store transcripts of the anonymised interviews.

What will happen to my data?

All interview and focus group recordings will be transcribed. The transcripts and additional data collected (surveys/ diaries) will be stored as explained in the previous section. We would also ask you whether we can use some of the data for educational purposes, such as teaching research students.

Data in our electronic systems will be held securely using state-of-the-art security techniques in computers administered by the Oxford University Hospitals NHS Foundation Trust. Sensitive information will be accessible exclusively by the
researchers participating to the study who have received clearance to access them. At the end of the study, identifiable data will be erased and the resulting research data-set will have all personal identifying data deleted from it.

**Will I be reimbursed for taking part?**

Any reasonable travel expenses incurred as a result of participation in this study will be reimbursed upon production of receipts for fares or a mileage claim as appropriate.

**What will happen if I don’t want to carry on with the study?**

If you should decide that you no longer wished to take part in the study you would be free to withdraw at any time without giving any reason. The clinical care you receive now and in the future would not be affected.

Participants will be able to withdraw from participating in the focus group at any time. However, any comments made at the focus group up to that point will be included in the transcript and analysis, as (a) it will not be possible to uniquely attribute any comments to a specific individual, and (b) any comments made by an individual are part of discussion and are likely to influence the comments made by another participant.

**What will happen to the results of the study?**

The results of this study will be presented in both academic and professional journals as well as conferences to inform other professionals of the work we have been doing. We will also provide a summary of the work to those who have taken part, and hold meetings where people who have taken part will be invited to attend.

We may use some of the things you might tell us during this study at conferences or in published articles. However your name will not mentioned nor will we give any other identifiable details of you. Audio recordings will be deleted three years after completion of the study and kept as anonymised transcripts.

**What if there is a problem?**

Given the nature of this study, it is highly unlikely that you would suffer harm by taking part. However, the University of Oxford, as Sponsor, has appropriate
insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study. NHS indemnity operates in respect of any advice or information which is provided.

If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study, you should contact Professor Andrew Farmer on phone: 01865 617942 or email: patoandrewfarmer@phc.ox.ac.uk or you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 572224, or the head of CTRG, email ctrg@admin.ox.ac.uk. The NHS Patient Advice and Liaison Service (PALS) is also available at http://www.pals.nhs.uk (Oxford telephone 01865 221473 / Manchester telephone 0161 276 8686). PALS is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. PALS is unable to provide information about this research study.

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

This study was designed following discussions with patients with type 2 diabetes and a group of patients have reviewed this form. There is also a patient representative as part of the study team.

Who is organising and funding the research?

The sponsor of this study is the University of Oxford. This research study is organised by the Nuffield Department of Primary Care Health Sciences and the Institute of Biomedical Engineering at the University of Oxford. Collaborators include the University of Manchester, Bangor University, University of Exeter, National University of Ireland Galway, University College London, with Oxford University Hospitals NHS Foundation Trust and Oxford Health NHS Foundation Trust.

The research is funded by the NIHR Programme Grants for Applied Research. The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health.

Who has reviewed this study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants’ interests. This study has been reviewed and given favourable opinion by the North West – Greater Manchester
West Research Ethics Committee (ref: 17/NW/0224).

**Participation in future research:**
If you chose to take part in this study, we would keep your name and contact details in a secure university computer system and may approach you to take part in further related research (for example to test further development of this system). If you did not wish to do this, your name would not be kept on our computer system.

**What will I have to do if I would like to take part in the study?**
If you would like to take part in the study, we would ask you to complete and return the reply slip at the end of this information sheet in the prepaid envelope with your contact details completed or alternatively contact the SuMMiT-D research team on phone: 01865 617959 (Oxford) / 01613 065436 (Manchester)
email: summit-d@phc.ox.ac.uk

If you do not want to take part in the study at all, you need to do nothing more.

**Further information and contact details**

*Oxford Contact details:*  
**Local study team:** Nuffield Department of Primary Care Health Sciences, University of Oxford  
**Jenny Riga**  
Phone: 01865 617959  
Email: summit-d@phc.ox.ac.uk  
**Chief Investigator:** Prof Andrew Farmer  
Phone: 01865 617942  
Email: patoandrewfarmer@phc.ox.ac.uk

*Manchester Contact details:*  
**Local study team:** Manchester Centre for Health Psychology, University of Manchester  
**Dr Kiera Bartlett**  
Phone: 01613 065436  
Email: kiera.bartlett@manchester.ac.uk  
**Investigator:** Prof David French
Feasibility study patients

REPLY-SLIP

Your name___________________________________________________________
Your address:
1st Line________________________________________________________________
2nd Line_________________________________________________________________
Town/City_________________________________________________________________
County_____________________________________________________________________
Post code_______________________________________________________________
GP surgery __________________________________________________________________

I am interested in taking part in the above study and would like to be contacted.
My preferred contact details are
Mobile ___________________________________
Home ___________________________________
Work ___________________________________
Best time to call ____________________________
Email ___________________________________

Please post this slip in the FREEPOST envelope provided to

SuMMiT-D study
Manchester Centre for Health Psychology, University of Manchester, Coupland 1
Building, Oxford Road, Manchester, M13 9PL

Or
or alternatively contact the research team:

Telephone: 01865 617959 (Oxford) / 01613 065436 (Manchester)

Email: summit-d@phc.ox.ac.uk